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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 20-F

(Mark One)

☐ **REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934**

OR

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2025

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

OR

☐ **SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

Date of event requiring this shell company report: Not applicable
For the transition period from____to____

Commission file number 001-43098

AgomAb Therapeutics NV
(Exact name of Registrant as specified in its charter)

Belgium
(Jurisdiction of incorporation or organization)

Posthoflei 1/6
2600 Antwerpen
Belgium
(Address of principal executive offices)

Tim Knotnerus, Chief Executive Officer
Tel: +32 3 318 91 70
info@agomab.com, Posthoflei 1/6 2600 Antwerpen, Belgium
(Name, Telephone, E-mail and/or Facsimile number and Address of Company Contact Person)

Securities registered or to be registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
American Depositary Shares, each representing one common share, no nominal value per share	AGMB	The Nasdaq Stock Market LLC
Common Shares, no nominal value per share*		The Nasdaq Stock Market LLC*
* Not for trading, but only in connection with the registration of the American Depositary Shares.		

Securities registered or to be registered pursuant to Section 12(g) of the Act:
None
(Title of Class)

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act:
None
(Title of Class)

Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as of the close of the period covered by the annual report.

Common shares, no nominal par value per share: 34,167,168 were outstanding as of December 31, 2025

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

☐ Yes ☒ No

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934.

☐ Yes ☒ No

Note – Checking the box above will not relieve any registrant required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 from their obligations under those Sections.

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

☒ Yes ☐ No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).

☒ Yes ☐ No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or an emerging growth company. See definition of "large accelerated filer", "accelerated filer", and "emerging growth company" in Rule 12b-2 of the Exchange Act. (Check one):

☐ Large accelerated filer ☐ Accelerated filer ☒ Non-accelerated filer ☒ Emerging growth company

If an emerging growth company that prepares its financial statements in accordance with U.S. GAAP, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards† provided pursuant to section 13(a) of the Exchange Act.

☐

†The term "new or revised financial accounting standard" refers to any update issued by the Financial Accounting Standards Board to its Accounting Standards Codification after April 5, 2012.

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report.

☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements.

☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b).

☐

Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this filing:

☐ U.S. GAAP ☒ International Financial Reporting Standards as issued by the International Accounting Standards Board ☐ Other

If "Other" has been checked in response to the previous question, indicate by check mark which financial statement item the registrant has elected to follow.

☐ Item 17 ☐ Item 18

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

☐ Yes ☒ No

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From time to time, we may use our website or our LinkedIn profile at https://www.linkedin.com/company/agomab/ to distribute material information. Our financial and other material information is routinely posted to and accessible on the Investors section of our website, available at www.agomab.com. Investors are encouraged to review the Investors section of our website because we may post material information on that site that is not otherwise disseminated by us. Information that is contained in and can be accessed through our website or our LinkedIn page is not incorporated into, and does not form a part of, this Annual Report on Form 20-F.

Introduction

This document contains information required for the Annual Report on Form 20-F for the year ended December 31, 2025, of AgomAb Therapeutics NV, or the Annual Report. Unless otherwise indicated or the context otherwise requires, all references in this Annual Report to "AgomAb" the "Company," "we," "our," "ours," "ourselves," "us," or similar terms refer to AgomAb Therapeutics NV and our subsidiaries, as identified below. We were initially incorporated under the laws of Belgium on April 13, 2017 as a Belgian private limited liability company (besloten vennootschap) and were converted under the laws of Belgium into a Belgian limited liability company (naamloze vennootschap) on March 14, 2019. Our principal executive offices are located at Posthoflei 1/6, 2600 Antwerpen, Belgium. Our telephone number at this address is +32 3 318 91 70. Our Spanish subsidiary, Agomab Spain, S.L.U., is headquartered at Parque Empresarial de Touro Fonte Diaz, A Coruña, Galicia, Spain. Our U.S. subsidiary, Agomab US, Inc. is headquartered in Cambridge, Massachusetts.

Our website address is www.agomab.com. The information contained on, or that can be accessed through, our website is not a part of, and shall not be incorporated by reference into, this Annual Report. We have included our website address as an inactive textual reference only.

Our agent for service of process in the United States is Cogency Global Inc.

IFRS Based Information

The audited financial statements as at December 31, 2025 and 2024, and for the years ended December 31, 2025, December 31, 2024 and December 31, 2023, included in the Annual Report have been prepared in accordance with IFRS Accounting Standards as issued by the International Accounting Standards Board (IASB).

Exchange Rates

All references in this Annual Report to "U.S. dollars" or "$" are to the legal currency of the United States, and all references to "€" or "euro" are to the currency of the European Economic and Monetary Union. Our business to date has been conducted primarily in the European Union, and we maintain our books and records in euro. We present our financial statements in euro, which is the Company's functional currency.

Fair Value Information

In presenting our financial position, fair values are used for the measurement of various items in accordance with the applicable accounting standards. These fair values are based on market prices, where available, and are obtained from sources that are deemed to be reliable. Readers are cautioned that these values are subject to changes over time and are only valid at the balance sheet date. When quoted prices or observable market values do not exist, fair values are estimated using valuation models, which we believe are appropriate for their purpose. They require management to make significant assumptions with respect to future developments which are inherently uncertain and may therefore deviate from actual developments. Critical assumptions used are disclosed in the financial statements. In certain cases, independent valuations are obtained to support management's determination of fair values.

Trademarks

We own various trademark registrations and applications, and unregistered trademarks, including our corporate logo. All other trade names, trademarks and service marks of other companies appearing in this Annual Report are the property of their respective holders. Solely for convenience, the trademarks and trade names in this Annual Report may be referred to without the ® and ™ symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto. We do not intend to use or display other companies' trademarks and trade names to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

Market, Industry and Other Data

Market data and certain other statistical information used throughout this Annual Report are based on independent industry publications, governmental publications, reports by market research firms or other independent sources that we believe to be reliable sources. Industry publications and third-party research, surveys, and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. In some cases, we do not expressly refer to the sources from which this data is derived. We are responsible for all of the disclosure contained in this Annual Report, and we believe that these sources are reliable. While we are not aware of any misstatements regarding any third-party information presented in this Annual Report, their estimates, in particular, as they relate to projections, involve numerous assumptions, are subject to risks and uncertainties, and are subject to change based on various factors, including those discussed under the section titled "Risk Factors" and elsewhere in this Annual Report and in the documents incorporated by reference herein. Some data are also based on our good faith estimates. These and other factors could cause results to differ materially from those expressed in the estimates made by the third parties or by us.

Cautionary Language Regarding Forward-looking Statements

This Annual Report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Exchange Act, that involve substantial risks and uncertainties. The forward-looking statements are contained principally in Part I, Item 4.B "Business Overview," Part I, Item 3.D. "Risk Factors," and Part I, Item 5. "Operating and Financial Review and Prospects," but are also contained elsewhere in this Annual Report. Forward-looking statements can be identified generally as those containing words as "aim," "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," or the negative of these terms, or other comparable terminology intended to identify statements about the future, although not all forward-looking statements contain these identifying words. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. The forward-looking statements contained in this Annual Report are based upon information available to us as of the date of this Annual Report and, while we believe we have a reasonable basis for each forward-looking statement contained this Annual Report, we caution you that these statements are based on a combination of facts and factors currently known by us and our expectations of the future, about which we cannot be certain.

By their nature, forward-looking statements involve risks and uncertainties because they relate to events, competitive dynamics and industry change, and depend on economic circumstances that may or may not occur in the future or may occur on longer or shorter timelines than anticipated. Although we believe that we have a reasonable basis for each forward-looking statement contained in this Annual Report, we caution you that forward-looking statements are not guarantees of future performance and involve known and unknown risks, uncertainties and other factors that are in some cases beyond our control, including risks inherent in biopharmaceutical product development. These forward-looking statements include, without limitation, statements about the following:

- the success, cost and timing of our product development activities and clinical trials of our lead product candidates as well as our other current product candidates and any future product candidates;
- our need to raise additional funding to further our development activities and clinical trials before we can expect to generate any revenues from product sales;
- our ability to obtain regulatory approval for our current or future product candidates that we may identify or develop;
- our ability to ensure adequate supply of our current or future product candidates;
- our ability to maintain third-party relationships necessary to conduct our business;
- our dependence upon the success of our research to generate and advance additional product candidates;
- our ability to establish an adequate safety or efficacy profile for our current or future product candidates that we may pursue;

- the implementation of our strategic plans for our business, our current or future product candidates we may develop and our technology;
- our intellectual property position, including the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates and technology, as well as our ability to enforce, protect and defend such intellectual property rights;
- the rate and degree of market acceptance and clinical utility for our current or future product candidates we may develop;
- our ability to attract and enroll patients in our clinical trials;
- our estimates about the size of our market opportunity;
- our expectations related to estimates of our expenses, future revenues, capital requirements and our needs for additional financing;
- our ability to maintain and establish collaborations;
- our financial performance and liquidity;
- our ability to effectively manage our potential growth;
- developments relating to our competitors and our industry, including the impact of government regulation;
- our ability to retain the continued service of our key professionals and consultants and to identify, hire and retain additional qualified professionals;
- our ability to maintain adequate internal controls over financial reporting and remediate and prevent material weaknesses; and
- other risks and uncertainties, including those listed under the section titled “Risk Factors.”

In addition, even if our results, performance, financial condition and liquidity, and the development of the industry in which we operate are consistent with such forward-looking statements, they may not be predictive of results or developments in future periods. Among the factors that may result in differences are our expectations regarding risks and uncertainties related to the impact of geopolitical developments on our business, operations, strategy, goals and anticipated milestones, including our ongoing and planned research activities, ability to conduct ongoing and planned clinical trials, clinical supply of current or future drug candidates, commercial supply of current or future approved products, and launching, marketing and selling current or future approved products, and our ability to obtain and maintain requisite regulatory approvals and to enroll patients and/or healthy volunteers in our planned clinical trials, additional interactions with regulatory authorities and expectations regarding future regulatory filings, our reliance on collaborations with third parties, estimating the commercial potential of our development programs and other risks indicated in the risk factors included in this report and other filings with the SEC.

Actual results could differ materially from our forward-looking statements due to a number of factors, including the risks set forth under the section “Risk Factors” and elsewhere in this Annual Report.

Any forward-looking statements that we make in this Annual Report are valid only as of the date of such statements, and we undertake no obligation to update such statements to reflect events or circumstances after the date of this Annual Report or to reflect the occurrence of unanticipated events.

Summary of the Material and Other Risks Associated with Our Business

Our business is subject to numerous material risks and uncertainties that you should be aware of in evaluating our business, including those described in Part I, Item 3.D: "Risk Factors" in this Annual Report on Form 20-F, or this Annual Report. These risks include, but are not limited to, the following:

- We are a clinical-stage biopharmaceutical company and have incurred significant losses every year since our inception. We expect to incur losses for the foreseeable future and may never achieve or maintain profitability.
- We will need to raise additional funding, which may not be available on acceptable terms, or at all. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate our product development efforts or other operations. The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.
- We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of ontunisertib, AGMB-447, or any other product candidates.
- If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.
- There is no established endpoint for FSCD and the development and validation of endpoints, including patient-reported outcomes, may delay the development of our product candidates or increase development costs.
- Our products and product candidates may have serious adverse, undesirable or unacceptable side effects, or even cause death, and we or others may identify undesirable or unacceptable side effects caused by any of our product candidates after they have received marketing approval.
- Even if we obtain approval from the FDA, the European Medicines Agency, or the EMA, or other applicable regulatory authorities for any product candidate that we may identify and pursue in the United States or Europe, we may never obtain approval to commercialize any such product candidates outside of those jurisdictions, which would limit our ability to realize their full market potential.
- The commercial success of our products and product candidates, including in new indications or methods of administration, will depend on the degree of market acceptance.
- We rely, and intend to rely, on third parties to conduct our clinical trials and perform some of our research and preclinical studies. If these third parties do not satisfactorily carry out their contractual duties or fail to meet expected deadlines, our development programs may be delayed or subject to increased costs, each of which may have an adverse effect on our business and prospects.
- Our commercial success depends on our ability to obtain, maintain, enforce, and otherwise protect our current and any future intellectual property and proprietary technology, and if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors or other third parties could develop and commercialize products and product candidates similar or identical to ours and our ability to successfully develop and commercialize our product candidates may be adversely affected.
- We will need to develop and expand our company, and we may encounter difficulties in managing this development and expansion, which could disrupt our operations.
- In the past, we have identified material weaknesses in our internal control over financial reporting. If we are unable to successfully remediate the existing material weaknesses in our internal control over financial reporting, the accuracy and timing of our financial reporting may be adversely affected.

- We are subject to privacy laws, regulation and potential enforcement and contractual obligations related to data privacy and security. Our failure to comply with these laws, regulations and contractual obligations could lead to potential government enforcement actions and significant penalties against us, and harm our results, operations and/or financial conditions.

- We are a Belgian limited liability company but are not a "listed company" within the meaning of the Belgian Companies and Associations Code, and shareholders of our company may have different and, in some cases, more limited shareholder rights than shareholders of such "listed company" in Belgium or of a U.S. listed corporation.

The material and other risks summarized above should be read together with the text of the full risk factors discussed in the section entitled "Risk Factors" and the other information set forth in this Annual Report, including our consolidated financial statements and the related notes, as well as in other documents that we file with the Securities and Exchange Commission, or the SEC. If any such material and other risks and uncertainties occur, our business, prospects, financial condition and results of operations could be materially and adversely affected. The risks summarized above or described in full elsewhere in this Annual Report are not the only risks that we face. Additional risks and uncertainties not currently known to us, or that we currently deem to be immaterial may also materially adversely affect our business, prospects, financial condition and results of operations.

Part I

Item 1: Identity of Directors, Senior Management and Advisers

Not applicable.

Item 2: Offer Statistics and Expected Timetable

Not applicable.

Item 3: Key Information

A. [Reserved]

Not applicable.

B. Capitalization and Indebtedness

Not applicable.

C. Reasons for the Offer and Use of Proceeds

Not applicable.

D. Risk Factors

You should consider carefully the risks and uncertainties described below, together with all of the other information in this Annual Report, including the financial statements and the related notes included elsewhere in this Annual Report. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties that we are unaware of, or that we currently believe are not material, may also become important factors that adversely affect our business. If any of the following risks actually occurs, our business, financial condition, results of operations, and future prospects could be materially and adversely affected.

Risks related to our limited operating history, financial position and need for additional capital

We are a clinical-stage biopharmaceutical company and have incurred significant losses since our inception. We expect to incur losses for the foreseeable future and may never achieve or maintain profitability.

We are a clinical-stage biopharmaceutical company and we have not generated any revenue to date. We have incurred net losses in each year since our inception in April 2017, including total comprehensive losses of €62.5 million and €46.4 million for the years ended December 31, 2025 and 2024, respectively. Our historical losses resulted principally from costs incurred in connection with research and development activities and general and administrative costs associated with our operations. In the future, we intend to continue to conduct research and development, preclinical testing, clinical trials, regulatory compliance, market access, commercialization and business development activities that, together with anticipated general and administrative expenses, will result in incurring further significant losses for at least the next several years. Our expected losses, among other things, may continue to cause our working capital and shareholders' equity to decrease.

We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. We anticipate that our expenses will increase substantially if and as we:

- continue our research and development activities of our product candidates, including through clinical development, and, if successful, later-stage clinical trials;
- expand the scope of our current clinical studies for our product candidates;

- initiate additional clinical or other studies for our product candidates;
- discover and develop new product candidates;
- add additional manufacturers or suppliers or increase our spending with current manufacturers or suppliers;
- seek regulatory and marketing approvals for our product candidates that successfully complete clinical studies;
- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- seek to identify and validate additional product candidates;
- acquire or in-license other product candidates or technologies;
- make payments under any in-license agreements;
- make milestone payments to Agomab Spain, S.L.U. former equity holders;
- maintain, protect, enforce and expand our intellectual property portfolio;
- attract and retain skilled personnel;
- create additional infrastructure to support our operations as a U.S. public company and our product development and planned future commercialization efforts; and
- experience any delays or encounter issues with any of the above.

To date, we have funded our operations through private placements of equity and our initial public offering, or IPO. To become and remain profitable, we will need to continue developing and eventually commercialize products that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing clinical trials of ontunisertib, AGMB-447, and other current and future product candidates, obtaining regulatory approval for any product candidates for which we successfully complete clinical trials, and establishing marketing capabilities. Even if any of the product candidates that we may develop are approved for commercial sale, we anticipate incurring significant costs associated with commercialization. We are only in the preliminary stages of most of these activities. We may never succeed in these activities and, even if we do, may never generate revenue that is significant enough to achieve profitability. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations.

Because of the numerous risks and uncertainties associated with the development of drugs and biologics, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. If we are required by the U.S. Food and Drug Administration, or the FDA, the European Medicines Agency, or the EMA, or other comparable foreign authorities to perform studies in addition to those we currently anticipate, or if there are any delays in completing our clinical trials or the development of ontunisertib, AGMB-447, or any other product candidates, our expenses could increase beyond our current expectations and revenue could be further delayed. Our failure to become and remain profitable would depress the market price of our American Depositary Shares, or ADSs, and could impair our ability to raise capital, expand our business or continue our operations. If we continue to suffer losses, investors may not receive any return on their investment and may lose their entire investment.

We will need to raise capital to finance our operations. Failure to obtain this necessary capital when needed, or on acceptable terms, may force us to delay, limit or terminate our product development efforts or other operations.

We are currently advancing ontunisertib and AGMB-447 through clinical development with one additional Phase 1-ready product candidate, AGMB-101, and multiple early discovery programs, in our portfolio. The research and development of biopharmaceutical products is expensive, and we expect our expenses to increase substantially in connection with our ongoing activities, particularly as we advance our product candidates in clinical studies.

As of December 31, 2025, our cash, cash equivalents and cash investments were €116.5 million. We expect our existing cash, cash equivalents and cash investments, including the net proceeds from our IPO, will be sufficient to fund our current operations into the first half of 2029. Changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned. Our future funding requirements, both short-term and long-term, will depend on many factors, including.

- the scope, progress, timing, costs, including those related to chemistry, manufacturing and controls, or CMC, and results of clinical trials of, and research and preclinical development efforts for, our current and future product candidates;
- the number of future product candidates and indications that we pursue and their development requirements;
- the outcome, timing and costs of seeking regulatory approvals;
- the costs of commercialization activities for any of our product candidates that receive marketing approval to the extent such costs are not the responsibility of any future collaborators, including the costs and timing of establishing product sales, marketing, distribution and commercial-scale manufacturing capabilities;
- the effect of competing technological and market developments;
- subject to receipt of marketing approval, revenue, if any, received from commercial sales of our current and future product candidates;
- our ability to enter into, and the terms and timing of, any collaborations, licensing or other arrangements;
- our headcount growth and associated costs as we expand our research and development activities;
- the costs of preparing, filing and prosecuting patent applications, maintaining, protecting and enforcing our intellectual property rights, including enforcing and defending intellectual property-related claims; and
- the costs of operating as a U.S. public company.

We may need to seek additional funds sooner than planned, through public or private equity or debt financings, government or other third-party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements or a combination of these approaches. In any event, we will require substantial additional capital to obtain regulatory approval for, and to commercialize, our product candidates. Even if we believe we have sufficient funds for our current or future operating plans, we may seek additional capital if market conditions are favorable or if we have specific strategic considerations.

Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. Moreover, the terms of any financing may adversely affect the holdings or the rights of our shareholders and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our ADSs to decline. The sale of additional equity or convertible securities would dilute all of our shareholders. The incurrence of indebtedness would result in increased fixed payment obligations and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. We could also be required to seek funds through arrangements with collaborative partners or otherwise at an earlier stage than otherwise would be desirable and we may be required to relinquish rights to some of our product candidates or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, operating results and prospects. Our current or future in-licenses may also be terminated if we are unable to meet the payment or other obligations under the agreements.

If we are unable to obtain funding on a timely basis, we may be required to significantly curtail, delay or discontinue one or more of our research or development programs or the clinical development or commercialization of any product candidates or be unable to expand our operations or otherwise capitalize on our business opportunities, as desired, which could materially affect our business, financial condition and results of operations.

We have never generated revenue from product sales and may never become profitable.

Our ability to generate revenue from product sales and achieve profitability depends on our ability, alone or with collaborative partners, to successfully complete the development of, and obtain the regulatory approvals necessary to commercialize, product candidates we may identify for development. We may not generate revenues from product sales for many years, if ever. Our ability to generate future revenues from product sales depends heavily on our or our collaborators' ability to successfully:

- identify product candidates and successfully complete research development of any product candidates we may identify;
- seek and obtain regulatory approvals for any product candidates for which we successfully complete clinical trials;
- launch and commercialize any product candidates for which we may obtain regulatory approval by establishing a sales force, marketing and distribution infrastructure, or alternatively, collaborating with a commercialization partner;
- qualify for adequate coverage and reimbursement by government and third-party payors for any product candidates for which we may obtain regulatory approval;
- establish and maintain supply and manufacturing relationships with third parties that can provide adequate, in both amount and quality, products and services to support clinical development and the market demand for any product candidates for which we obtain regulatory approval;
- develop, maintain and enhance a sustainable, scalable, reproducible and transferable manufacturing process for the product candidates we may develop;
- address competing technological and market developments;
- negotiate favorable terms in any collaboration, licensing or other arrangements into which we may enter and performing our obligations in such collaborations;
- receive market acceptance by physicians, patients, healthcare payors, and others in the medical community;
- maintain, protect, enforce, defend and expand our portfolio of intellectual property and other proprietary rights, including patents, trade secrets and know-how;
- defend against third-party intellectual property claims of infringement, misappropriation or other violation; and

- attract, hire and retain qualified personnel.

Our expenses could increase beyond expectations if we are required by the FDA or the EMA, or other regulatory authorities to perform preclinical studies or clinical trials in addition to those that we currently anticipate. Even if one or more of the product candidates we may develop are approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate. Additionally, such products may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives. Even if we are able to generate revenues from the sale of any approved product candidates, we may not become profitable and may need to obtain additional funding to continue operations.

Our limited operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

We are a clinical-stage biopharmaceutical company with a limited operating history. We were incorporated in April 2017 and, to date, we have invested most of our resources in developing ontunisertib, AGMB-447 and our other product candidates, acquiring our Spanish subsidiary, and providing administrative support for these operations. We have not yet demonstrated an ability to successfully complete later-stage clinical trials beyond Phase 2a, obtain regulatory approvals, manufacture a commercial-scale product, or conduct sales and marketing activities necessary for successful product commercialization or obtain reimbursement in the countries of sale. Advancing our programs through clinical trials will require substantial additional development and clinical research time and resources before we would be able to apply for or receive regulatory approvals and begin generating revenue from product sales.

We may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving our business objectives. We will eventually need to transition from a company with a development focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

Risks related to the discovery and development of our product candidates

Clinical development involves a lengthy, complex, and expensive process, with an uncertain outcome.

To obtain the requisite regulatory approvals to commercialize any product candidates, we must demonstrate through extensive preclinical studies and clinical trials that our product candidates are safe and effective in humans. To do so, we must also generate data to support our IND or planned IND applications in the United States, or our clinical trial applications, or CTAs, in the United Kingdom, or UK, or in the European Union, or EU, or a comparable application in other jurisdictions. We cannot be sure that we will be able to submit INDs or CTAs or comparable applications for our preclinical programs on the timelines we expect, if at all. We also cannot guarantee that submission of INDs or CTAs or comparable applications will result in the FDA, the EMA, the Medicines and Healthcare products Regulatory Agency, or MHRA, or other regulatory authorities allowing clinical trials to even begin.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. In particular, FDA approval has generally required evidence of effectiveness derived from two adequate and well-controlled clinical trials; however, in February 2026, the FDA publicly indicated that a single such trial will be the FDA's default standard moving forward for novel products, together with confirmatory evidence. The FDA retains broad discretion to determine the adequacy of the evidentiary package for any particular product candidate, and may require a second adequate and well-controlled clinical trial in some circumstances. Phase 3 clinical trials typically involve hundreds to thousands of patients, have significant costs and take years to complete.

A product candidate can fail at any stage of testing, even after observing promising signals of activity in earlier preclinical studies or earlier stage clinical trials. Product candidates that appear promising in the early phases of development may fail to complete development or reach the market for several reasons, including:

- preclinical studies or clinical trials may show the product candidates to be less effective than expected (e.g., a clinical trial could fail to meet its primary endpoint(s) or to have unacceptable side effects or toxicities);
- failure to establish clinical endpoints that applicable regulatory authorities would consider clinically meaningful;
- development of competing products in the same disease state;

- manufacturing costs, formulation issues, pricing or reimbursement issues, or other factors that make a product candidate uneconomical; and

- the proprietary rights of others and their competing products and technologies that may prevent one or more of our product candidates from being commercialized.

In addition, differences in trial design between early-stage clinical trials and later-stage clinical trials make it difficult to extrapolate the results of earlier clinical trials to later clinical trials. Clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in clinical trials have nonetheless failed to obtain marketing approval.

Additionally, some of our planned trials are open label studies, where both the patient and investigator know whether the patient is receiving the investigational product candidate or either an existing approved drug or placebo. Most typically, open label clinical trials test only the investigational product candidate and sometimes do so at different dose levels. Open label clinical trials are subject to various limitations that may exaggerate any therapeutic effect as patients in open label clinical trials are aware when they are receiving treatment. In addition, open label clinical trials may be subject to an "investigator bias" where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge. Therefore, it is possible that positive results observed in open label trials will not be replicated in later placebo-controlled trials.

In addition, the standards that the FDA and comparable foreign regulatory authorities use when regulating us require judgment and can change, which makes it difficult to predict with certainty how they will be applied. As approval procedures can vary among countries and may change over time, this can require additional clinical testing and the time required to obtain approval may differ. We can provide no assurances that such approval will be obtained on the timeline that we expect or at all. Although we are initially focusing our efforts on the clinical development of small molecule drug products, we also anticipate commencing clinical development of biological products, which could make us subject to additional regulatory requirements. Any analysis we perform of data from preclinical and clinical activities is subject to confirmation and interpretation by regulatory authorities, which could delay, limit or prevent further development. We may also encounter unexpected delays or increased costs due to new government regulations. Examples of such regulations include future legislation or administrative action, or changes in FDA or comparable foreign regulatory policy during the period of product development and FDA and comparable foreign regulatory review. It is impossible to predict whether legislative changes will be enacted, or whether FDA or foreign regulations, guidance or interpretations will be changed, or what the impact of such changes, if any, may be. If ontunisertib, AGMB-447, or our other current or future product candidates, are not approved in one or more jurisdictions, or if such approvals are significantly delayed, it could have a material adverse effect on our business. It is possible that none of our other existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval in any other jurisdiction or indication. Moreover, we must obtain separate regulatory approvals in each jurisdiction where we want to market and approval by one regulatory authority does not ensure approval by any other regulatory authority. As approval procedures can vary among countries and may change over time, this can require additional clinical testing and the time required to obtain approval may differ. We can provide no assurances that such approval will be obtained on the timeline that we expect or at all. Successful completion of clinical trials is a prerequisite to submitting a marketing application to the FDA and comparable foreign regulatory authorities for each product candidate. We may experience negative or inconclusive results, which may result in our deciding, or our being required by regulators, to conduct additional clinical studies or trials or abandon some or all of our product development programs, which could have a material adverse effect on our business.

We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of ontunisertib, AGMB-447, or any other product candidates.

We may experience delays in initiating or completing clinical trials. We also may experience numerous unforeseen events during, or as a result of, any future clinical trials that could delay or prevent our ability to receive marketing approval or commercialize any product candidates, including:

- regulators or central and or local institutional review boards, or IRBs, or ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;

- the FDA or other comparable regulatory authorities may disagree with our clinical trial design, including with respect to dosing levels administered in our planned clinical trials, which may delay or prevent us from initiating our clinical trials with our originally intended trial design;

- we may encounter challenges designing our trials, including developing and reaching agreements with the FDA or other comparable authorities on the appropriate clinical endpoints, the design of the trial itself, the development of a patient-reported outcome, or PRO, as an endpoint, and the validation of a PRO;

- we may experience delays in reaching, or fail to reach, agreement on acceptable terms with prospective trial sites and prospective contract research organizations, or CROs, which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;

- the number of subjects required for clinical trials of any product candidates may be larger than we anticipate or subjects may drop out of these clinical trials or fail to return for post-treatment follow-up at a higher rate than we anticipate;

- our third-party contractors may fail to comply with regulatory requirements, including those promulgated by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use, good clinical practices, of GCPs, and current good manufacturing practices, or cGMPs, or meet their contractual obligations to us in a timely manner, or at all, or may deviate from the clinical trial protocol or drop out of the trial, which may require that we add new clinical trial sites or investigators;

- we may experience delays or interruptions to our manufacturing supply chain, or we could suffer delays in reaching, or we may fail to reach, agreement on acceptable terms with third-party service providers on whom we rely;

- additional delays and interruptions to our clinical trials could extend the duration of the trials and increase the overall costs to finish the trials as our fixed costs are not substantially reduced during delays;

- we may elect to, or regulators, IRBs, Data Safety Monitoring Boards, or DSMBs, or ethics committees may require that we or our investigators suspend or terminate clinical research or trials for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;

- we may not have the financial resources available to begin and complete the planned trials, or the cost of clinical trials of any product candidates may be greater than we anticipate;

- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate to initiate or complete a given clinical trial; and

- the FDA or other comparable foreign regulatory authorities may require us to submit additional data such as long-term toxicology studies, or impose other requirements before permitting us to initiate a clinical trial.

We are currently conducting a Phase 1 trial of AGMB-447 and have received regulatory authorization to initiate a Phase 1 single ascending dose trial of AGMB-101 in healthy participants and liver cirrhosis patients. The cost of compliance with regulations, requirements or guidelines of the FDA or other applicable regulatory authorities could be substantial. If we experience delays in the completion of, or termination of, any clinical trial of our product candidates, the costs of our clinical trials may increase, the commercial prospects of our products and product candidates may be harmed, and our ability to generate product revenues from any of these products and product candidates will be delayed. Significant clinical trial delays could also allow our competitors to bring products to market before we do or shorten any periods during which we have the exclusive right to commercialize our products and product candidates.

Our product development costs will increase if we experience additional delays in clinical testing or in obtaining marketing approvals. We do not know whether any of our clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. If we do not achieve our product development goals in the timeframes we announce and expect, the approval and commercialization of our product candidates may be delayed or prevented entirely. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates and may allow our competitors to bring products to market before we do, potentially impairing our ability to successfully commercialize our product candidates and harming our business and results of operations. Any delays in our clinical development programs may harm our business, financial condition, and results of operations significantly.

Due to our limited resources and access to capital, we must, and have in the past decided to, prioritize development of certain product candidates over other potential candidates. These decisions may prove to have been wrong and may adversely affect our revenues.

Because we have limited resources and access to capital to fund our operations, we must decide which product candidates to pursue and the amount of resources to allocate to each. Our decisions concerning the allocation of research, collaboration, management and financial resources toward particular compounds, product candidates or therapeutic areas may not lead to the development of viable commercial products and may divert resources away from better opportunities. Similarly, our decisions to delay, terminate or collaborate with third parties in respect of certain product development programs may also prove not to be optimal and could cause us to miss valuable opportunities. If we make incorrect determinations regarding the market potential of our product candidates or misread trends in the biopharmaceutical industry, in particular for our lead product candidates, our business, financial condition and results of operations could be adversely affected.

If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the trial until its conclusion. Enrollment of patients depends on many factors, including:

- the patient eligibility and exclusion criteria defined in the protocol;
- the size of the patient population required for analysis of the trial's primary endpoints and the process for identifying patients;
- the willingness or availability of patients to participate in our trials;
- the proximity of patients to trial sites;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- clinicians' and patients' perceptions as to the potential advantages and risks of the product candidate being studied in relation to other available therapies, including any new products that may be approved for the indications we are investigating or other studies enrolling for similar diseases;
- the availability of competing commercially available therapies and other competing product candidates' clinical trials;
- our ability to obtain and maintain patient informed consents; and
- the risk that patients enrolled in clinical trials will drop out of the trials before completion.

In addition, our clinical trials compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials in such clinical trial site. Other effects on recruitment and retention of patients may hinder or delay a clinical trial and could cause a significant setback to an applicable program.

Interim, topline and preliminary data from our preclinical studies and clinical trials that we announce or publish from time to time may change as more patient data becomes available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publish interim, topline or preliminary data from our preclinical studies and clinical trials. Preliminary and interim data from our clinical trials may change as more patient data become available. Preliminary or interim data from our clinical trials are not necessarily predictive of final results. Preliminary and interim data are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues, more patient data become available and we issue our final clinical trial report. Interim, topline and preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. For example, our announced topline results of the global randomized, double-blind, placebo-controlled Phase 2a trial of ontunisertib may be materially different from the final data. As a result, preliminary and interim data should be viewed with caution until the final data are available. Material adverse changes in the final data compared to the interim data could significantly harm our business prospects.

The results of preclinical studies and early-stage clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. Initial success in our ongoing clinical trials may not be indicative of results obtained when these trials are completed or in later stage trials.

Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. Furthermore, there can be no assurance that any of our clinical trials will ultimately be successful or support further clinical development of any of our product candidates. For example, because there is no established endpoint for FSCD and there is a lack of precedent for clinical trial design, there can be no assurance that ontunisertib will meet its endpoints in our ongoing and planned clinical trials. There is a high failure rate for drugs and biologics proceeding through clinical trials. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in clinical development even after achieving promising results in earlier studies, and any such setbacks in our clinical development could have a material adverse effect on our business and operating results.

There is no established endpoint for FSCD therapies, and the development and validation of efficacy endpoints to support approval may delay the development of our product candidates or increase development costs.

There are no approved pharmacologic therapies for FSCD, and there are currently no regulatory guidelines specific for FSCD, and no established efficacy endpoint to support registration. We are developing and evaluating several endpoints in our clinical trials, to potentially be used as registrational endpoints for ontunisertib in FSCD. Based on our interactions with regulatory authorities, we believe that these authorities may require both clinical and imaging outcomes as endpoints. FDA has recently issued guidance outlining the Agency's expectations for the development and validation of Clinical Outcome Assessments, or COAs, to support regulatory decision making. COAs may have an important role in the development and regulatory approval of any of our product candidates. COAs may include Patient Reported Outcomes, or PROs, which involve patients' subjective assessments of efficacy, and this subjectivity increases the variability of these instruments and may limit their ability to detect a therapeutic effect. Furthermore, it may be challenging to identify symptoms which are sufficiently specific for FSCD. Such assessments can be influenced by factors outside of our control and can vary widely from day-to-day for a particular patient, as well as from patient-to-patient, site-to-site, and culture-to-culture, within a clinical trial. Use of COAs may make the outcome of clinical trials more uncertain and may increase our costs and time to complete trials for regulatory approval. Additionally, we will need to provide information to the FDA, and potentially to comparable foreign regulatory authorities, to help establish the validity and reliability of the COAs we develop. Additionally, regulators may require us to demonstrate an effect of ontunisertib on stricture severity by imaging. There is currently no approved imaging endpoint for FSCD, and we are working with imaging experts to develop such an endpoint or endpoints. We will need to provide information to the FDA, and potentially to comparable foreign regulatory authorities, to help establish the validity and reliability of any imaging endpoint(s) we develop. Currently, magnetic resonance enterography, or MRE, is commonly used in clinical practice to evaluate stricture severity. Computed tomography enterography, or CTE, performs similarly to MRE and may be used in future clinical trials. While MRE and CTE can measure relevant stricture-related features with precision, these imaging modalities might not be able to capture meaningful therapeutic effects within the timeframe of a clinical trial.

An additional imaging modality is endoscopy, which can evaluate both luminal inflammation and stricture severity. The Simple Endoscopic Score in Crohn's Disease, or SES-CD, is supported by FDA and other regulatory agencies as a co-primary efficacy endpoint suitable for the registration of novel therapies in luminal Crohn's disease. We are evaluating the value of the SES-CD as a potential registrational endpoint in FSCD. However, the SES-CD has not been specifically validated in FSCD patients and may not be supported by regulatory agencies for the registration of new therapies in this indication.

Separately from clinical and radiological responses, adverse clinical outcomes can represent a potential efficacy endpoint in FSCD. Specifically, registration may be granted to a novel agent able to reduce the incidence or delay the occurrence of adverse clinical outcomes such as Crohn's disease related death, bowel surgery, endoscopic balloon dilation, and hospitalization. However, the occurrence of these events may be too low in the context of a clinical trial of reasonable size and duration, which would preclude the use of such outcome measures.

We may encounter challenges reaching an agreement with the FDA or a comparable foreign regulatory authority on the validation of the endpoints that we are developing for use in the FSCD clinical program, as well as whether the endpoints selected are appropriate endpoints to support approval.

We have conducted and may continue to conduct clinical trials for our product candidates outside of the U.S., and the FDA may not accept data from such trials, in which case our development plans may be delayed, which could materially harm our business.

We have in the past conducted, and in the future intend to continue to conduct, clinical trials or a portion of our clinical trials for our drug and biological product candidates outside the U.S. The acceptance of study data from clinical trials conducted outside the U.S. or another jurisdiction by the FDA or comparable foreign regulatory authority may be subject to certain conditions or may not be accepted at all. For example, we are conducting the Phase 1 trial of AGMB-447 solely in the United Kingdom, and we have only interacted with the MHRA thus far. The FDA or other foreign regulatory authorities may not agree that the preclinical and clinical data we have generated are sufficient to initiate subsequent clinical trials in the United States or other jurisdictions.

In cases where data from foreign clinical trials are intended to serve as the sole basis for marketing approval in the United States, for example, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice; (ii) the trials were performed by clinical investigators of recognized competence and pursuant to GCP regulations; and (iii) the data may be considered valid without the need for an on-site inspection by the FDA, or if the FDA considers such inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. In addition, even where the foreign study data are not intended to serve as the sole basis for approval, the FDA will not accept the data as support for an application for marketing approval unless the study is well-designed and well-conducted in accordance with GCP requirements and the FDA is able to validate the data from the study through an on-site inspection if deemed necessary. Further, if our target patient population is smaller than expected, we are unable to successfully enroll and retain patients in our clinical trials, or experience significant delays in doing so, we may not satisfy the FDA, the EMA or other applicable regulatory authorities standards for number of patients enrolled due to enrollment being too low. Many foreign regulatory authorities have similar requirements for clinical data gathered outside of their respective jurisdictions. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the U.S. or the relevant jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept such data, it may result in the need for additional trials, which could be costly and time-consuming, and which may result in current or future product candidates that we may develop not receiving approval for, or experiencing delays in, commercialization in the applicable jurisdiction.

Our products and product candidates may have serious adverse, undesirable or unacceptable side effects, or even cause death, and we or others may identify undesirable or unacceptable side effects caused by any of our product candidates during clinical trials or after they have received marketing approval.

Undesirable side effects that may be caused by our product candidates, or by the combination of our product candidates with other medical products, could cause us or regulatory authorities to interrupt, delay or halt clinical trials, including full or partial clinical holds on ongoing or planned trials, and could result in more restrictive labeling or the delay or denial of regulatory approval by the FDA or other applicable regulatory authorities. While our preclinical studies and clinical trials to date show that our clinical-stage product candidates have generally been well tolerated from a risk-benefit perspective, we have observed adverse events, in our clinical trials, and we may see additional adverse events and/or treatment emergent adverse events, or TEAEs, in our ongoing and future clinical trials. Such side effects may be more serious than those observed to date, and as a result, our ongoing and future clinical trials may be negatively impacted. For example, previous ALK5 inhibitors, which are similar to the product candidates we are developing, have been associated with systemic toxicities, mainly cardiac toxicity and bone adverse effects, that have limited their further development. Although we have designed our lead product candidates with the goal of avoiding the types of toxicities associated with systemic inhibition of transforming growth factor β, or TGFβ, future preclinical studies may still show the presence of such toxicities, and patients in our current or future trials may experience the types of adverse events associated with these toxicities. Moreover, as we seek to develop product candidates, including products in new indications, patients may experience new or more serious effects. Drug and biologic-related side effects could affect patient recruitment, the ability of enrolled patients to complete the clinical trial, result in potential product liability claims, damage sales of any existing products, result in significant reputational damage for us and our product development, and other issues including the delay of other programs.

Additionally, if we or others identify undesirable or unacceptable side effects or perceived risks caused by our product candidates after they receive marketing approval, a number of potentially significant negative consequences could arise, including:

- regulatory authorities may withdraw approvals or revoke licenses of such products and require us to take such products off the market;
- regulatory authorities may require the addition of labeling statements, specific warnings, or a contraindication or request the issuance of field alerts to physicians and pharmacies;
- regulatory authorities may require a medication guide outlining the risks of such side effects for distribution to patients, or a Risk Evaluation and Mitigation Strategy, or a REMS, to ensure that the benefits of the product outweigh its risks;
- regulatory authorities may require us to demonstrate that the clinical and other benefits of any of our product candidates outweigh any safety or other perceived risks, which we may be unable to achieve;

- we may be required to change the way the product is administered, conduct additional clinical trials or change the labeling of the product;
- we may be subject to limitations on how we may promote the product;
- we may be subject to boxed warnings, labeling restrictions or dose limitations in certain jurisdictions, which could have a material adverse impact on our ability to market our product candidates in those jurisdictions;
- sales of the product may decrease significantly;
- we may be subject to litigation, product liability claims, or criminal prosecution; and
- our reputation may suffer.

Any of these events could negatively impact us, our collaborators or our potential future partners and have a material adverse effect on our ability to commercialize our product candidates.

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.

The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any product candidate and it is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval.

Our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;
- the results of toxicology studies in humans or animals conducted by us or third parties may not be to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe for future preclinical studies or clinical trials;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of a New Drug Application, or NDA, or Biologics License Application, or BLA, to the FDA or any other submission to obtain regulatory approval in the EU, or elsewhere;
- the FDA or comparable foreign regulatory authorities may find deficiencies with or fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies;

- the FDA or comparable foreign regulatory authorities may find deficiencies in the quality and characterization of the product candidate's drug substance and product to be commercialized; and

- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

This lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market any of our product candidates, which would significantly harm our business, results of operations and prospects. The FDA and other comparable foreign authorities have substantial discretion in the approval process, and determining when or whether regulatory approval will be obtained for any of our product candidates. Even if we believe the data collected from clinical trials of our product candidates are promising, such data may not be sufficient to support approval by the FDA or any other regulatory authority.

In addition, even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

We have obtained orphan drug designation for AGMB-447 and may seek orphan drug designation for a product candidate that we develop, and we may be unsuccessful; if we fail to obtain orphan drug designation or fail to obtain and/or maintain orphan drug exclusivity for our products or product candidates, our revenue may be reduced.

Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is intended to treat a rare disease or condition, defined as a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States In the EU, after a recommendation from the EMA's Committee for Orphan Medicinal Products, the European Commission may grant orphan designation if the sponsor can establish that: (1) the product is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition, (2) either (i) the prevalence of the condition is not more than five in 10,000 persons in the EU when the application is made, or (ii) without incentives it is unlikely that the marketing of the product in the EU would generate sufficient return to justify the necessary investment in its development and (3) there exists no satisfactory method of diagnosis, prevention, or treatment of the condition in question that has been authorized in the EU or, if such method exists, the product will be of a significant benefit compared to the other products available for the condition.

In the United States, orphan drug designation entitles a party to financial incentives such as tax advantages and user fee waivers. In addition, if a product receives the first FDA approval for the indication for which it has orphan designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other application submitted by another applicant to market a same drug or biological product for the same indication for period of seven years, except in limited circumstances. Whether a biological product is the same as another product is based on whether the two products have the same principal molecular structural features. Orphan designation does not, however, truncate the duration of the regulatory review and approval process.

In the EU, orphan designation entitles a party to financial incentives such as reduction of fees or fee waivers and 10 years of market exclusivity following marketing approval. This period may be reduced to six years if, at the end of the fifth year, it is established that orphan designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity. If we fail to obtain or if we lose orphan drug status for one or more of our products and product candidates, the aforementioned incentives and market exclusivity may not or no longer be available to us, which is likely to increase the overall cost of development and to decrease the competitive position of such product and product candidate including from biosimilars. Similar considerations apply in the UK.

We may from time to time seek orphan drug designation in the United States or the EU for certain indications addressed by our products and product candidates. For example, the FDA has granted orphan drug designation for AGMB-447 for the treatment of idiopathic pulmonary fibrosis. With regard to these designations or future designations we may obtain, we may not be the first to obtain marketing approval of these drugs for such indication due to the uncertainties associated with developing therapeutic products, and we may not obtain or maintain orphan designation upon approval. In addition, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan-designated indication or may be lost if the FDA later determines that the request for designation was materially defective or if we are unable to assure sufficient quantities of the product to meet the needs of patients with the disease or condition. Further, even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties or different principal molecular structural features can be approved for the same condition. Even after an orphan drug is approved, the FDA, EMA or other foreign regulator can subsequently approve the same drug for the same condition if the regulator concludes that the later drug is safer, more effective, or makes a major contribution to patient care.

If we decide to pursue accelerated approval for any of our product candidates, it may not lead to a faster development or regulatory review or approval process and does not increase the likelihood that our product candidates will receive marketing approval. If we are unable to obtain approval under an accelerated pathway, we may be required to conduct additional clinical trials beyond those that we contemplate, which could increase the expense of obtaining, reduce the likelihood of obtaining, and/or delay the timing of obtaining, necessary marketing approvals.

In the future, we may decide to pursue accelerated approval for one or more of our product candidates. For example, under the FDA's accelerated approval program, the FDA may approve a drug or biological product for a serious or life-threatening disease or condition that provides a meaningful advantage over available therapies based upon a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit. For products granted accelerated approval, post-marketing confirmatory clinical trials are required to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. These confirmatory clinical trials must be completed with due diligence, and the FDA may require that the clinical trial be designed, initiated, and/or fully enrolled prior to approval. If we were to pursue accelerated approval for a product candidate for a disease or condition, we would do so on the basis that there is no available therapy for that disease or condition. If standard of care were to evolve or if any of our competitors were to receive full approval on the basis of a confirmatory clinical trial for a drug or biological product for a disease or condition for which we are seeking accelerated approval before we receive accelerated approval, the disease or condition may no longer qualify as one for which there is no available therapy, and we may not be able to obtain accelerated approval of our product candidate.

Moreover, the FDA may withdraw approval of any product candidate approved under the accelerated approval pathway if, for example:

- the clinical trial or clinical trials required to verify the predicted clinical benefit of our product candidate fail to verify such benefit or do not demonstrate sufficient clinical benefit to justify the risks associated with such product;
- other evidence demonstrates that our product candidate is not shown to be safe or effective under the conditions of use;
- we fail to conduct any required post-approval trial of our product candidate with due diligence; or
- we disseminate false or misleading promotional materials relating to the relevant product candidate.

Pursuant to the Food and Drug Omnibus Reform Act, or FDORA, the FDA is authorized to require a post-approval clinical trial to be underway prior to approval or within a specified time period following approval. FDORA also requires the FDA to specify conditions of any required post-approval clinical trial and requires sponsors to submit progress reports for required post-approval studies. In addition, FDORA enables the FDA to initiate enforcement action for the failure to conduct with due diligence a required post-approval clinical trial, including a failure to meet any required conditions specified by the FDA or to submit timely reports.

Failure to obtain accelerated approval for our product candidates could result in a longer time period to commercialization of such product candidate, if any, and could increase the cost of development of such product candidate and harm our competitive position in the marketplace.

We have obtained Fast Track Designation for ontunisertib and may seek Breakthrough Therapy Designation by the FDA or Priority Medicine, or PRIME, designation from the EMA for a product candidate that we develop, and we may be unsuccessful. If we are successful, the designation may not actually lead to a faster development or regulatory review or approval process.

If a drug or biological product candidate is intended for the treatment of a serious or life-threatening condition and non-clinical and clinical data demonstrate the potential for the drug or biological product candidate to address an unmet medical need for this condition, the product candidate may qualify for FDA Fast Track Designation for a particular indication, for which sponsors must apply. Ontunisertib has received the first ever Fast Track Designation for the treatment of FSCD by the FDA. Additionally, we may seek Fast Track Designation for our current or future product candidates, but there is no assurance that the FDA will grant this status to any of our proposed product candidates. If granted, Fast Track Designation makes a sponsor eligible for more frequent interactions with FDA to discuss the development plan and clinical trial design for the product granted Fast Track Designation, as well as eligible for rolling review of the Fast Track product's marketing application, which means that the sponsor can submit completed sections of its marketing application for review prior to completion of the entire submission. Marketing applications of product candidates with Fast Track Designation may qualify for priority review if they meet the applicable criteria, but Fast Track Designation does not assure any such qualification or ultimate marketing approval by the FDA. The FDA has broad discretion whether or not to grant Fast Track Designation, so even if we believe a particular product candidate is eligible for this designation, there can be no assurance that the FDA would decide to grant it. Even if we do receive Fast Track Designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures, and receiving a Fast Track Designation does not provide any assurance of ultimate FDA approval. In addition, the FDA may withdraw Fast Track Designation if it believes that the designation is no longer supported by data from our clinical development program. In addition, the FDA may withdraw any Fast Track Designation at any time.

Additionally, we may seek Breakthrough Track Designation for our current or future product candidates, but there is no assurance that the FDA will grant this status to any of our proposed product candidates. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over currently approved therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as breakthrough therapies by the FDA are also eligible for accelerated approval and priority review. Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe a product candidate we develop meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of Breakthrough Therapy Designation for a product candidate may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if any product candidate we develop qualifies as a breakthrough therapy, the FDA may later decide that the drug no longer meets the conditions for qualification and rescind the designation.

In the EU, the PRIME designation is similar to the breakthrough designation. The EMA has implemented the PRIME designation to support the development and accelerate the approval of complex, innovative medicinal products addressing an unmet medical need. The PRIME designation enables early dialogue with the relevant EMA scientific committees and, possibly, some payors and thus reinforces the EMA's scientific and regulatory support. The PRIME designation, which is granted at the EMA's discretion, focuses on medicinal products the marketing authorization of which qualifies for accelerated assessment (medicinal products of major interest from a public health perspective, in particular from a therapeutic innovation perspective). Even if we believe a particular product candidate is eligible for this designation, there can be no assurance that the EMA would decide to grant it. Further, even if we do receive PRIME designation, we may not experience a faster development process, review or approval compared to conventional EMA procedures, and receiving a PRIME designation does not provide any assurance of ultimate EMA approval. In addition, the EMA may withdraw PRIME designation if it believes that the designation is no longer supported by data from our clinical development program. In addition, the EMA may withdraw any PRIME Designation at any time.

Even if we obtain approval from the FDA, the EMA or other applicable regulatory authorities for any product candidate that we may identify and pursue in the United States or Europe, we may never obtain approval to commercialize any such product candidates outside of those jurisdictions, which would limit our ability to realize their full market potential.

In order to market any products outside of the United States, we must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval processes vary among countries and can involve additional product testing and validation and additional or different administrative review periods from those in the United States, including additional preclinical studies or clinical trials. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

Seeking foreign regulatory approval would result in difficulties and costs and may require additional preclinical studies or clinical trials which could be costly and time-consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our product candidates or any other product candidate we may develop in those countries. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. We do not have any product candidates approved for sale in any jurisdiction, including international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approval in international markets is delayed, our target market will be reduced and our ability to realize the full market potential of our current product candidates or any other product candidates we may develop will be harmed.

Risks related to commercialization

The commercial success of our products and product candidates, including in new indications or methods of administration, will depend on the degree of market acceptance.

Our products and product candidates, including for new indications or methods of administration, if and when approved and available on the market, may never achieve an adequate level of acceptance by physicians, patients, the medical community, or healthcare payors for us to be profitable. This will depend on a number of factors, many of which are beyond our control, including, but not limited to:

- the efficacy and safety as demonstrated by clinical trials and subsequent prevalence and severity of any side effects;
- approval for indications, dosage and methods of administration or patient populations that are not as broad as intended or desired;
- changes in the standard of care for the targeted indications for any product and product candidate;
- availability of alternative approved therapies;
- sales, marketing and distribution support;
- potential product liability claims;
- acceptance by physicians, patients and healthcare payors of each product as safe, effective and cost-effective;
- relative convenience, ease of use, including administration, perceived dosing complexity and other perceived advantages over alternative and/or new products;
- prevalence and severity of adverse events discovered before or after marketing approval has been received;

- consumer perceptions or publicity regarding our business or the safety and quality of our product and product candidates, clinical trials for new indications, or any similar products distributed by other companies;
- limitations, precautions or warnings listed in the summary of product characteristics, patient information leaflet, wording of package labeling or instructions for use, and any subsequent changes thereof;
- the cost of treatment with our products in general and in relation to alternative and/or new treatments;
- the impact of the combination of our product candidate with a drug delivery device on cost of treatment with our products or the convenience for patients, if approved;
- the extent to which products are approved for inclusion and reimbursed on formularies of hospitals and managed care organizations, and any subsequent changes thereof; and
- whether our products are designated in the label, under physician treatment guidelines or under reimbursement guidelines as a front-line or later-line therapy, and any subsequent changes thereof.

In addition, because we are developing our products and product candidates for the treatment of different indications, negative results in a clinical trial evaluating the efficacy and safety of a product or product candidate for one indication could negatively impact the perception of the efficacy and safety of such product or product candidate in a different indication, or another similar product or product candidate, which could have an adverse effect on our reputation, commercialization efforts and financial condition.

Moreover, efforts to educate the medical community and third-party payors on the benefits of our products and product candidates may require significant resources and may never be successful. If our product candidates or methods of use of existing products or new indications fail to gain market acceptance, this will have a material adverse impact on our ability to generate revenues. Even if some products achieve market acceptance, they may not be able to retain market acceptance and/or the market may prove not to be large enough to allow us to generate significant revenues.

Even if we receive regulatory approval of any of our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.

If any of our product candidates are approved for marketing, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies, pharmacovigilance, and submission of safety, efficacy and other post-market information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities. In addition, we will be subject to continued compliance with current cGMP and GCP requirements for any clinical trials that we conduct post-approval.

Manufacturers and their facilities are required to comply with extensive FDA and comparable foreign regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to cGMP regulations. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any marketing application, and previous responses to inspection observations. Accordingly, we and others with whom we work must continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production and quality control.

Any regulatory approvals that we receive for our product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials and surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a REMS as a condition of approval of our product candidates, which could entail requirements for long-term patient follow-up, a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves our product candidates, we will have to comply with requirements including submissions of safety and other post-marketing information and reports and registration.

The FDA or any other foreign regulatory authority may impose consent decrees or withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of our products, withdrawal of the product from the market or voluntary or mandatory product recalls;
- fines, warning letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of license approvals;
- voluntary or mandatory product recalls and related publicity requirements;
- total or partial suspension of production;
- product seizure or detention or refusal to permit the import or export of our product candidates; and
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising, and promotion of products that are placed on the market. Products may be promoted only for the approved indications and consistent with the provisions of the approved label. The FDA and other agencies enforce the laws and regulations prohibiting the promotion of off-label uses and a company that is found to have improperly promoted off-label uses may be subject to significant liability. The policies of the FDA and of other regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

If our target patient population is smaller than expected, we are unable to successfully enroll and retain patients in our clinical trials, or experience significant delays in doing so, we may not realize the full commercial potential of any product candidates.

Currently, we mainly develop our product candidates for the treatment of fibrotic diseases for which the target patient population can be small. If the actual number of patients with these disorders is smaller than we expected, we may encounter difficulties in enrolling sufficient patients in our clinical trials, thereby delaying or preventing development and approval of our product candidates. Physicians, who are an important source of referral of patients for clinical trials, may also be less familiar with these diseases and may therefore fail to identify these conditions in their patients and therefore may not refer them to our clinical trials.

Patient enrollment, a significant factor in the timing of clinical trials, depends on many factors, including the size and nature of the patient population, eligibility criteria for the clinical trial, the proximity of patients to clinical sites, competition for patient recruitment from competing clinical trials, the design of the clinical protocol, the eligibility criteria for the clinical trials, the availability of alternate approved therapies for the indication the clinical trial is investigating, the length of treatment duration, the number of invasive or noninvasive procedures, the frequency of visits to the treatment site, the number of participating clinic sites, the capabilities of a participating CRO, and clinicians' and patients' perceptions as to the potential advantages of the drug or biologic being studied in relation to other available therapies. We compete with other companies to enroll target patient populations. Even if product candidates obtain significant market share for their approved indications, because certain potential target populations are small, we may never recoup our investment in such product candidate without obtaining regulatory approval for additional indications for such product candidates. Even once enrolled, we may be unable to retain a sufficient number of patients to complete any of our clinical trials. For example, presently in clinical trials with ontunisertib, patients will be required to use contraceptive measures, since, as identified in preclinical studies, inhibiting ALK5 poses a risk to embryonic development in line with the well described role of TGFβ during embryogenesis. Clinical trial restrictions such as this may have the effect of discouraging female participants of child-bearing potential to enroll in or complete our clinical trials.

In addition, any negative results we may report in clinical trials of our drug or biologic candidates may make it difficult or impossible to recruit and retain patients in other clinical trials of that same drug or biologic candidate. Delays in the completion of any clinical trial of our product candidates will increase our costs, slow down our product candidate development and approval process and delay or potentially jeopardize our ability to commence product sales and generate revenue. In addition, some of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

Our product candidates may face competition generally and sooner than expected.

We face intense competition for our small molecule and biologic product candidates or future product candidates. For more information see Item 4.B: "Business Overview-Competition." If competitors develop technologies or drug candidates more rapidly than we do, or if their technologies or drug candidates are more effective, our ability to develop and successfully commercialize drug candidates may be adversely affected.

In the United States, for the Federal Food, Drug, and Cosmetic Act, or the FD&C Act, provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to gain approval of an NDA for a drug where the FDA has not previously approved any other new drug containing the same active molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated NDA or a 505(b)(2) NDA submitted by another company for a generic version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement. The FD&C Act also provides three years of marketing exclusivity for an NDA, 505(b)(2) NDA or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, which were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example, new indications, dosages or strengths of an existing drug. As such, we may face competition from generic versions of our small molecule product candidates, which will negatively impact our long-term business prospects and marketing opportunities.

For biologics, the Biologics Price Competition and Innovation Act, or the BPCIA, created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with a FDA-licensed reference biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full biologics license application, or BLA, for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product.

In the EU, innovative medicinal products approved on the basis of a complete and independent data package, qualify for eight years of data exclusivity upon marketing authorization and an additional two years of market exclusivity. The overall ten-year period will be extended to a maximum of eleven years if, during the first eight years of those ten years, the marketing authorization holder obtains a marketing authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are determined to bring a significant clinical benefit in comparison with existing therapies.

Following those periods of regulatory exclusivity, we must enforce our patent rights against generic products or biosimilar products that infringe the patent claims of these products. However, there is no assurance any of our product candidates will qualify, and even if they do qualify there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA or similar regulatory authority will not consider our biologic product candidates to be reference products for competing products, potentially creating the opportunity for competition by biosimilar products sooner than anticipated.

We cannot predict with accuracy the timing or impact of the introduction of competitive products that treat diseases and conditions like those treated by our product candidates. In addition, our competitors and potential competitors compete with us in recruiting and retaining qualified scientific, clinical research and development and management personnel, establishing clinical trial sites, registering patients for clinical trials, as well as in acquiring technologies complementary to, or necessary for, the development of our products. There can be no assurance that our competitors are not currently developing, or will not in the future develop, product candidates that are equally or more effective, are more economically attractive, and can be administered more easily than any of our current or future product candidates.

Even if we are able to commercialize any product candidate, such product candidate may become subject to unfavorable pricing regulations or third-party coverage and reimbursement policies, which could harm our business.

In the United States and markets in other countries, patients generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. See Item 4.B: “Business Overview” in this Annual Report.

Patients who are prescribed medications for the treatment of their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their prescription drugs. Coverage and adequate reimbursement from federal government healthcare programs, such as Medicare and Medicaid, and private health insurers are critical to new product acceptance. Patients are unlikely to use our future products, if any, unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost.

In the United States, we will be required to participate in various government programs for our products, if approved, to be reimbursed through government programs or to be purchased by the federal government. We expect to participate in programs such as the Medicaid Drug Rebate Program, the 340B drug discount program, Medicare Part B, Medicare Part D and the U.S. Department of Veterans Affairs Federal Supply Schedule pricing program. Compliance requirements vary by program, but among these and any other programs in which we participate, we will be, among other things, required to enter into agreements with and calculate and report prices and other information to certain government agencies, charge no more than statutorily mandated ceiling prices and calculate and pay rebates and refunds for certain products.

The calculations are mandated by statue, are complex and are often subject to interpretation by us, governmental agencies and the courts. If we determine that the prices we reported were in error, we may be required to restate those prices and pay additional rebates or refunds to the extent we understated the rebate or overcharged the government due to the error. Additionally, there are penalties associated with submission of incorrect pricing or other data. We may incur significant civil monetary penalties if we are found to have knowingly submitted false prices or other information to the government, or to have charged 340B entities covered by these government programs more than any the statutorily mandated price. Certain failures to timely submit required data also could result in a civil monetary penalty for each day the information is late. We could also become subject to allegations under the False Claims Act and other laws and regulations. In addition, misreporting and failure to timely report data to Centers for Medicare & Medicaid Services, or CMS, also can be grounds for CMS to terminate a Medicaid rebate agreement, pursuant to which a company is able to participate in the Medicaid Drug Rebate Program. Maintaining compliance with these government price reporting and other obligations is time-consuming and costly, and a failure to comply can result in substantial fines, penalties, all of which could adversely impact our financial results.

In addition, cost-containment is a priority in the United States healthcare industry and elsewhere. As a result, government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Third-party payors also may request additional clinical evidence beyond the data required to obtain marketing approval, requiring a company to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of its product. Commercial third-party payors often rely upon Medicare coverage policy and payment limitations in setting their reimbursement rates, but also have their own methods and approval process apart from Medicare determinations. Therefore, coverage and reimbursement for pharmaceutical products in the United States can differ significantly from payor to payor. We cannot be sure that coverage and adequate reimbursement will be available for any product that we commercialize and, if reimbursement is available, that the level of reimbursement will be adequate. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If coverage and reimbursement are not available or are available only at limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval.

Additionally, the regulations that govern regulatory approvals, pricing and reimbursement for new drugs vary widely from country to country. Some countries require approval of the sale price of a drug or therapeutic biologic before it can be marketed. In many countries, the pricing review period begins after marketing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain regulatory approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenues we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain regulatory approval.

Enacted and future healthcare reform legislation could impact demand for our product candidates, if approved, which could impact our business and future results of operations.

The United States and several other jurisdictions are considering, or have already enacted, a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell any of our product candidates profitably, if approved. Among policy-makers and payers in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems, with the stated goals of containing healthcare costs, improving quality and expanding access to healthcare. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. See the section titled “Business-Government Regulation-Healthcare Reform” in this Annual Report.

We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations, and other payers of healthcare services to contain or reduce the costs of healthcare may adversely affect:

- The demand for any of our product candidates, if approved;
- Our ability to set a price that we believe is fair for any of our product candidates, if approved;
- Our ability to generate revenues or maintain profitability;
- The level of taxes that we are required to pay; and
- The availability of capital.

Legislative and regulatory proposals have been made to expand post-approval requirements and to restrict sales and promotional activities for pharmaceutical and biologic products. We cannot be sure whether additional legislative changes will be enacted, or whether FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by Congress of the FDA’s approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our product candidates, if approved. There has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been many recent U.S. Congressional inquiries, proposed and enacted federal and state legislation, proposed and finalized executive orders, and federal regulatory efforts designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs in the United States, review the relationship between pricing and patient access, and reform government program reimbursement methodologies for drugs.

We expect that the healthcare reform measures that have been adopted and may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product and could harm our future revenues. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products.

If, in the future, we are unable to establish sales and marketing and patient support capabilities or enter into agreements with third parties to sell and market our current or future product candidates, we may not be successful in commercializing our current or future product candidates if and when they are approved, and we may not be able to generate any revenue.

We do not currently have a sales or marketing infrastructure and have limited experience in the sales, marketing, patient support or distribution of drugs. To achieve commercial success for any approved product candidate for which we retain sales and marketing responsibilities, we must build our internal sales, marketing, patient support, managerial and other non-technical capabilities, which will require significant capital expenditures, management resources and time. If we are unable or decide not to establish internal sales and marketing capabilities, we may make arrangements with third parties to perform these services.

There are risks involved with both establishing our own sales and marketing and patient support capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time consuming and could delay any drug launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to commercialize our current or future product candidates on our own include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe any future drugs;
- the lack of complementary drugs to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we enter into arrangements with third parties to perform sales, marketing, patient support and distribution services, our drug revenues or the profitability of these drug revenues to us are likely to be lower than if we were to market and sell any current or future product candidates that we develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell and market our current or future product candidates or may be unable to do so on terms that are favorable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our current or future product candidates effectively. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our current or future product candidates. Further, our business, results of operations, financial condition and prospects will be materially adversely affected.

Changes in funding for, or other disruptions to the operations of, the FDA, U.S. Securities and Exchange Commission, or the SEC, and other government agencies, foreign or domestic, could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA or other regulatory body to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including foreign regulatory bodies, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable. The Trump Administration has issued executive orders seeking to greatly reduce the size of the federal workforce, including through layoffs and severance packages offered to employees of federal agencies within the executive branch and independent agencies, including the FDA. Any such reduction in personnel may result in longer review times by the FDA and other agencies.

Disruptions at the FDA and other agencies, including substantial leadership departures, personnel cuts, and policy changes, may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. Changes and cuts in FDA staffing have been reported within the pharmaceutical industry as creating instances of delays in the FDA's responsiveness or in its ability to review investigational new drug, or IND, submissions or applications, issue regulations or guidance, or implement or enforce regulatory requirements in a timely fashion. There is also substantial uncertainty as to how regulatory reform measures being implemented by the current U.S. administration, and other political developments, such as government shutdowns or work stoppages, would impact other U.S. regulatory agencies, such as the FDA, SEC and U.S. Patent and Trademark Office ("USPTO"), on which our operations rely. For example, in March 2025, the Department of Health and Human Services announced a broad-scale restructuring effort designed to significantly reduce FDA headcount. In April 2025, FDA employees began to receive reduction in force notices.

In addition, the United States government has shut down several times, including October 2025, and certain regulatory agencies, such as the FDA and the SEC, have previously had to furlough critical employees and stop critical activities. A prolonged government shutdown, significant leadership, personnel, and/or policy changes, or substantial modification in agency activities (including due to global health concerns) could prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities. A prolonged shutdown could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business, including INDs placed on clinical holds or delayed new drug approvals. Further, in our operations as a public company, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

With the change in the United States presidential administration in 2025, there continues to be substantial uncertainty as to whether and how the Trump administration will seek to modify or revise the requirements and policies of the FDA and other regulatory agencies with jurisdiction over our product candidates and any products for which we obtain approval. This uncertainty could present new challenges as we navigate development and approval of our product candidates. Additionally, the current U.S. administration could issue or promulgate executive orders, regulations, policies or guidance that adversely affect us or create a more challenging or costly environment to pursue the development of new therapeutic candidates.

We may encounter difficulties efficiently managing our growth and our increasing development, regulatory and sales and marketing capabilities, which could disrupt our operations.

We have grown in the number of employees and scope of operations over recent years and expect to experience significant growth in the number of our employees and the scope of our operations also in the near future, particularly in the areas of drug research, drug development, regulatory affairs, operations, corporate and sales and marketing. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. In particular, we must efficiently leverage our own sales and marketing capabilities in order to launch or market our product candidates effectively.

Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. Our limited financial, manufacturing and management resources could cause us to forgo or delay the pursuit of opportunities with potential product candidates that later prove to have greater market potential, fail to capitalize on viable commercial products or profitable market opportunities or relinquish rights to such product candidates through collaborations, licensing or royalty arrangements in circumstances where it would have been more advantageous for us to retain sole development and commercialization rights. Any inability to manage growth could delay the execution of our strategic objectives or disrupt our operations, which in turn could materially harm our business and prospects.

We have in the past and may in the future undertake strategic acquisitions and any difficulties from integrating such acquisitions could adversely affect the price of the ADSs, operating results and results of operations.

We have in the past and may in the future acquire companies, businesses and products that complement or augment our existing business. We may not be able to integrate any acquired business successfully or operate any acquired business profitably. Integrating any newly acquired business could be expensive and time-consuming. Integration efforts often take a significant amount of time, place a significant strain on managerial, operational and financial resources, result in loss of key personnel and could prove to be more difficult or expensive than we predict. The diversion of our management's attention and any delay or difficulties encountered in connection with any future acquisitions we may consummate could result in the disruption of our on-going business or inconsistencies in standards and controls that could negatively affect our ability to maintain third-party relationships. Moreover, we may need to raise additional funds through public or private debt or equity financing, or issue additional shares or financial instruments convertible, exchangeable or exercisable for shares, any of which could be substantial, to acquire any businesses or products, which may result in dilution for shareholders or the incurrence of indebtedness.

As part of our efforts to acquire companies, businesses or product candidates or to enter into other significant transactions, we conduct business, legal and financial due diligence with the goal of identifying and evaluating material risks involved in the transaction. Despite our efforts, we ultimately may be unsuccessful in ascertaining or evaluating all such risks and, as a result, might not realize the intended advantages of the transaction. If we fail to realize the expected benefits from acquisitions we may consummate in the future or have consummated in the past, whether as a result of unidentified risks or liabilities, integration difficulties, regulatory setbacks, litigation with current or former employees and other events, our business, results of operations and financial condition could be adversely affected. If we acquire product candidates, we will also need to make certain assumptions about, among other things, development costs, the likelihood of receiving regulatory approval and the market for such product candidates. Our assumptions may prove to be incorrect, which could cause us to fail to realize the anticipated benefits of these transactions. In addition, we will likely experience significant charges to earnings in connection with our efforts, if any, to consummate acquisitions. For transactions that are ultimately not consummated, these charges may include fees and expenses for investment bankers, attorneys, accountants and other advisors in connection with our efforts. Even if our efforts are successful, we may incur, as part of a transaction, substantial charges for closure costs associated with elimination of duplicate operations and facilities and acquired in-process research and development charges. In either case, the incurrence of these charges could adversely affect our results of operations for particular periods.

We are subject to healthcare laws, regulation and enforcement. The failure to comply with these laws could harm our results, operations and/or financial conditions.

Healthcare providers, physicians and third-party payors, among others, will play a primary role in the prescription and recommendation of any product candidates for which we obtain marketing approval. Our current and future arrangements with third-party payors, providers and customers, among others, may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our product candidates for which we obtain marketing approval. See the section titled "Business-Government Regulation-Healthcare Law and Regulation" in this Annual Report.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions, and settlements in the healthcare industry.

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current of future statures, regulations, agency guidance, or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including administrative, civil, and criminal penalties, damages, fines, disgorgement, the exclusion from participation in federal and state healthcare programs, individual imprisonment, reputational harm, and curtailment or restructuring of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws. Further, defending against any such actions can be costly and time consuming, and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. If any of the physicians or other providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil, or administrative sanctions, including exclusion from government funded healthcare programs and imprisonment. If any of the above occur, our ability to operate our business and our results of operations could be adversely affected.

We may become exposed to costly and damaging liability claims.

We are exposed to potential product liability and professional indemnity risks that are inherent in the research, development, manufacturing, marketing and use of pharmaceutical products and marketing of human therapeutic products. The use of products, if any of our product candidates are approved, and of any of our current or future product candidates by us and our collaborators in clinical trials and the sale of any approved products may further expose us to liability claims. If any of our product candidates were to cause adverse side effects during clinical trials or after approval of the product candidate, we may be exposed to substantial liabilities. These claims might be made by patients who use the product, healthcare providers, pharmaceutical companies, physicians, payors, caregivers, investors, employees, government agencies, or our collaborators or others selling such products. Physicians and patients may not comply with any warnings that identify known potential adverse effects and patients who should not use our product candidates. Any claims against us, regardless of their merit, could be difficult and costly to defend and could materially adversely affect the market for our products and product candidates or any prospects for commercialization of our products and product candidates. Any such claims, regardless of their merit, could also adversely affect our reputation and the trust that physician and patients place in our products. Product liability risk in the EU is expected to increase following the adoption of Directive (EU) 2024/2853, which expands the no-fault regime through presumptions of defectiveness and causality, extends the limitation period to 25 years for latent damage, and introduces court-ordered disclosure obligations. Member States must transpose the relevant directive by December 2026.

Regardless of the merits or eventual outcome litigation or liability claims may result in:

- decreased demand for our products due to negative public perception;
- damage to our reputation;
- withdrawal of clinical trial participants or difficulties in recruiting new clinical trial participants;
- initiation of investigations by regulators;
- costs to defend or settle the related litigation;
- a diversion of management’s time and our resources;
- substantial monetary awards to clinical trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenues from product sales; and

- the inability to successfully commercialize any of our product candidates, if approved.

We may not be able to obtain insurance coverage at a reasonable cost or to obtain adequate insurance coverage to satisfy any liability that may arise. Product liability claims could delay or prevent completion of our clinical development programs. In addition, claims made by patients, healthcare professionals or others might not be fully covered by product liability insurance and could result in investigations of the safety of our products or product candidates or may result in recalls. If a successful product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims and our business, financial condition and results of operations would be adversely affected.

Risk Factors Related to Other Government Regulations

Failure to comply with anti-corruption laws and regulations, anti-money laundering laws and regulations, economic sanctions and/or export control regulations and other laws governing our operations such as in relation to sustainability could have an adverse impact on our business.

We are or may become subject to various laws and regulations regarding anti-corruption, anti-money laundering, economic sanctions, investment restrictions, anti-fraud and export control regulations issued by multiple jurisdictions. These include the UK Bribery Act 2010 and the U.S. Foreign Corrupt Practices Act of 1977, as amended, which prohibits, among other things, payments, offers, or promises made for the purpose of improperly influencing any act or decision of a foreign official. The nature of our business means that we engage in significant interactions with foreign officials. We are also subject to economic sanctions and export control rules and regulations imposed by, amongst others, the U.S. Department of the Treasury's Office of Foreign Assets Control, other agencies of the U.S. government, HM Treasury and other agencies of the UK government, the EU, and the United Nations. Any change in export or import regulations, economic sanctions regulations or related legislation, shift in the enforcement or scope of existing regulations, or change in the countries, governments, persons or technologies targeted by such regulations, could decrease our ability to manufacture, import, export or sell our products internationally. Any limitation on our ability to manufacture, import, export or sell our products could adversely affect our business.

We adopted an Anti-Bribery and Anti-Corruption Policy on December 6, 2024 and we intend to establish further policies and procedures to ensure compliance with such rules and regulations. The creation, implementation and maintenance of international business practices compliance programs is costly and such programs are difficult to enforce, particularly where reliance on third parties is required. There can be no assurance that our policies and procedures will be followed at all times or will effectively detect and/or prevent violations of applicable compliance regimes by our employees, directors, consultants, contractors, agents and partners. As a result, in the event of non-compliance, we could be subject to substantial civil or criminal penalties, including economic sanctions against us, incarceration for responsible employees and managers, the possible loss of export or import privileges, reputational harm, and resulting loss of revenue and profits, which could have a material adverse impact on our business, financial conditions and operations.

Moreover, a growing number of investors, regulators, self-regulatory organizations and other stakeholders have expressed an interest in setting Environmental, Social and Governance, or ESG, goals and requiring the provision of new and more robust disclosure of steps taken to implement such goals. On March 6, 2024, the SEC adopted final rules aimed at enhancing and standardizing climate-related disclosures relating to climate-related risks, Scope 1 and Scope 2 greenhouse gas emissions and climate-related financial metrics, or the SEC Climate Rules. On March 27, 2025, the SEC voted to end its defense of the SEC Climate Rules. There is potential for the SEC to revisit adopting similar climate related disclosure rules in the future.

In response to new ESG initiatives and regulations we may voluntarily elect, or be required, to adopt strategies, policies, or procedures related to ESG matters. Reporting on ESG goals and objectives may cause us to expend capital and human resources, and could divert management's attention from central operational matters. Reports could also lead to the disclosure of information that which may have a negative impact on our operations and reputation which may lead to additional exposure. Failure to accurately comply with any ESG reporting obligations may result in enforcement actions, sanctions, reputational harm or private litigation.

We may become exposed to liability and substantial expenses in connection with environmental compliance or remediation activities.

Our operations, including our research, development, testing and third-party manufacturing activities, are subject to numerous environmental, health and safety laws and regulations and for which we may become liable. If we or one of our contract manufacturing organizations, or CMOs, manufacturers fail to comply with such laws and regulations, such failure could result in substantial fines, penalties or other sanctions which could also bring significant reputational loss to our business.

We face a risk of environmental liability inherent in our current and historical activities, including liability relating to releases of our exposure to hazardous or biological materials. Furthermore, environmental, health and safety laws and regulations are becoming more stringent. Both us and our CMOs and any licensees may be required to incur substantial expenses in connection with future environmental compliance or remediation activities, in which case, our production and development efforts may be interrupted or delayed, and our financial condition and results of operations may be materially adversely affected.

Significant political, trade, regulatory developments, and other circumstances beyond our control, could have a material adverse effect on our financial condition or results of operations.

Significant political, trade, or regulatory developments, such as those stemming from the change in U.S. federal administration, are difficult to predict and may have a material adverse effect on us. Similarly, changes in U.S. federal policy that affect the geopolitical landscape could give rise to circumstances outside our control that could have negative impacts on our business operations. In 2017, the U.S. Congress and the Trump administration made substantial changes to U.S. policies, which included comprehensive corporate and individual tax reform. In addition, the Trump administration called for significant changes to U.S. trade, healthcare, immigration and government regulatory policy. Since the start of the Trump administration in 2025, U.S. policy changes have been implemented at a rapid pace and additional changes are likely. Changes to U.S. policy implemented by the U.S. Congress, the Trump administration or any new administration have impacted and may in the future impact, among other things, the U.S. and global economy, international trade relations, unemployment, immigration, healthcare, taxation, the U.S. regulatory environment, inflation and other areas. On July 4, 2025, the One Big Beautiful Bill Act (the "OBBBA") was enacted into law. The OBBBA includes significant changes to the U.S. federal income tax code, including restoration of immediate recognition of domestic research and development expenditures and reinstatement of 100% bonus depreciation for qualifying property. Future changes in tax laws could have a material adverse effect on our business, cash flow, financial condition or results of operations. The U.S. and E.U. recently agreed on a 15% blanket tariff on most E.U. goods imported to the U.S. Before the U.S. and E.U. agreed on 15%, the Trump administration was proposing a 30% blanket tariff on most E.U. goods. The Trump administration has threatened to continue to broadly impose tariffs and increase existing tariffs, which could lead to corresponding punitive actions by the countries with which the U.S. trades. Historically, tariffs have led to increased trade and political tensions. In response to tariffs, other countries have implemented or threatened to implement retaliatory tariffs on U.S. goods. Political tensions as a result of trade policies could reduce trade volume, investment, technological exchange and other economic activities between major international economies, resulting in a material adverse effect on global economic conditions and the stability of global financial markets. Any changes in political, trade, regulatory, and economic conditions, including U.S. trade policies, could have a material adverse effect on our financial condition or results of operations. Until we know what policy changes are made, whether those policy changes are challenged and subsequently upheld by the court system and how those changes impact our business and the business of our competitors over the long term, we will not know if, overall, we will benefit from them or be negatively affected by them.

Healthcare legislative reform measures may have a material adverse effect on our business and results of operations.

On April 15, 2025, the Trump Administration published Executive Order 14273, "Lowering Drug Prices by Once Again Putting Americans First," which generally directs the federal government to take measures to reduce drug prices, including eliminating the so-called "pill penalty" under the Inflation Reduction Act that creates a distinction between small molecule and large molecule products for purposes of determining when a drug may be eligible for drug price negotiation. On May 12, 2025, the Trump Administration published Executive Order 14297, "Delivering Most-Favored-Nation Prescription Drug Pricing to American Patients" which generally, among other things, directs the federal government to establish and communicate most-favored-nation price targets to pharmaceutical manufacturers to bring prices for American patients in line with comparably developed nations. Further, the Executive Order directs the federal government to support regulatory paths to allow direct to-patient sales for companies that meet these targets. It also states that the Administration will take additional aggressive action (for example, examining whether marketing approvals should be modified or rescinded or opening the door for individual drug importation waivers) should manufacturers fail to offer American consumers the most-favored-nation lowest price. It also directs the Secretary of Commerce and the U.S. Trade Representative to "take all necessary and appropriate action to ensure foreign countries are not engaged in any act, policy, or practice that may be unreasonable or discriminatory or that may impair United States national security, including by suppressing the price of pharmaceutical products below fair market value in foreign countries." Notably, a similar "Most Favored Nation" pricing rule enacted under the first Trump Administration was subject to an injunction resulting from judicial challenges to the rule, which was formally rescinded by the former Biden Administration in August 2021.

Our revenue prospects could be affected by changes in healthcare spending and policy in the United States and abroad. We operate in a highly regulated industry and new laws, regulations or judicial decisions, or new interpretations of existing laws, regulations or decisions, related to healthcare availability, the method of delivery or payment for healthcare products and services could negatively impact our business, operations and financial condition.

Risks related to our reliance on third parties

We rely, and intend to rely, on third parties to conduct our clinical trials and perform some of our research and preclinical studies. If these third parties do not satisfactorily carry out their contractual duties or fail to meet expected deadlines, our development programs may be delayed or subject to increased costs, each of which may have an adverse effect on our business and prospects.

We do not have the ability to conduct all aspects of our preclinical testing or clinical trials ourselves. As a result, we are, and expect to remain, dependent on third parties to conduct our ongoing and planned preclinical activities and clinical trials of our product candidates, and any future preclinical activities and clinical trials of any other product candidates. The timing of the initiation and completion of these trials will therefore be partially controlled by such third parties and may result in delays to our development programs. Specifically, we expect CROs, clinical investigators, and consultants to play a significant role in the conduct of these trials and the subsequent collection and analysis of data. For example, we have had to repeat preclinical studies due to lack of reliability of data collection, resulting in delays in our preclinical studies. We cannot assure you that we will not experience additional delays in the future or that we will be able to control all aspects of our CROs' activities. Nevertheless, we are responsible for ensuring that each clinical trial is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on the CROs and other third parties does not relieve us of our regulatory responsibilities. We and our CROs are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for all of our product candidates in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, clinical trial investigators and clinical trial sites. If we or any of our CROs, preclinical trial sites or clinical trial sites fail to comply with applicable good laboratory practice, or GLP, or good clinical practice, or GCP, requirements, the data generated in our preclinical and clinical trials may be deemed unreliable, and the FDA or comparable foreign regulatory authorities may require us to perform additional preclinical or clinical trials. In addition, our clinical trials must be conducted with product candidates produced under cGMP regulations. Our failure to comply with these regulations may require us to stop and/or repeat clinical trials, which would delay the marketing approval process.

There is no guarantee that any such CROs, clinical trial investigators or other third parties on which we rely will devote adequate time and resources to our development activities or perform as contractually required. Demand for CROs and their resources and services has increased in recent years, which has impacted performance timelines. Furthermore, there are shortages in the supply of materials and animal availability for nonclinical testing. This has led us to experience increased competition for CRO services, including scheduling nonclinical studies and delays in study reporting, which could impact development timelines.

If any of these third parties fails to meet expected deadlines, adhere to our clinical protocols or meet regulatory requirements, otherwise performs in a substandard manner, or terminates its engagement with us, the timelines for our development programs may be extended or delayed or our development activities may be suspended or terminated. If one of our clinical trial sites terminates for any reason, we may experience the loss of follow-up information on subjects enrolled in such clinical trial unless we are able to transfer those subjects to another qualified clinical trial site, which may be difficult or impossible. If we need to enter into alternative arrangements or if we need to change a CRO for an ongoing clinical trial, which we have done in the past, we might experience delays in our clinical development activities. In addition, clinical trial investigators for our clinical trial may serve as scientific advisors or consultants to us from time to time and may receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or the FDA or comparable foreign regulatory authorities conclude that the financial relationship may have affected the interpretation of the trial, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection of any marketing application we submit by the FDA or any comparable foreign regulatory authority. Any such delay or rejection could prevent us from commercializing our product candidates.

Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors for whom they may also be conducting clinical trials or other drug development activities that could harm our competitive position. If conflicts arise between these third parties and us, the other party may act in a manner adverse to us and could limit our ability to implement our strategies. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our products.

Our supply of product for our preclinical studies and clinical trials is dependent upon relationships with third- party manufacturers and suppliers.

We do not own or operate, and currently have no plans to establish, any manufacturing facilities. We currently rely, and expect to continue to rely, on contract development and manufacturing organizations, or CDMOs, for the manufacture and supply of the active pharmaceutical ingredients, or APIs, of ontunisertib, AGMB-447, and our other product candidates for preclinical studies and clinical trials, as well as for the commercial manufacture and supply of our product candidates, if approved.

We cannot assure you that we will successfully manufacture any product candidate we may develop, either independently or under manufacturing arrangements, if any, with our third-party CDMOs. We have in the past and may in the future experience manufacturing delays from our CDMOs. Moreover, if our CDMOs should cease doing business with us or experience delays, shortages of supply or excessive demands on their capacity, we may not be able to obtain adequate quantities of product in a timely manner, or at all.

If we are not able to continue to operate our business relationships in a manner that is sufficiently profitable for us and our suppliers, certain members of our supply chain could compete with us through supply to competitors, such as generic drug companies, through breach of our agreements or otherwise.

Even if we are able to establish and maintain arrangements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- the failure of the third-party manufacturer to comply with applicable regulatory requirements and reliance on third-parties for manufacturing process development, regulatory compliance and quality assurance;
- manufacturing delays if our third-party manufacturers give greater priority to the supply of other products over our product candidates or otherwise do not satisfactorily perform according to the terms of the agreement between us;
- limitations on supply availability resulting from capacity and scheduling constraints of third parties;
- the possible breach of manufacturing agreements by third-parties because of factors beyond our control;

- the possible termination or non-renewal of the manufacturing agreements by the third-party, at a time that is costly or inconvenient to us;
- the possible negative reputational impact on us of a decline in the reputation of our third-party manufacturers and suppliers; and
- the possible misappropriation of our proprietary information, including our trade secrets and know-how.

Any manufacturing problem, natural or manmade disaster affecting manufacturing facilities, government action, or the loss of a CDMO could be disruptive to our operations. Any reliance on suppliers may involve several risks, including a potential inability to obtain critical materials and reduced control over production costs, delivery schedules, reliability and quality. Any unanticipated disruption to future CDMOs caused by problems at suppliers could delay shipment of products and increase our cost of goods sold. If our suppliers were unable to supply us with adequate volumes of API, it would have a material adverse effect on our ability to continue to conduct preclinical studies and clinical trials of our product candidates.

There can be no guarantee that current suppliers and future suppliers with which we have contracted to encapsulate API will be continually qualified to manufacture the product to our specifications or that current and any future suppliers will have the manufacturing capacity to meet anticipated demand for our products.

Furthermore, if any CDMO with whom we contract fails to perform its obligations, we may be forced to manufacture the materials ourselves, for which we may not have the capabilities or resources, or enter into an agreement with a different CDMO, which we may not be able to do on reasonable terms, if at all. In either scenario, our clinical trial supply could be delayed significantly as we establish alternative supply sources. In some cases, the technical skills required to manufacture our product candidates may be unique or proprietary to the original CDMO and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills to a back-up or alternate supplier, or we may be unable to transfer such skills at all. In addition, if we are required to change CDMOs for any reason, we will be required to verify that the new CDMO maintains facilities and procedures that comply with quality standards and with all applicable regulations. We will also need to verify, such as through a manufacturing comparability study, that any new manufacturing process will produce our product candidate according to the specifications previously submitted to the FDA or another regulatory authority. The delays associated with the verification of a new CDMO could negatively affect our ability to develop product candidates or commercialize our products in a timely manner or within budget.

We intend to deliver AGMB-447 via a drug delivery device that will have its own regulatory, development, supply and other risks.

We intend to deliver AGMB-447 via a drug delivery device, a nebulizer, and there may be unforeseen technical complications related to the development activities required to bring such a product to market, including container compatibility and/or dose volume requirements. AGMB-447 and any of our future product candidates which may be delivered via drug delivery devices may not be approved or may be substantially delayed in receiving approval if the devices do not gain and/or maintain their own regulatory approvals or clearances. Where approval of the drug product and device is sought under a single application, the increased complexity of the review process may delay approval. In addition, there are a limited number of unaffiliated third party-companies that supply drug delivery devices we intend to use for AGMB-447. We may seek to obtain licenses from third parties for the intellectual property of drug delivery devices for AGMB-447 or any of our future product candidates that utilize a drug delivery device, and we cannot guarantee that we will reach preferable commercial terms for such licenses. We expect we will be dependent on the sustained cooperation and effort of those third-party companies both to supply the devices and, in some cases, to conduct the studies required for approval or other regulatory clearance of the devices, and if received, we expect we will be dependent on those third-party companies continuing to maintain such approvals or clearances. Failure of third-party companies to supply the devices, to successfully complete studies on the device for AGMB-447 or for any future devices we may utilize for any of our product candidate in a timely manner, or to obtain or maintain required approvals or clearances of the devices could result in increased development costs, delays in or failure to obtain regulatory approval, and delays in our product candidates reaching the market initially and/or expanding to new indications.

Risks related to our intellectual property

Our commercial success depends on our ability to obtain, maintain, enforce, and otherwise protect our current and any future intellectual property and proprietary technology, and if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors or other third parties could develop and commercialize products and product candidates similar or identical to ours and our ability to successfully develop and commercialize our product candidates may be adversely affected.

Our commercial success depends, in large part, on our ability to obtain and maintain intellectual property rights protection through patents, trademarks, and trade secrets in the United States and other countries with respect to our technology and product candidates, as well as our ability to operate without infringing, misappropriating or otherwise violating the proprietary rights of others. If we do not adequately protect our intellectual property rights, competitors or other third parties may be able to erode, negate or preempt any competitive advantage we may have, which could harm our business and ability to achieve profitability. To protect our proprietary position, we have filed patent applications and may file other patent applications in the United States or abroad related to our product candidates that are important to our business; we may also license or purchase patents or patent applications filed by others. The patent application process is expensive, time-consuming and complex. We may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patent applications at a reasonable cost or in a timely manner. Our patent portfolio directed to the AGMB-101, ontunisertib and AGMB-447 product candidates is at an early stage. Although we have pending patent applications, we currently have only one issued patent in the United States for ontunisertib (AGMB-129) and one issued patent in the United States for AGMB-447. There is no assurance that our patent applications will issue as patents or, if issued, will afford sufficient protection of our product candidates or their intended uses against competitors, nor can there be any assurance that the patents issued will not be infringed, designed around, invalidated by third parties or provide any commercial or competitive advantage.

We may not be able to obtain patents on certain inventions if those inventions are publicly disclosed prior to our filing a patent application covering them. We enter into nondisclosure and confidentiality agreements with parties, such as our employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors and other third parties who have access to confidential information, including confidential information regarding inventions not yet disclosed in patent applications. We cannot guarantee that any of these parties will not breach these confidentiality agreements and publicly disclose any of our inventions before a patent application is filed covering such inventions. If such confidential information is publicly disclosed, we may not be able to successfully patent it and consequently, we may not be able to prevent third parties from using such inventions.

Composition of matter patents for pharmaceutical and biological product candidates can provide a strong form of intellectual property protection for those types of products, as such patents provide protection without regard to any method of use. However, we cannot be certain that the claims in our pending patent applications directed to the composition of matter of our product candidates will be considered patentable by the United States Patent and Trademark Office, or USPTO, or by patent offices in foreign countries, or that the claims in any of the issued patents we may own will be considered valid and enforceable by courts in the United States or foreign countries. Method of use patents protect the use of a product for the specified method. This type of patent does not prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method. Moreover, even if competitors do not actively promote their product for our targeted indications, physicians may prescribe such products “off-label.” Although off-label prescriptions may infringe or contribute to the infringement of method of use patents, the practice is common and such infringement is difficult to prevent or prosecute.

If the scope of the patent protection we obtain is not sufficiently broad, we may not be able to prevent others from developing and commercializing technology and products similar or identical to ours. The degree of patent protection we require to successfully compete in the marketplace may be unavailable or severely limited in some cases and may not adequately protect our rights or permit us to gain or keep any competitive advantage. We cannot provide any assurances that any of our patents have, or that any of our pending patent applications that mature into issued patents will include, claims with a scope sufficient to protect our product candidates or otherwise provide any competitive advantage. Other parties have developed or may develop technologies that may be related to or competitive with our approach, and may have filed or may file patent applications and may have been issued or may be issued patents with claims that overlap or conflict with our patent portfolio, either by claiming the same compounds, formulations or methods or by claiming subject matter that could dominate our patent position. We may not be aware of all third-party intellectual property rights potentially relating to our product candidates. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Furthermore, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally twenty years after it is filed. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Given the amount of time required for the development, testing and regulatory review of product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our patent portfolio may not provide us with adequate and continuing patent protection sufficient to exclude others from commercializing products similar or identical to ours.

Even if they are unchallenged, our patents and pending patent applications, if issued, may not provide us with any meaningful protection or prevent competitors from designing around our patent claims to circumvent our patent portfolio by developing similar or alternative product candidates in a non-infringing manner. For example, a third party may develop a product candidate that provides benefits similar to one of our product candidates but falls outside the scope of our patent protection. If the patent protection provided by the patent and patent applications we hold or pursue with respect to such product candidate is not sufficiently broad to impede such competition, our ability to successfully commercialize our product candidate could be negatively affected, which would harm our business.

We, or any future partners, collaborators, or licensees, may fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Therefore, we may miss potential opportunities to strengthen our patent position.

It is possible that defects of form in the preparation or filing of our patent portfolio may exist, or may arise in the future, for example with respect to proper priority claims, inventorship, foreign filing licenses, claim scope, or requests for patent term adjustments or extensions. If we or our partners, collaborators or licensors, whether current or future, fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If there are material defects in the form, preparation, prosecution or enforcement of our patent portfolio, such patents may be invalid and/or unenforceable, and such applications may never result in valid, enforceable patents. Periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and/or applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our patents and patent applications. The USPTO and various non-U.S. government patent agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can, in many cases, be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliant events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

Pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. Assuming the other requirements for patentability are met, currently, the first to file a patent application is generally entitled to the patent. However, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to file for patent protection of such inventions.

Moreover, because the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, our current or future patents may be challenged in the courts or patent offices in the United States and abroad. There is no assurance that all the potentially relevant prior art relating to our patent portfolio has been found. If such prior art exists, it may be used to invalidate a patent, or may prevent a patent from issuing from a pending patent application. For example, such patent filings may be subject to a third-party submission of prior art to the USPTO, or to other patent offices around the world. Alternately or additionally, we may become involved in post-grant review, derivation, interference, ex parte reexamination, or inter partes review proceedings before the USPTO or challenges in district court in the United States, or similar proceedings in various foreign jurisdictions, including both national and regional jurisdictions, challenging patents or patent applications in which we have rights, including patents on which we rely to protect our business. An adverse determination in any such challenges may result in loss of the patent or claims in the patent portfolio being narrowed, invalidated or held unenforceable, in whole or in part, or in denial of the patent application or loss or reduction in the scope of one or more claims of the patent portfolio, any of which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Such challenges also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. Any of the foregoing could have a material adverse effect on our business, prospects, financial condition and results of operations.

The patent position of biotechnology and pharmaceutical companies carries uncertainty and has, in recent years, been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are characterized by uncertainty. Our pending and future patent applications may not result in patents being issued that protect our business, in whole or in part, or which effectively prevent others from commercializing competitive products. Further, changes in either the patent laws or interpretation of the patent laws in the United States and other countries also may diminish the value of our patent rights or narrow the scope of our patent protection. If these developments were to occur, they could have a material adverse effect on our ability to generate revenue. In addition, the laws of foreign countries may not protect our rights to the same extent or in the same manner as the laws of the United States. For example, patent laws in various jurisdictions, including jurisdictions covering significant commercial markets, such as the European Patent Office, China, and Japan, restrict the patentability of methods of treatment of the human body more than United States law does.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our future development partners will be successful in protecting our product candidates by obtaining and defending patents. These risks and uncertainties include the following:

- the USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. There are situations in which noncompliance, whether intentional or not, can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case;

- patent applications may not result in any patents being issued;

- patents that have been issued or may be issued in the future may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable or otherwise may not provide any competitive advantage;

- our competitors, many of whom have substantially greater resources and many of whom have made significant investments in competing technologies, may seek or may have already obtained patents that will limit, interfere with or eliminate our ability to make, use, and sell our product candidates, if approved;

- there may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns;

- countries other than the United States may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing foreign competitors a better opportunity to create, develop and market competing products; and

- countries other than the United States may, under certain circumstances, force us to grant a license under our patent rights to a competitor, thus allowing the competitor to compete with us in that jurisdiction or forcing us to lower the price of our drug in that jurisdiction.

Our issued patents may not provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our patent rights by developing similar or alternative technologies or products in a non-infringing manner. Our competitors may also seek approval to market their own products similar to or otherwise competitive with our products. In these circumstances, we may need to defend or assert our patent rights, or both, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or other agency with jurisdiction may find our current or future patents invalid or unenforceable, or that our competitors do not infringe such patents. Thus, even if we have valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives.

It is difficult and costly to protect our intellectual property and our proprietary technologies, and we may not be able to ensure their protection.

Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection for our product candidates, as well as on successfully defending these patents against potential third-party challenges. Our ability to protect our product candidates from unauthorized making, using, selling, offering to sell or importing by third parties is dependent on the extent to which we have rights under valid and enforceable patents that cover these activities.

The patent positions of pharmaceutical, biotechnology and other life sciences companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved and have in recent years been the subject of much litigation. Changes in either the patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. Over the past decade, U.S. federal courts have increasingly invalidated pharmaceutical and biotechnology patents during litigation often based on changing interpretations of patent law. Further, the determination that a patent application or patent claim meets all the requirements for patentability is a subjective determination based on the application of law and jurisprudence. The ultimate determination by the USPTO or by a court or other trier of fact in the United States, or corresponding foreign national patent offices or courts, on whether a claim meets all requirements of patentability cannot be assured. Although we have conducted searches for third-party publications, patents and other information that may affect the patentability of claims in our patent portfolio, we cannot be certain that all relevant information has been identified. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our patent portfolio.

Our pending patent applications relating to ontunisertib and our AGMB-447 product candidate are at an early stage of prosecution and although we have pending patent applications, we currently have only one issued patent in the United States for ontunisertib and one issued patent in the United States for AGMB-447. We cannot provide assurances that any of these patents or patent applications will be found to be patentable, including over our own prior art publications or patent literature, or that pending patent applications will issue as patents. The patent protection that the USPTO or European Patent Office may grant with respect to antibodies, such as the antibody in our AGMB-101 program, is also uncertain. Furthermore, we cannot make assurances as to the scope of any claims that may issue from our pending and future patent applications nor to the outcome of any proceedings by any potential third parties that could challenge the patentability, validity or enforceability of our patent portfolio in the United States or foreign jurisdictions. Any such challenge, if successful, could limit patent protection for our product candidates and/or materially harm our business.

In addition to challenges during litigation, third parties can challenge the validity of our current or future patents in the United States using post-grant review and *inter partes* review proceedings, which some third parties have been using to cause the cancellation of selected or all claims of issued patents of competitors. For a patent filed March 16, 2013 or later, a petition for post-grant review can be filed by a third party in a nine-month window from issuance of the patent. A petition for *inter partes* review can be filed immediately following the issuance of a patent if the patent has an effective filing date prior to March 16, 2013. A petition for *inter partes* review can be filed after the nine-month period for filing a post-grant review petition has expired for a patent with an effective filing date of March 16, 2013 or later. Post-grant review proceedings can be brought on any ground of invalidity, whereas *inter partes* review proceedings can only raise an invalidity challenge based on published prior art and patents. These adversarial actions at the USPTO review patent claims without the presumption of validity afforded to U.S. patents in lawsuits in U.S. federal courts and use a lower burden of proof than used in litigation in U.S. federal courts. Therefore, it is generally considered easier for a competitor or third party to have a U.S. patent invalidated in a USPTO post-grant review or *inter partes* review proceeding than invalidated in a litigation in a U.S. federal court. If any of our current or future patents are challenged by a third party in such a USPTO proceeding, there is no guarantee that we will be successful in defending the patent, which may result in a loss of the challenged patent right to us.

Our existing patents and any future patents we obtain or license may not be sufficiently broad to prevent others from using our technology or from developing competing products and technologies. Any failure to obtain or maintain patent protection with respect to ontunisertib, AGMB-447 and our other product candidates could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- we may not be able to generate sufficient data to support full patent applications that protect the entire breadth of developments in one or more of our programs;
- it is possible that one or more of our pending patent applications will not become an issued patent or, if issued, that the patent claims will not have sufficient scope to protect our technology, provide us with commercially viable patent protection or provide us with any competitive advantages;
- our current and future patents may be challenged by third parties as invalid or unenforceable under United States or foreign laws;
- we may not successfully commercialize our product candidates, if approved, before our relevant patents expire;
- we may not be the first to file patent applications for the inventions covered by our patent portfolio; or
- we may not develop additional proprietary technologies that are separately patentable.

In addition, to the extent that we are unable to obtain and maintain patent protection for our product candidates, or in the event that such patent protection expires, it may no longer be cost-effective to extend our portfolio by pursuing additional development of any of our product candidates for follow-on indications.

Patent terms may be inadequate to protect our competitive position on our products for an adequate amount of time.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. The patent term of a U.S. patent may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the USPTO in granting a patent, or may be shortened if a patent is terminally disclaimed over another earlier-filed patent having an earlier expiration date.

Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Given the amount of time required for the development, testing and regulatory review of product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our patent portfolio may not provide us with adequate and continuing patent protection sufficient to exclude others from commercializing products similar or identical to ours.

In the United States, the Drug Price Competition and Patent Term Restoration Act of 1984 permits a Patent Term Extension, or PTE, of up to five years beyond the normal expiration of the patent to compensate patent owners for loss of enforceable patent term due to the lengthy regulatory approval process. A PTE grant cannot extend the remaining term of a patent beyond a total of 14 years from the date of the product approval. Further, PTE may only be applied once per product, and only with respect to an approved indication-in other words, only one patent (for example, covering the product itself, an approved use of said product, or a method of manufacturing said product) can be extended by PTE. Moreover, the scope of protection during the period of the PTE does not extend to the full scope of the claim, but instead only to the scope of the product as approved. We anticipate applying for PTE in the United States. Similar extensions may be available in other countries where we are prosecuting patents and we likewise anticipate applying for such extensions.

The granting of such patent term extensions is not guaranteed and is subject to numerous requirements. We might not be granted an extension because of, for example, failure to apply within applicable periods, failure to apply prior to the expiration of relevant patents, failure to exercise due diligence during the testing phase or regulatory review process or any other failure to satisfy any of the numerous applicable requirements. Moreover, the applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to any of our patents, or may grant more limited extensions than we request. If this occurs, our competitors may be able to obtain approval of competing products following our patent expiration by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case. If this were to occur, it could have a material adverse effect on our ability to generate revenue.

Changes in the interpretation of patent law in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products.

The U.S. Congress is responsible for passing laws establishing patentability standards. As with any laws, implementation is left to federal agencies and the federal courts based on their interpretations of the laws. Interpretation of patent standards can vary significantly within the USPTO, and across the various federal courts, including the U.S. Supreme Court. The Supreme Court has ruled on several patent cases, generally limiting the types of inventions that can be patented. Further, there are open questions regarding interpretation of patentability standards that the Supreme Court has yet to decisively address. Absent clear guidance from the Supreme Court, the USPTO has become increasingly conservative in its interpretation of patent laws and standards.

In addition to increasing uncertainty with regard to our ability to obtain patents in the future, the legal landscape in the U.S. and other countries has created uncertainty with respect to the value of patents. Depending on any actions by Congress, and future decisions by the lower federal courts and the U.S. Supreme Court, along with interpretations by the USPTO, the laws and regulations governing U.S. patents could change in unpredictable ways and could weaken our ability to obtain or to enforce our U.S. patents. Depending on future actions by the relevant law-making bodies in foreign jurisdictions, the laws and regulations governing foreign patents could also change in unpredictable ways and could weaken our ability to obtain new foreign patents or to enforce our foreign patents.

Patent reform legislation in the United States and other countries, including the Leahy-Smith America Invents Act, or the Leahy-Smith Act, signed into law on September 16, 2011, created certain uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. The Leahy-Smith Act included a number of significant changes to U.S. patent law. These included provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents, including allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, such as post-grant review, inter partes review, and derivation proceedings. Further, because of a lower evidentiary standard in these USPTO post-grant proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Thus, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Under the Leahy-Smith Act, the United States transitioned to a first inventor to file system in which, assuming that the other statutory requirements are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether this inventor was the first to invent the claimed invention. As a result, a third party that files a patent application in the USPTO after March 16, 2013, but before we file an application covering the same invention, could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing until publication or issuance, we cannot be certain that we were the first to file any patent application related to our product candidates and other proprietary technologies we may develop. Even where we have a valid and enforceable patent, we may not be able to exclude others from practicing the claimed invention where the other party can show that they used the invention in commerce before our filing date. Accordingly, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain or to enforce our current or future U.S. patents. The U.S. Supreme Court has ruled on several patent cases in recent years; these cases often narrow the scope of patent protection available to inventions in the biotechnology and pharmaceutical spaces. For example, in *Amgen Inc. v. Sanofi*, the U.S. Supreme Court held that certain of Amgen's patent claims defined a class of antibodies by their function of binding to a particular antigen. The U.S. Supreme Court further wrote that because the patent claims defined the claimed class of antibodies only by their function of binding to a particular antigen, a skilled artisan would have to use significant trial and error to identify and make all of the molecules in that class. The U.S. Supreme Court ultimately held that Amgen failed to properly enable its patent claims. In 2023, the Federal Circuit issued a decision in *In re Cellect, LLC* involving the interaction of patent term adjustment, or PTA, terminal disclaimers, and obviousness-type double patenting which may affect the patent term of any issued patents that rely on any PTA.

Further, a new court system recently became operational in the EU. The Unified Patent Court, or UPC, began accepting patent cases on June 1, 2023. The UPC is a common patent court with jurisdiction over patent infringement and revocation proceedings effective for multiple member states of the EU. The broad geographic reach of the UPC could enable third parties to seek revocation of any of the European patents we may own in the future in a single proceeding at the UPC rather than through multiple proceedings in each of the individual EU Member States in which the European patent is validated. Under the UPC, a successful revocation proceeding for a European Patent under the UPC would result in loss of patent protection in those EU countries. Accordingly, a single proceeding under the UPC could result in the partial or complete loss of patent protection in numerous EU countries. Such a loss of patent protection could have a material adverse impact on our business and our ability to commercialize our technology and product candidates and, resultantly, on our business, financial condition, prospects and results of operations. Moreover, the controlling laws and regulations of the UPC will develop over time and we cannot predict what the outcomes of cases tried before the UPC will be. The case law of the UPC may adversely affect our ability to enforce or defend the validity of such future European patents. Patent owners presently have the option to opt-out their European Patents from the jurisdiction of the UPC, defaulting to pre-UPC enforcement mechanisms. We may elect to opt out certain future European patents from the UPC. However, if certain formalities and requirements are not met, our future European patents could be subject to the jurisdiction of the UPC. We cannot be certain that such European patents will avoid falling under the jurisdiction of the UPC, if we decide to opt out of the UPC. Furthermore, the ability of patent owners to opt out their European patents from the jurisdiction of the UPC may be curtailed in the future and, if this were to happen, this could expose our European patents to the risks of the UPC system.

We may not be able to seek or obtain patent protection throughout the world or enforce such patent protection once obtained.

Filing, prosecuting, enforcing, and defending patents protecting our product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. The requirements for patentability may differ in certain countries, particularly in developing countries; thus, even in countries where we do pursue patent protection, there can be no assurance that any patents will issue with claims that cover our products.

Moreover, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws. Additionally, laws of some countries outside of the United States and Europe do not afford intellectual property protection to the same extent as the laws of the United States and Europe. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. This could make it difficult for us to stop the infringement of our patents or the misappropriation of our other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. Consequently, we may not be able to prevent third parties from practicing our inventions in certain countries outside the United States and Europe or from selling or importing products made from our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop and market their own products and, further, may export otherwise infringing products to territories where we have patent protection, if our ability to enforce our patents to stop infringing activities is inadequate. These products may compete with our products, and our patent rights or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Proceedings to enforce our patent rights, whether successful or not, could result in substantial costs and divert our efforts and resources from other aspects of our business. Further, such proceedings could put our patents at risk of being invalidated, held unenforceable or interpreted narrowly; put our pending patent applications at risk of not issuing; and provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Furthermore, while we intend to protect our intellectual property rights in major markets for our products, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our products, if approved. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate. Geopolitical actions in the United States and in foreign countries could increase the uncertainties and costs surrounding the prosecution or maintenance of our patent applications and the maintenance, enforcement or defense of our issued patents. For example, further to the United States and foreign government actions related to Russia's invasion of Ukraine, the Kremlin issued Decree 299 stating that Russian companies and individuals can use patented inventions without the owner's permission or compensation, if the patent is held by owners from "unfriendly countries," which include Belgium and Spain. As a result, we would not be able to enforce our otherwise valid patent rights against an infringer in Russia.

Further, the standards applied by the USPTO and foreign patent offices in granting patents are not always applied uniformly or predictably. As such, we do not know the degree of future protection that we will have on our technologies, products and product candidates. While we will endeavor to try to protect our technologies, products and product candidates with intellectual property rights such as patents, as appropriate, the process of obtaining patents is time consuming, expensive and unpredictable.

In order to protect our competitive position around our product candidates, we may become involved in lawsuits to enforce our patents or other intellectual property, which could be expensive, time consuming and unsuccessful and which may result in our patents being found invalid or unenforceable.

Competitors may seek to commercialize competitive products to our product candidates. In order to protect our competitive position, we may become involved in lawsuits asserting infringement of patent rights, or misappropriation or other violations of other of our intellectual property rights. Litigation is expensive and time consuming and would likely divert the time and attention of our management and scientific personnel. There can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings.

If we file a patent infringement lawsuit against a perceived infringer, such a lawsuit could provoke the defendant to counterclaim that we infringe their patents and/or that our patents are invalid and/or unenforceable. In patent litigation in the United States, it is commonplace for a defendant to counterclaim alleging invalidity and/or unenforceability. In any patent litigation there is a risk that a court will decide that the asserted patents are invalid or unenforceable, in whole or in part, and that we do not have the right to stop the defendant from using the invention at issue. With respect to a counterclaim of invalidity, we cannot be certain that there is no invalidating prior art of which we and the patent examiner were unaware during prosecution. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention. If any of our patents are found invalid or unenforceable, or construed narrowly, our ability to stop the other party from launching a competitive product would be materially impaired. Further, such adverse outcomes could limit our ability to assert those patents against future competitors. Loss of patent protection would have a material adverse impact on our business.

Even if we establish infringement of any of our patent rights by a competitive product, a court may decide not to grant an injunction against further infringing activity, thus allowing the competitive product to continue to be marketed by the competitor. It is difficult to obtain an injunction in U.S. litigation and a court could decide that the competitor should instead pay us a "reasonable royalty" as determined by the court, and/or other monetary damages. A reasonable royalty or other monetary damages may or may not be an adequate remedy. Loss of exclusivity and/or competition from a related product would have a material adverse impact on our business. Litigation often involves significant amounts of public disclosures. Such disclosures could have a materially adverse impact on our competitive position or our stock prices. During U.S. litigation we would be required to produce voluminous records related to our patent rights and our research and development activities in a process called discovery. The discovery process may result in the disclosure of some of our confidential information. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could adversely affect the price of our ADSs.

Litigation is inherently expensive, and the outcome is often uncertain. Any litigation likely would substantially increase our operating costs and reduce our resources available for development activities. Further, we may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. As a result, we may conclude that even if a competitor is infringing our patents, the risk-adjusted cost of bringing and enforcing such a claim or action may be too high or not in the best interest of our company or our stockholders. In such cases, we may decide that the more prudent course of action is to simply monitor the situation or initiate or seek some other non-litigious action or solution. If in the future, we in-license any patent rights, we may not have the right to file a lawsuit for infringement and may have to rely on a licensor to enforce these rights for us. If we are unable to directly assert our licensed patent rights against infringers or if a licensor does not vigorously prosecute any infringement claims on our behalf, we may have difficulty competing in certain markets where such potential infringers conduct their business, and our commercialization efforts may suffer as a result.

Concurrently with an infringement litigation, third parties may also be able to challenge the validity of our patents before administrative bodies in the United States or abroad. Such mechanisms include re-examination, post-grant review, inter partes review, and equivalent proceedings in foreign jurisdictions, e.g., opposition proceedings. Such proceedings could result in revocation or amendment of our patents in such a way that they no longer cover our products, potentially negatively impacting any concurrent litigation.

If we are sued for infringing intellectual property rights of third parties, such litigation could be costly and time consuming and could prevent or delay us from developing or commercializing our product candidates.

Our commercial success depends, in part, on our ability to develop, manufacture, market and sell our product candidates without infringing, misappropriating or otherwise violating the intellectual property and other proprietary rights of third parties. However, our research, development and commercialization activities may be subject to claims that we infringe, misappropriate or otherwise violate patents or other intellectual property rights owned or controlled by third parties. Third parties may have U.S. and non-U.S. issued patents and pending patent applications relating to compounds, methods of manufacturing compounds and/or methods of use for the treatment of the disease indications for which we are developing our product candidates. If any third-party patents or patent applications are found to cover our product candidates, or their methods of use or manufacture, we may not be free to manufacture or market such product candidates as planned without obtaining a license, which may not be available on commercially reasonable terms, or at all.

There is a substantial amount of intellectual property litigation in the biotechnology and pharmaceutical industries, and we may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property rights with respect to our product candidates, including patent infringement lawsuits in the United States or abroad. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the composition, use or manufacture of our product candidates. Third parties may assert infringement claims against us based on patents that they own or in-license, regardless of the merit of such patents or infringement claims. Moreover, we may face patent infringement claims from nonpracticing entities that have no relevant product revenue and against whom our patent portfolio may therefore have no deterrent effect. If our defenses to such assertions of infringement are unsuccessful, we could be liable for a court-determined reasonable royalty on our existing sales and further damages to the patent owner (or licensee), such as lost profits. Such royalties and damages could be significant. If we are found to have willfully infringed the claims of a third party's patent, the third party could be awarded treble damages and attorney's fees. Further, unless we obtain a license to such patent, we may be precluded from commercializing the infringing product candidate. Any of the aforementioned could have a material adverse effect on our business, financial condition, results of operations and prospects.

While we perform periodic searches for relevant patents and patent applications with respect to our product candidates, we cannot guarantee the completeness or thoroughness of any of our patent searches or analyses including, but not limited to, the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, nor can we be certain that we have identified each and every patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of any of our product candidates in any jurisdiction. Patent applications in the United States and elsewhere are typically published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Certain U.S. applications that will not be filed outside the U.S. can remain confidential until patents issue. As a result, we may be unable to identify such patents or patent applications despite our best efforts. In addition, patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that any of our product candidates may be accused of infringing. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes these patents. Accordingly, third parties may assert infringement claims against us based on intellectual property rights that exist now or arise in the future. The pharmaceutical and biotechnology industries have produced a significant number of patents, and it may not always be clear to industry participants, including us, which patents cover various types of products or methods of use or manufacture. The scope of protection afforded by a patent is subject to interpretation by the courts, and the interpretation is not always uniform. If we are sued for patent infringement, we would need to demonstrate that the relevant product or methods of using the product either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, and we may not be able to do this. Proving invalidity is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could significantly harm our business and operating results. In addition, parties making claims against us may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources, and we may not have sufficient resources to bring these actions to a successful conclusion.

If we are found to infringe, misappropriate or otherwise violate a third party's intellectual property rights, we could be forced, including by court order, to cease developing, manufacturing or commercializing the infringing product or cease some of our business operations, which could harm our business. Alternatively, we may be required to obtain a license from such third party in order to use the infringing technology and continue developing, manufacturing or marketing the infringing product. We cannot guarantee that any such license will be available on commercially reasonable terms, if at all. Even if we are able to obtain a license to continue to manufacture or market the affected product, we may be required to pay substantial royalties or grant cross-licenses to our patent rights. Furthermore, such license could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us; alternatively or additionally it could include terms that impede or destroy our ability to compete successfully in the commercial marketplace. In addition, we could be found liable for significant monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

The outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance, including the demeanor and credibility of witnesses and the identity of any adverse party. This is especially true in intellectual property cases that may turn on the testimony of experts as to technical facts upon which experts may reasonably disagree. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analyst or investors perceive these results to be negative, it could adversely affect the price of our ADSs. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, results of operations, financial condition and prospects.

Others may challenge inventorship or claim an ownership interest in our intellectual property which could expose it to litigation and have a significant adverse effect on its prospects.

We may be subject to claims that former employees, consultants, contractors, collaborators or other third parties have an interest in our patent rights or other intellectual property as an inventor or co-inventor. The failure to name the proper inventors on a patent application can result in the patents issuing thereon being unenforceable. Inventorship disputes may arise from conflicting views regarding the contributions of different individuals named as inventors or the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent. Furthermore, ownership disputes may arise from alleged contributions of third parties involved in developing our product candidates and may result in joint ownership of our inventions. Litigation may be necessary to resolve these and other claims challenging inventorship and/or ownership. Any disagreement over inventorship could force us to defend our determination of inventorship in a legal action which could result in substantial costs and be a distraction to our senior management and scientific personnel. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, license or sell, valuable intellectual property. Alternatively, or additionally, we may enter into agreements to clarify the scope of our rights in such intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Although we typically require employees, consultants and contractors who may develop intellectual property on our behalf to execute agreements assigning such intellectual property to us, we may be unsuccessful in obtaining executed assignments from each party who in fact develops intellectual property that we regard as our own. Moreover, even when we obtain agreements assigning intellectual property to us, the assignment of intellectual property rights may not be self-executing or the assignment agreements may be deficient or breached. In either case, we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Any defect in our title to intellectual property we purport to own could also prevent or limit our ability to enforce such intellectual property against third parties. Furthermore, individuals executing agreements with us may have preexisting or competing obligations to a third party, such as an academic institution, and thus an agreement with us may be ineffective in perfecting ownership of inventions developed by that individual. If we are unsuccessful in obtaining assignment agreements from an employee, consultant or contractor who develops intellectual property on our behalf, the employee, consultant or contractor may later claim ownership of the invention. Any disagreement over ownership of intellectual property could result in our losing ownership, or exclusive ownership, of the contested intellectual property, paying monetary damages and/or being enjoined from clinical testing, manufacturing and marketing of the affected product candidate(s). Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our senior management and scientific personnel.

We may be subject to claims that we have wrongfully hired an employee from a competitor or by third parties asserting that our employees or we have misappropriated their intellectual property or claiming ownership of what we regard as our own intellectual property.

Many of our current and former employees, including our senior management, were previously employed at universities or at other biotechnology or pharmaceutical companies, including some which may be competitors or potential competitors. Although we take commercially reasonable steps to ensure that our employees do not use the proprietary information, know-how or trade secrets of others in their work for us, including incorporating such intellectual property into our product candidates, we may be subject to claims that we or these employees have misappropriated the intellectual property of a third party.

If we or any of our employees are accused of misappropriating the proprietary information, know-how or trade secrets of a third party, we may be forced to defend such claims in litigation. If we are found to have misappropriated the intellectual property rights of a third party, we may be forced to pay monetary damages, sustain reputational damage, lose key personnel, or lose valuable intellectual property rights. Further, it may become necessary for us to obtain a license from such third party to commercialize any of our product candidates. Such a license may not be available on commercially reasonable terms or at all. Any of the aforementioned could materially affect the commercialization of any of our product candidates. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

We may rely on trade secrets and proprietary know-how which can be difficult to trace and enforce and, if we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

We consider proprietary trade secrets or confidential know-how and unpatented know-how to be important to our business. We may rely on trade secrets or confidential know-how to protect our technology, especially where patent protection is believed by us to be of limited value. We expect to rely on third parties for future manufacturing of our product candidates. We also expect to collaborate with third parties on the development of our product candidates and as a result must, at times, share trade secrets or confidential know-how with our collaborators. We may also conduct joint research and development programs that may require us to share trade secrets or confidential know-how under the terms of research and development partnerships or similar agreements.

Trade secrets or confidential know-how can be difficult to maintain as confidential. To protect this type of information against disclosure or appropriation by competitors, our policy is to require our employees, consultants, contractors and advisors to enter into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with us prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. However, current or former employees, consultants, contractors and advisers may unintentionally or willfully disclose our confidential information to competitors, and confidentiality agreements may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. Additionally, we cannot provide any assurances that all such confidentiality agreements have been duly executed, and the enforceability of confidentiality agreements may also vary from jurisdiction to jurisdiction. Moreover, third parties may still obtain this information or may come upon this or similar information independently. It is possible that technology relevant to our business will be independently developed by a person who is not a party to such a confidentiality or invention assignment agreement. If any of our trade secrets were to be independently developed by a competitor or other third party, we would have no right to prevent such competitor or third party, or those to whom they communicate such independently-developed information, from using that information to compete with us. The need to share trade secrets and other confidential information, including with future business partners, collaborators, contractors and others located in countries at heightened risk of theft of trade secrets, increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have an adverse effect on our business and results of operations. Enforcing a claim that a third party obtained illegally and is using trade secrets or confidential know-how is expensive, time consuming and unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets and know-how. The enforceability of confidentiality agreements may vary from jurisdiction to jurisdiction. Monitoring unauthorized uses and disclosures is difficult and we do not know whether the steps we have taken to protect our proprietary technologies will be effective.

In addition, confidentiality agreements typically restrict the ability of our advisors, employees, third-party contractors and consultants to publish data potentially relating to our trade secrets, although our agreements may contain certain limited publication rights. Despite our efforts to protect our trade secrets, if our competitors discover our trade secrets, through breach of our agreements with third parties, independent development or publication of information by any of our third-party collaborators, we would have no right to prevent them from using that technology or information to compete with us. A competitor's discovery of our trade secrets would impair our competitive position and have an adverse impact on our business.

We may need to acquire or license additional intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms.

A third party may hold intellectual property, including patent rights that are important or necessary to the development of our product candidates. It may be necessary for us to use the patented or proprietary technology of one or more third parties to commercialize our current and future product candidates.

The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development. If we are unable to acquire such intellectual property outright, or obtain licenses to such intellectual property from such third parties when needed or on commercially reasonable terms, our ability to commercialize our product candidates, if approved, would likely be delayed or we may have to abandon development of that product candidate and our business and financial condition could suffer.

If we in-license other product candidates in the future, we might become dependent on proprietary rights from third parties with respect to those product candidates. Any termination of such licenses could result in the loss of significant rights and would cause material adverse harm to our ability to develop and commercialize any product candidates subject to such licenses. Even if we are able to in-license any such necessary intellectual property, it could be on nonexclusive terms, including with respect to the use, field or territory of the licensed intellectual property, thereby giving our competitors and other third parties access to the same intellectual property licensed to us. In-licensing intellectual property rights could require us to make substantial licensing and royalty payments. Patents licensed to us could be put at risk of being invalidated or interpreted narrowly in litigation filed by or against our licensors or another licensee or in administrative proceedings. If any in-licensed patents are invalidated or held unenforceable, we may not be able to prevent competitors or other third parties from developing and commercializing competitive products.

We may not have the right to control the prosecution, maintenance, enforcement or defense of patents and patent applications that we license from third parties. In such cases, we would be reliant on the licensor to take any necessary actions. We cannot be certain that such licensor would act with our best interests in mind, or in compliance with applicable laws and regulations, or that their actions would result in valid and enforceable patents. If our licensors are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. For example, it is possible that a licensor's actions in enforcing and/or defending a patent licensed by us may be less vigorous than had we conducted them ourselves. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

Our future licensors may rely upon third-party consultants or collaborators or on funds from third parties such that our future licensors may not be the sole and exclusive owners of the patents we in-license. If other third parties have ownership rights to our future in-licensed patents, they may be able to license such patents to our competitors, and our competitors could market competing products and technology. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects. Disputes may also arise between us and our future licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- our financial or other obligations under the license agreement;
- whether and the extent to which our technology and processes infringe intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patent and other rights to third parties under collaborative development relationships;
- our diligence obligations with respect to the use of licensed technology in relation to our development and commercialization of our product candidates and what activities satisfy those diligence obligations;
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and

- the priority of invention of patented technology.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates.

The risks described elsewhere pertaining to our intellectual property rights may also apply to the intellectual property rights that we own or in-license in the future, and any failure by us or our future licensors to obtain, maintain, defend and enforce these rights could have an adverse effect on our business. In some cases we may not have control over the prosecution, maintenance or enforcement of the patents that we license, and may not have sufficient ability to provide input into the patent prosecution, maintenance and defense process with respect to such patents, and potential future licensors may fail to take the steps that we believe are necessary or desirable in order to obtain, maintain, defend and enforce the licensed patents.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our trademarks of interest and our business may be adversely affected.

Our current or future trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We rely on both registration and common law protection for our trademarks. While we may have common law protection for certain of our trademarks and trade names, it may be harder for us to rely on any such common law protection to prevent third parties from copying or using our trademarks or trade names without our permission. As a means to enforce our trademark rights and prevent infringement, we may be required to file trademark claims against third parties or initiate trademark opposition proceedings. This can be expensive and time-consuming, particularly for a company of our size. We may not be able to protect our rights to our trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected.

During trademark registration proceedings, we may receive rejections. Although we would be given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings.

Furthermore, in many countries, owning and maintaining a trademark registration may not provide an adequate defense against a subsequent infringement claim asserted by the owner of a senior trademark. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected.

Any name we propose to use for our products in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. Similar requirements exist in Europe. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA (or an equivalent administrative body in a foreign jurisdiction) objects to any of our proposed product names, we may be required to expend significant additional resources in an effort to identify a usable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. Our efforts to enforce or protect our proprietary rights related to trademarks or other intellectual property may be ineffective and could result in substantial costs and diversion of resources. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

Intellectual property rights do not necessarily address all potential threats to our business.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain our competitive advantage. The following examples are illustrative:

- others may be able to make products that are competitive to our product candidates or any of our future product candidates that are not covered by the claims of our patent portfolio;
- others may independently develop similar or alternative technologies or otherwise circumvent any of our technologies without infringing our patent rights;
- we or any of our collaborators might not have been the first to invent the inventions covered by our patent portfolio;
- we or any of our collaborators might not have been the first to file patent applications directed to any inventions that we or they own or will own in the future;
- it is possible that our pending patent applications or those that we or our collaborators may file in the future will not lead to issued patents;
- others may have access to the same intellectual property rights licensed to us on a non-exclusive basis in the future;
- our issued patents may not provide us with any competitive advantage, or may be held invalid or unenforceable, including as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights, or in countries where research and development safe harbor laws exist, and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- we cannot predict the scope of protection of any patent issuing based on our patent applications, including whether our patent applications will result in issued patents with claims that cover our product candidates or uses thereof in the United States or in other foreign countries;
- the claims of any patent issuing based on our patent applications may not provide protection against competitors or any competitive advantages, or may be challenged by third parties;
- if enforced, a court may not hold that our patents are valid, enforceable and infringed;
- we may need to initiate litigation or administrative proceedings to enforce and/or defend our patent rights which will be costly whether we win or lose;
- ownership of our patent portfolio may be challenged by third parties;
- the patents of third parties or pending or future applications of third parties, if issued, may have an adverse effect on our business;
- patent enforcement is expensive and time-consuming and difficult to predict; thus, we may not be able to enforce any of our patents against a competitor;
- the patents of others may have an adverse effect on our business, including if others obtain patents claiming subject matter similar to or improving that covered by our patent rights; and

- we may choose not to file a patent application for certain inventions, instead choosing to rely on trade secret protection, and a third party may subsequently file a patent application covering such intellectual property.

Should any of these or similar events occur, they could significantly harm our business, results of operations and prospects.

Risks related to data privacy

We are subject to privacy laws, regulation and potential enforcement and contractual obligations related to data privacy and security. Our failure to comply with these laws, regulations and contractual obligations could lead to potential government enforcement actions and significant penalties against us, and harm our results, operations and/or financial conditions.

Privacy laws, regulation and potential enforcement are particularly relevant to our business as we collect, store and process patient data, including sensitive health data as well as human biological samples such as blood or tissue, in the context of our clinical development activities, post-marketing approval monitoring obligations, and associated activities. We also collaborate on a regular basis with third parties where we may seek to use data collected by third parties on our or their behalf, or we may seek to share data collected by us with such third parties to further our research or commercial initiatives. Many jurisdictions have enacted or are considering enacting or revising legislation addressing privacy, data protection or data security, including laws, rules and regulations applying to the collection, use, storage, transfer, disclosure, retention, transmission, processing and security of personal information. Laws, rules and regulations relating to privacy, data protection and data security are evolving and subject to potentially differing interpretations. These requirements may be modified, interpreted and applied in a manner that is inconsistent from one jurisdiction to another or may conflict with other laws, rules or regulations, other requirements or legal obligations or our practices.

For example, in the EU, the EU General Data Protection Regulation, or the GDPR, imposes several requirements relating to the consent of the individuals to whom personal data relates, the information provided to such individuals, the security and confidentiality of personal data, data breach notification, the adoption of appropriate privacy governance, including policies, procedures, training and audits, and the use of third-party processors in connection with the processing. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to ensuring an appropriate legal basis or condition applies to the processing of personal information, where required explicit consent of the individuals is obtained, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, under certain conditions, appointing a data protection officer, providing notification of data breaches, and taking certain measures when engaging third-party processors.

The GDPR also imposes strict rules on the transfer of personal data to countries outside of the European Economic Area, or the EEA, including the United States. The GDPR allows the imposition of substantial penalties in the event of non-compliance, including fines of up to €20 million or up to 4% of total worldwide annual turnover of the preceding fiscal year, whichever is greater. The GDPR also confers a private right of action on data subjects and representative bodies/associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. We face uncertainty as to the exact interpretation of the requirements under the GDPR, and we may be unsuccessful in implementing all measures required by data protection authorities or courts in interpretation of the GDPR. The GDPR also imposes a broad range of strict requirements on companies, including, with respect to cross-border transfers of personal data out of the EU, including to the U.S. In July 2023, the European Commission adopted an adequacy decision in relation to the new EU-U.S. Data Privacy Framework, or DPF, rendering the DPF effective as a GDPR transfer mechanism for personal data transferred from the EEA to the U.S. by U.S. entities self-certified under the DPF.

However, the DPF adequacy decisions do not foreclose, and have faced and are likely to continue to face, legal challenges and the ongoing legal uncertainty with respect to international data transfers may increase our costs and our ability to efficiently process personal data from the EEA. Other data transfer mechanisms such as the Standard Contractual Clauses approved by the European Commission have faced challenges in European courts, may require additional risk analysis and supplemental measures to be used, and may be challenged, suspended or invalidated. Such developments may cause us to have to make further expenditures on local infrastructure, limit our ability to process personal data, change internal business processes or otherwise affect or restrict sales and operation.

In addition, the GDPR also provides that EU Member States may partially deviate from the GDPR and impose different obligations from country to country, so that we do not operate in a uniform legal landscape in the EU. Also, in the field of handling genetic data, the GDPR specifically allows EU Member States' laws to impose additional and more specific requirements or restrictions, and European national laws have historically differed quite substantially in this field, leading to additional uncertainty, which could limit our ability to collect, use and share EU data, and could cause our compliance costs to increase, ultimately having an adverse impact on our business, and harming our business, financial condition, and results of operations.

Following its departure from the EU, the UK, has maintained in force substantially equivalent provisions to the GDPR, or the UK GDPR. The GDPR and UK GDPR exposes us to two parallel regimes, each of which authorizes similar fines and other potentially divergent enforcement actions for certain violations. With respect to transfers of personal data from the EEA to the UK, the European Commission has published a decision finding that the UK ensures an adequate level of data protection, although such decision is subject to renewal and may be revised or revoked in the interim, resulting in uncertainty and the potential for increasing scope for divergence in application, interpretation and enforcement of the data protection law as between the UK and EEA. Fines for non-compliance with the UK GDPR can amount up to £17.5 million or 4% of annual global revenue, whichever is greater. Other countries have also passed or are considering passing laws requiring local data residency or restricting the international transfer of data. Similar concerns as those described above apply to our compliance with the UK GDPR and other UK data protection rules.

The relationship between the UK and the EU in relation to certain other aspects of data protection law remains unclear, and it is unclear how UK data protection laws and regulations will develop in the medium to longer term, and how data transfers to and from the UK will be regulated in the long term. For example, the UK government has also introduced the Data (Use and Access) Act 2025, which became law on June 19, 2025 (phasing in between June 2025 and June 2026), to reform the UK's data protection regime. This Data (Use and Access) Act 2025 further alters the similarities between the UK and EU data protection regimes and could impact the UK adequacy decision granted by the European Commission. Coupled with the existing flexibility under the GDPR that allows EU Member States to implement national derogations and apply varying interpretations through their respective authorities, we are exposed to two overlapping but increasingly divergent regimes. Each can impose significant fines and may diverge further over time. We do not expect to operate within a uniform legal framework across the UK and EU. The UK's evolving regulatory landscape and further divergence from the EU framework may lead to additional compliance, legal risk, complexity, costs and overall risk to our handling of personal data, and may require us to adapt our privacy and data security compliance programs to account for increasing legal and regulatory divergence between the UK and the EU.

Beyond the EU and UK, privacy and data protection laws and regulations continue to develop and expand around the world, including in other jurisdictions in which we operate, such as the U.S., Japan, and Canada. Such laws and regulations impose increasing restrictions and obligations on the processing of personal data, including sensitive personal data such as genetic data. For example, in the United States, the federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, or HIPAA, imposes specific requirements relating to the privacy, security, and transmission of individually identifiable health information, and requires the implementation of administrative, physical and technological safeguards to protect the privacy of protected health information and ensure the confidentiality, integrity and availability of electronic protected health information. Determining whether protected health information has been handled in compliance with applicable privacy standards and our contractual obligations can be complex and may be subject to changing interpretation.

If we are unable to properly protect the privacy and security of protected health information, we could be found to have breached our contracts. Further, if we fail to comply with applicable privacy laws, including applicable HIPAA privacy and security standards, we could face significant administrative, civil and criminal penalties. The U.S. Department of Health and Human Services, or HHS, has the discretion to impose penalties without attempting to first resolve violations. HHS enforcement activity can result in financial liability and reputational harm, and responses to such enforcement activity can consume significant internal resources. In addition, state attorneys general are authorized to bring civil actions seeking either injunctions or damages in response to violations that threaten the privacy or security of the personal information of state residents. We cannot be sure how these regulations will be interpreted, enforced or applied to our operations. In addition to the risks associated with enforcement activities and potential contractual liabilities, our ongoing efforts to comply with evolving laws and regulations at the federal and state level may be costly and require ongoing modifications to our policies, procedures and systems.

Additionally, in the United States, at the state level, state privacy laws, such as the California Consumer Privacy Act of 2018, or the CCPA, impose obligations on covered businesses, including, but not limited to, providing specific disclosures in privacy notices and affording residents certain rights related to their personal data, including the right to opt out of certain disclosures of their information. The CCPA also provides for civil penalties as well as a private right of action with statutory damages for certain data breaches, thereby potentially increasing risks associated with a data breach. Additionally, effective as of January 1, 2023, the California Privacy Rights Act of 2020, or the CPRA, imposes additional obligations on companies covered by the legislation and has and will continue to significantly modify the CCPA, including by expanding consumers' rights with respect to certain sensitive personal information. The CPRA also creates a new state agency that will be vested with authority to implement and enforce the CCPA and the CPRA. The CCPA and CPRA may require us to modify our data processing practices and policies and may cause us to incur substantial costs and expenses in order to comply.

There are also states that have enacted legislation specifically regulating health-related information. For example, Washington state passed a health privacy law that, as of March 31, 2024, regulates the collection and sharing of health information, and which has a private right of action, which may further increase our compliance risk. Connecticut and Nevada have also passed similar laws regulating consumer health data. In addition, other states have proposed and/or passed legislation that regulates the privacy and/or security of certain specific types of information. For example, a small number of states have passed laws that regulate biometric data specifically. These various privacy and security laws may impact our business activities, including our identification of research subjects, relationships with business partners and ultimately the marketing and distribution of our products. State laws are changing rapidly and there is discussion in the U.S. Congress of a new comprehensive federal data privacy law to which we may become subject, if enacted. Furthermore, the enacted laws in a number of U.S., states and the proposed state laws in others creates the potential for a patchwork of overlapping but different state laws and could mark the beginning of a trend toward more stringent privacy legislation in the United States, which could increase our potential liability and adversely affect our business, financial condition, and results of operations. Laws in all 50 states require businesses to provide notice under certain circumstances to customers whose personal information has been disclosed as a result of a data breach. Additionally, the Federal Trade Commission and many state attorneys general are interpreting federal, state and international consumer protection laws to impose standards for the online collection, use, dissemination and security of data.

The effects of these laws, including the CCPA and the CPRA, are potentially significant and may require us to modify our data collection or processing practices and policies and to incur substantial costs and expenses in an effort to comply and increase our potential exposure to regulatory enforcement and/or litigation. If we are investigated by a data protection authority, we may face fines and other penalties. Any such investigation or charges by such data protection authorities could have a negative effect on our existing business and on our ability to attract and retain new clients or pharmaceutical partners.

It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices and our efforts to comply with the evolving data protection rules may be unsuccessful. If so, this could result in government-imposed fines or orders requiring that we change our practices, which could adversely affect our business. We must devote significant resources to understanding and complying with this changing landscape.

Failure to comply with federal, state and international laws regarding privacy and security of personal information could expose us to penalties under such laws. Any such failure by us or our third party processors to comply with data protection and privacy laws could result in significant government-imposed fines or orders requiring that we change our practices, claims for damages or other liabilities, regulatory investigations and enforcement action, litigation and significant costs for remediation, any of which could adversely affect our business. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our business, prospects, financial condition and results of operations.

We may also experience hesitancy, reluctance, or refusal by clients or pharmaceutical partners to continue to use our products and solutions due to the potential risk exposure as a result of the current (and, in particular, future) data protection obligations imposed on them by certain data protection authorities in interpretation of current law. Such clients or pharmaceutical partners may also view any alternative approaches to compliance as being too costly, too burdensome, too legally uncertain, or otherwise objectionable and therefore decide not to do business with us. Any of the foregoing could harm our business, prospects, financial condition and results of operations.

The use of new and evolving technologies, such as artificial intelligence, in our business may result in spending material resources and presents risks and challenges that can impact our business including by posing security and other risks to our confidential and/or proprietary information, including personal information, and as a result we may be exposed to reputational harm and liability.

We may use and integrate artificial intelligence, including generative artificial intelligence, into our business processes, and this innovation presents risks and challenges that could affect its adoption, and therefore our business. However, there can be no assurance that our use will enhance our business processes, or result in our business processes being more efficient or profitable. If we enable or offer solutions that draw controversy due to perceived or actual negative societal impact, we may experience brand or reputational harm, competitive harm or legal liability. For example, artificial intelligence technology can give rise to intellectual property risks, including compromises to proprietary intellectual property and intellectual property infringement. Algorithms may be flawed, insufficient, of poor quality, reflect unwanted forms of bias, or contain other errors or inadequacies, any of which may not be easily detectable; artificial intelligence has been known to produce false or "hallucinatory" inferences or outputs; artificial intelligence can present ethical issues and may subject us to new or heightened legal, regulatory, ethical, or other challenges; and inappropriate or controversial data practices by developers and end-users, or other factors adversely affecting public opinion of artificial intelligence, could impair the acceptance of artificial intelligence solutions, including those incorporated in our activities. If the artificial intelligence solutions that we create or use are deficient, inaccurate or controversial, we could incur operational inefficiencies, competitive harm, legal liability, brand or reputational harm, or other adverse impacts on our business and financial results. If we do not have sufficient rights to use the data or other material or content on which our artificial intelligence solutions or other artificial intelligence tools we use rely, we also may incur liability through the violation of applicable laws, third-party intellectual property, privacy or other rights, or contracts to which we are a party.

Additionally, we expect to see increasing government and supranational regulation related to artificial intelligence use and ethics, which may also significantly increase the burden and cost of research, development and compliance in this area. For example, the EU's Artificial Intelligence Act, or the AI Act,-the world's first comprehensive Artificial Intelligence, or AI, law-entered into force on August 1, 2024, gradually applies and with some exceptions, will be effective as of August 2, 2026. This legislation imposes significant obligations on providers and deployers of high risk artificial intelligence systems, and encourages providers and deployers of artificial intelligence systems to account for EU ethical principles in their development and use of these systems. If we develop or use artificial intelligence systems that are governed by the AI Act, it may necessitate ensuring higher standards of data quality, transparency, and human oversight, as well as adhering to specific and potentially burdensome and costly ethical, accountability, and administrative requirements. The rapid evolution of artificial intelligence will require the application of significant resources to design, develop, test and maintain our products and services to help ensure that artificial intelligence is implemented in accordance with applicable law and regulation and in a socially responsible manner and to minimize any real or perceived unintended harmful impacts. We may not be able to anticipate how to respond to these rapidly evolving frameworks, and we may need to expend resources to adjust our offerings in certain jurisdictions if the legal frameworks are inconsistent across jurisdictions. Furthermore, because artificial intelligence technology itself is highly complex and rapidly developing, it is not possible to predict all of the legal, operational or technological risks that may arise relating to the use of artificial intelligence. Our vendors may in turn incorporate artificial intelligence tools into their offerings, and the providers of these artificial intelligence tools may not meet existing or rapidly evolving regulatory or industry standards, including with respect to privacy and data security. Further, bad actors around the world use increasingly sophisticated methods, including the use of artificial intelligence, to engage in illegal activities involving the theft and misuse of personal information, confidential information and intellectual property. Any of these effects could damage our reputation, result in the loss of valuable property and information, cause us to breach applicable laws and regulations, and adversely impact our business.

Our internal computer systems, or those of our third-party collaborators or other contractors or consultants, may fail or suffer cybersecurity incidents or breaches, which could result in a material disruption of our current or future product candidates' development programs, the disclosure of confidential or proprietary information, including personal data, damage our reputation, and subject us to significant financial and legal exposure.

We are increasingly dependent upon information technology systems, infrastructure, and data to operate our business. In the ordinary course of business, we collect, store, and transmit large amounts of confidential information, including, but not limited to, intellectual property, proprietary business information, and personal information. It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. A successful cyberattack could result in the theft or destruction of intellectual property, data or other misappropriation of assets, or otherwise compromise our confidential or proprietary information and disrupt our operations. In addition to such risks, the adoption of new technologies may also increase our exposure to cybersecurity incidents or breaches and failures.

Cyberattacks are increasing in their frequency, sophistication, and intensity, and have become increasingly difficult to detect. Cyberattacks could include wrongful conduct by hostile foreign governments, industrial espionage, wire fraud and other forms of cyber fraud, the deployment of harmful malware, ransomware, denial-of-service, social engineering fraud (such as phishing attacks) or other means to threaten data security, confidentiality, integrity and availability. A successful cyberattack could cause serious negative consequences for us, including, without limitation, the disruption of operations, the misappropriation of confidential business information, including financial information, trade secrets, financial loss and the disclosure of corporate strategic plans. There can be no assurance that we will not experience a cybersecurity incident or breach that would result in business, legal, financial or reputational harm to us, or would have a material adverse effect on our results of operations and financial condition.

Despite the implementation of security measures, our internal computer systems and those of our third-party collaborators and consultants are vulnerable to damage from service interruptions, system malfunction, computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Such information technology systems are additionally vulnerable to security incidents from inadvertent or intentional actions by our employees, third-party vendors, contractors, consultants, business partners, or other third parties, or from cyberattacks by malicious third parties (including the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering (including phishing attacks), and other means to affect service reliability and threaten the confidentiality, integrity, and availability of information). Significant disruptions of our internal information technology systems or those of our third-party vendors and other contractors and consultants, or cybersecurity incidents or breaches could result in the loss, misappropriation, or unauthorized access, use, or disclosure of, or the prevention of access to, confidential information, which could result in financial, legal, business and reputational harm to us. For example, any such event that leads to actual or perceived unauthorized access, use, or disclosure of personal information, including personal information regarding our customers or employees, could harm our reputation directly, compel us to comply with federal or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information, which could result in significant legal and financial exposure and reputational damages that could potentially have a material adverse effect on our business, financial condition, results of operations and prospects. Any failure by us or our third-party vendors and other contractors and consultants to prevent or mitigate cybersecurity incidents or breaches or improper access to or disclosure of such information could have similarly adverse consequences for us. If we are unable to prevent or mitigate the impact of such cybersecurity incidents or breaches, we could be exposed to litigation and governmental investigations, which could lead to a potential disruption to our business.

The risk of a cybersecurity incident, breach or disruption, particularly through cyberattacks including supply chain attacks such as SolarWinds or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity, and sophistication of attempted attacks and intrusions from around the world have increased. While we have not experienced any such system failure, accident, or cybersecurity incident or breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our programs. For example, the loss of preclinical or clinical trial data for our current or future product candidates could result in delays in or inhibit our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or cybersecurity incident or breach results in a loss of or damage to our data or applications or other data or applications relating to our technology or current or future product candidates, or inappropriate disclosure of confidential or proprietary information, we could incur liabilities and the further development of our current or future product candidates could be delayed. We may not be able to anticipate all types of security threats, and we may not be able to implement preventive measures effective against all such security threats. The techniques used by cyber criminals change frequently, may not be recognized until launched, and can originate from a wide variety of sources, including outside groups such as third-party service providers, organized crime affiliates, terrorist organizations, or hostile foreign governments or agencies.

We also have outsourced elements of our operations to third parties, and as a result we manage a number of third-party vendors who may or could have access to our confidential information. Our third-party collaborators also have access to large amounts of confidential information relating to our operations, including our research and development efforts. The size and complexity of our information technology systems, and those of third-party vendors and collaborators, and the large amounts of confidential information stored on those systems, make such systems potentially vulnerable to service interruptions or systems failures, or to cybersecurity incidents or breaches from inadvertent or intentional actions by our employees, consultants, contractors, third-party vendors, and/or business partners, or from cyber-attacks by malicious third parties. We rely on our third-party providers to implement effective security measures, according to market standards (such as, ISO27001 and NEN7510), and identify and correct for any such failures, deficiencies, cybersecurity incidents or breaches. We also rely on our employees, contractors and consultants to safeguard their security credentials and follow our policies and procedures regarding use and access of computers and other devices that may contain our sensitive information. If the information technology systems of our third-party vendors and other contractors and consultants become subject to disruptions or cybersecurity incidents or breaches, we may have insufficient recourse against such third parties and we may have to expend significant resources to mitigate the impact of such an event, and to develop and implement protections to prevent future events of this nature from occurring. The costs related to significant cybersecurity incidents, breaches or other disruptions could be material and cause us to incur significant expenses and any cybersecurity insurance that we may have in place may not cover such expenses.

Any failure to prevent or mitigate cybersecurity incidents or breaches or improper access to, use of, or disclosure of our clinical data or patients' personal data could result in significant liability under state (e.g., state breach notification laws), federal (e.g., the Health Insurance Portability and Accountability Act of 1966, as amended by the Health Information Technology for Economic and Clinical Health Act), and international law (e.g., the GDPR) and may cause a material adverse impact to our reputation, affect our ability to use collected data, conduct new studies and potentially disrupt our business. Furthermore, considering our activities, further requirements relating to cybersecurity standards, incident response, implementation, training and compliance result from the Directive (EU) 2022/2555, or the NIS 2 Directive. Non-compliance therewith may result in liability of both the company and its directors, as well as administrative enforcement by competent authorities. The NIS2 Directive was transposed into Belgian law by the law of April 26, 2024 establishing a framework for the cybersecurity of network and information system of general importance for public safety, which was implemented by Belgian royal decree of June 9, 2024.

If we or our third-party providers fail to maintain or protect our information technology systems and data integrity effectively or fail to anticipate, plan for or manage significant disruptions to our information technology systems, we or our third-party providers could have difficulty preventing, detecting and controlling such cyber-attacks and any such attacks could result in losses described above as well as disputes with employees, consultants, contractors, physicians, patients and our partners, regulatory sanctions or penalties, increases in operating expenses, expenses or lost revenues or other adverse consequences, any of which could have a material adverse effect on our business, results of operations, financial condition, prospects and cash flows.

Risks related to our operations, employee matters, and growth management

We will incur significant costs as a result of operating as a U.S. public company and our management will need to devote substantial time to U.S. public company compliance programs.

As a U.S. public company, and particularly once we are no longer an emerging growth company, we will incur significant legal, accounting, and other expenses due to our compliance with regulations and disclosure obligations applicable to us, including compliance with the Sarbanes-Oxley Act, as well as rules implemented by the SEC, including as a result of the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, and the Nasdaq Stock Market LLC, or Nasdaq. The SEC and other regulatory authorities have continued to adopt new rules and regulations and make additional changes to existing regulations that require our compliance. Shareholder activism, the current political environment, and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact, in ways we cannot currently anticipate, and the manner in which we operate our business. Our management and other personnel will need to devote a substantial amount of time to these compliance programs and monitoring of public company reporting obligations, and as a result of the new corporate governance- and executive compensation-related rules, regulations, and guidelines prompted by the Dodd-Frank Act, and further regulations and disclosure obligations expected in the future, we will likely need to devote additional time and costs to comply with such compliance programs and rules. These rules and regulations will cause us to incur significant legal and financial compliance costs and will make some activities more time-consuming and costly.

To comply with the requirements of being a U.S. public company, we may need to undertake various actions, including implementing new internal controls and procedures and hiring new accounting or internal audit staff. The Sarbanes-Oxley Act requires that we maintain effective disclosure controls and procedures and internal control over financial reporting. We are continuing to develop and refine our disclosure controls and other procedures that are designed to ensure that information required to be disclosed by us in the reports that we file with the SEC is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms, and that information required to be disclosed in reports under the Securities Exchange Act of 1934, as amended, or the Exchange Act, is accumulated and communicated to our principal executive and financial officers. Our current controls and any new controls that we develop may become inadequate, and weaknesses in our internal control over financial reporting may be discovered in the future. Any failure to develop or maintain effective controls could adversely affect the results of periodic management evaluations and annual independent registered public accounting firm attestation reports regarding the effectiveness of our internal control over financial reporting, which we may be required to include in the periodic reports we file with the SEC under Section 404 of the Sarbanes-Oxley Act, or Section 404, and could harm our operating results, cause us to fail to meet our reporting obligations, or result in a restatement of our prior period consolidated financial statements. In the event that we are not able to remediate the material weaknesses or demonstrate compliance with the Sarbanes-Oxley Act, that our internal control over financial reporting is perceived as inadequate, or that we are unable to produce timely or accurate consolidated financial statements, investors may lose confidence in our operating results, and the price of the ADSs could decline.

Pursuant to Section 404, we will be required to furnish a report by our management on our internal control over financial reporting, including an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. However, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. We could be an emerging growth company for up to five years. To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that neither we nor our independent registered public accounting firm will be able to conclude within the prescribed timeframe that our internal control over financial reporting is effective as required by Section 404. Additionally, during the evaluation and testing process, if we identify additional material weaknesses in our internal control over financial reporting or if we are unable to complete our evaluation, testing, and any required remediation in a timely fashion, we will be unable to assert that our internal control over financial reporting is effective. See "- We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, and we cannot be certain if the reduced disclosure requirements applicable to emerging growth companies will make the ADSs less attractive to investors."

We identified material weaknesses in our internal control over financial reporting. If we are unable to successfully remediate the existing material weaknesses in our internal control over financial reporting, the accuracy and timing of our financial reporting may be adversely affected.

Although as an Emerging Growth Company we are not yet subject to the certification or attestation requirements of Section 404, in conjunction with preparing our financial statements as of and for the years ended December 31, 2025, 2024 and 2023, our management identified deficiencies that we concluded represented material weaknesses in our internal control over financial reporting attributable to our lack of a formal, documented implemented processes, controls and review procedures. PCAOB guidance regarding management's report on internal control over financial reporting defines a material weakness as a deficiency or combination of deficiencies in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected and corrected on a timely basis.

We have commenced measures to remediate the material weaknesses. We have started to expand our finance and accounting team by hiring additional experienced employees to provide more review and oversight over our financial processes. There can be no assurance that we will be successful in pursuing these measures or that these measures will significantly improve or remediate the material weaknesses described in Item 15: Controls and Procedures. There is also no assurance that we have identified all of our material weaknesses or that we will not in the future have additional material weaknesses. If we fail to remediate the material weaknesses or to meet the demands that will be placed upon us as a U.S. public company, including the requirements of the Sarbanes-Oxley Act, we may be unable to accurately report our financial results, or report them within the time frames required by law or the Nasdaq Global Select Market.

Failure to comply with Section 404 could also potentially subject us to sanctions or investigations by the SEC or other regulatory authorities. There is no assurance that we will be able to remediate the material weaknesses in a timely manner, or at all, or that in the future, additional material weaknesses will not exist or otherwise be discovered. If our efforts to remediate the material weaknesses identified are not successful, or if other material weaknesses or other deficiencies occur, our ability to accurately and timely report our financial position could be impaired, which could result in late filings of our required reports under the Exchange Act, restatements of our consolidated financial statements, a decline in the price of our ADSs, suspension or delisting of our ADSs from Nasdaq, and could adversely affect our reputation, results of operations and financial condition. Accordingly, material weaknesses may still exist when we report on the effectiveness of our internal control over financial reporting for purposes of our attestation when required by reporting requirements under the Exchange Act or Section 404.

We cannot assure you that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting once that firm begins its Section 404 reviews, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our ADSs could decline, and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

If we fail to implement and maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results, and our internal control over financial reporting may not prevent or detect all errors or acts of fraud. As a result, shareholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of the ADSs.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404, or any subsequent testing by our independent registered public accounting firm, may reveal additional deficiencies in our internal control over financial reporting that are deemed to be material weaknesses that were not previously identified. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could harm our business and have a negative effect on the trading price of our ADSs. For example, we have identified material weaknesses in our internal control over financial reporting for the years ended December 31, 2025 and 2024.

We will be required to disclose changes made in our internal controls and procedures and our management will be required to assess the effectiveness of these controls annually. Our assessment of internal controls and procedures may not detect material weaknesses in our internal control over financial reporting. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by an unauthorized override of the controls.

Accordingly, because of the inherent limitations in our control system, misstatements or insufficient disclosures due to error or fraud may occur and not be detected. Undetected material weaknesses in our internal control over financial reporting could lead to financial statement restatements and require us to incur the expense of remediation, which could have a negative effect on the trading price of our ADSs.

Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.

We are highly dependent on the research and development, clinical and business development expertise of our chief executive officer, chief business officer, chief financial officer, chief medical officer, and chief development officer, as well as the other principal members of our management, scientific and clinical teams. Although we have employment agreements, each of our executive officers may terminate their employment with us at any time. See “Management-Compensation of members of our executive committee and our directors.” We do not maintain “key person” insurance for any of our executives or other employees. In addition, we rely on consultants, contractors and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants, contractors and advisors are employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel and engage qualified advisors, contractors and consultants, our ability to pursue our growth strategy will be limited.

Recruiting and retaining qualified scientific, clinical, manufacturing and sales and marketing personnel will also be critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize drugs. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. Failure to succeed in clinical trials may make it more challenging to recruit and retain qualified personnel.

We will need to develop and expand our company, and we may encounter difficulties in managing this development and expansion, which could disrupt our operations.

As of December 31, 2025, we had 62 employees and 18 consultants. To manage our anticipated development and expansion, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Also, our management may need to divert a disproportionate amount of its attention away from its day-to-day activities and devote a substantial amount of time to managing these development activities. Due to our limited resources, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. This may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. The physical expansion of our operations may lead to significant costs and may divert financial resources from other projects, such as the development of our current or future product candidates. If our management is unable to effectively manage our expected development and expansion, our expenses may increase more than expected, our ability to generate or increase our revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize our current or future product candidates, if approved, and compete effectively will depend, in part, on our ability to effectively manage the future development and expansion of our company.

Our employees, directors, principal investigators, CROs, contractors and consultants may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.

We are exposed to the risk that our employees, directors, principal investigators, CROs, contractors and consultants may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violate the regulations of the FDA and other regulatory authorities, including those laws requiring the reporting of true, complete and accurate information to such authorities; healthcare fraud and abuse laws and regulations in the United States and abroad; or laws that require the reporting of financial information or data accurately. In particular, sales, marketing, patient support and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws also involve the improper use of information obtained in the course of clinical trials or creating fraudulent data in our preclinical studies or clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. We have adopted a code of conduct applicable to all of our employees, but it is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. Additionally, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Efforts to ensure that our business arrangements with consultants, contractors and other third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant criminal, civil and administrative sanctions including monetary penalties, damages, fines, disgorgement, individual imprisonment, and exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, reputational harm, and we may be required to curtail or restructure our operations, any of which could adversely affect our ability to operate our business and our results of operations.

The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance and/or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements.

We may be forced to repay the technological innovation grants if we fail to comply with our contractual obligations under the applicable grant agreements.

We have received several technological innovation grants to date in Belgium, totaling €2.8 million as of December 31, 2025, to support various research programs from an agency of the Flemish government to support technological innovation in Flanders. These grants carry clauses which require us to maintain a presence in the Flemish region for a number of years, raise additional financing and invest according to pre-agreed budgets. If we fail to comply with our contractual obligations under the applicable technological innovation grant agreements, we could be forced to repay all or part of the grants received. Such repayment could adversely affect our ability to finance our research and development projects. In addition, we cannot ensure that we will then have the additional financial resources needed, the time or the ability to replace these financial resources with others.

Risks related to ownership of the ADSs

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, and we cannot be certain if the reduced disclosure requirements applicable to emerging growth companies will make the ADSs less attractive to investors.

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404, the ability to present only two years of audited consolidated financial statements, in addition to any required unaudited interim condensed consolidated financial statements in this Annual Report, with correspondingly reduced "Management's Discussion and Analysis of Financial and Results of Operations" disclosure, and, to the extent we no longer qualify as a foreign private issuer, exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. We could be an emerging growth company for up to five years, although circumstances could cause us to lose that status earlier, including if the market value of the ADSs held by non-affiliates exceeds $700.0 million as of any June 30 before that time or if we have total annual gross revenue of $1.235 billion or more during any fiscal year before that time, in which cases we would no longer be an emerging growth company as of the following December 31 or, if we issue more than $1.0 billion in non-convertible debt during any three-year period before that time, we would cease to be an emerging growth company immediately. We cannot predict if investors will find the ADSs less attractive because we may rely on these exemptions. If some investors find the ADSs less attractive as a result, there may be a less active trading market for the ADSs and our share price may be more volatile.

Our independent registered public accounting firm is not required to formally attest to the effectiveness of our internal control over financial reporting until the later of our second annual report or the first annual report required to be filed with the SEC following the date that we are no longer an "emerging growth company" as defined in the JOBS Act. We have identified material weaknesses in our internal control over financial reporting, and we cannot assure you that there will not be material weaknesses or significant deficiencies in our internal controls in the future.

The market price of the ADSs may be volatile and fluctuate substantially (including due to different factors beyond our control), which could result in substantial losses for purchasers of the ADSs and may subject us to securities litigation suits.

The trading price of the ADSs has been and could continue to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. In addition to the factors discussed in this Item 3.D: "Risk Factors" and elsewhere in this Annual Report, the market price for the ADSs may be influenced by, among others, the following factors:

- actual or anticipated fluctuations in our financial condition;
- failure to meet or exceed expectations around the nature and timing of any transactions we may undertake;
- issuance of new or updated research or reports by securities or industry analysts;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- the commencement, enrollment or results of our clinical trials of our product candidates or those of our competitors;
- potential clinical holds for any of our clinical trials of our product candidates or those of our competitors;
- the success of competitive products or therapies or announcements by potential competitors of their product development efforts;
- regulatory or legal developments or regulatory guidance or decisions in the United States, Belgium, Europe more broadly and other jurisdictions;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;

- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- developments of or speculation of licensing transactions, mergers, acquisitions, partnerships or collaborations involving us or our competitors;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including patent or shareholder litigation;
- market volatility;
- additions or departures of key management or scientific personnel;
- ADSs price and volume fluctuations attributable to inconsistent trading volume levels of the ADSs;
- sales of additional ADSs by us, our insiders or our other security holders;
- announcement or expectation of additional financing efforts or sales by our shareholders;
- general economic, political, and market conditions and overall fluctuations in the financial markets in the United States, Europe and elsewhere;
- currency fluctuations;
- public concern relating to the commercial value or safety of any of our products or product candidates;
- the outcome of regulatory review of our product candidates;
- changes in the structure of healthcare payment systems; and
- investors' general perception of us and our business.

In addition, some companies that have experienced volatility in the trading price of their shares have been the subject of securities class action litigation. Any lawsuit to which we are a party, with or without merit, may result in an unfavorable judgment. We also may decide to settle lawsuits on unfavorable terms. Any such negative outcome could result in payments of substantial damages or fines, damage to our reputation or adverse changes to our business practices. Defending against litigation is costly and time-consuming, and could divert our management's attention and our resources, even if we are ultimately successful. Furthermore, during the course of litigation, there could be negative public announcements of the results of hearings, motions or other interim proceedings or developments, which could have a negative effect on the market price of the ADSs.

If we fail to establish and maintain proper internal controls, our ability to produce accurate financial statements or comply with applicable regulations could be impaired. As a result, shareholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our ADSs.

Section 404(a) of the Sarbanes-Oxley Act, or Section 404(a), requires that beginning with our second annual report following our initial public offering, management assess and report annually on the effectiveness of our internal control over financial reporting and identify any material weaknesses in our internal control over financial reporting. Although Section 404(b) of the Sarbanes-Oxley Act, or Section 404(b), requires our independent registered public accounting firm to issue an annual report that addresses the effectiveness of our internal control over financial reporting, we have opted to rely on the exemptions provided in the JOBS Act, and consequently will not be required to comply with SEC rules that implement Section 404(b) until such time as we are no longer an EGC.

We expect our first Section 404(a) assessment will take place for our Annual Report for the fiscal year ending December 31, 2026. The presence of a material weakness could result in financial statement errors which, in turn, could lead to errors in our financial reports, delays in our financial reporting, which could require us to restate our operating results or our auditors may be required to issue a qualified audit report. We might not identify one or more material weaknesses in our internal controls in connection with evaluating our compliance with Section 404(a). In order to maintain and improve the effectiveness of our disclosure controls and procedures and internal control over financial reporting, we will need to expend significant resources and provide significant management oversight. Implementing any appropriate changes to our internal control may require specific compliance training of our directors and employees, entail substantial costs in order to modify our existing accounting systems, take a significant period of time to complete and divert management's attention from other business concerns. These changes may not, however, be effective in maintaining the adequacy of our internal control.

If either we are unable to conclude that we have effective internal control over financial reporting or, at the appropriate time, our independent auditors are unwilling or unable to provide us with an unqualified report on the effectiveness of our internal control over financial reporting as required by Section 404(b), investors may lose confidence in our operating results, the price of our ADSs could decline and we may be subject to litigation or regulatory enforcement actions. In addition, if we are unable to meet the requirements of Section 404, we may not be able to remain listed on The Nasdaq Global Select Market.

Holders of ADSs are not treated as shareholders of our company.

Holders of ADSs with underlying shares in a Belgian limited liability company are not treated as shareholders of our company, unless they withdraw the common shares underlying the ADSs that they hold. The depositary is the holder of the common shares underlying the ADSs. Holders of ADSs therefore do not have any rights as shareholders of our company, other than the rights that they have pursuant to the deposit agreement.

Holders of ADSs cannot directly vote the common shares underlying their ADSs.

ADS holders do not have the same rights as our shareholders. ADS holders may not attend shareholders' meetings or directly exercise the voting rights attaching to the common shares underlying their ADSs. ADS holders may vote only by instructing the depositary to vote on their behalf. If we request the depositary to solicit your voting instructions (and we are not required to do so), the depositary will notify you of a shareholders' meeting and send or make voting materials available to you. Those materials will describe the matters to be voted on and explain how ADS holders may instruct the depositary how to vote. For instructions to be valid, they must reach the depositary by a date set by the depositary. If we asked the depositary to solicit voting instructions, the depositary will try, as far as practical, to vote or to have its agents vote the deposited common shares as instructed by ADS holders. If we do not request the depositary to solicit your voting instructions, you can still send voting instructions, and, in that case, the depositary may try to vote as you instruct, but it is not required to do so. Except by instructing the depositary as described above, you will not be able to exercise voting rights unless you surrender your ADSs and withdraw the common shares. However, you may not know about the meeting enough in advance to withdraw the common shares. We cannot assure you that you will receive the voting materials in time to ensure that you can instruct the depositary to vote your common shares. In addition, the depositary and its agents are not responsible for failing to carry out voting instructions or for the manner of carrying out voting instructions. This means that you may not be able to exercise voting rights and there may be nothing you can do if your common shares are not voted as you requested. In addition, ADS holders have no right to call a shareholders' meeting.

Holders of ADSs, as such, have no rights to call shareholders' meetings or to submit shareholder proposals, which could adversely affect their ability to participate in the governance of our company.

Except under limited circumstances, only the board of directors may call a shareholders' meeting. Shareholders who collectively own at least 10% of the outstanding shares of our company may require the board of directors or the statutory auditor to convene a special or an extraordinary general meeting of shareholders. As a result, the ability of individual shareholders to influence the governance of our company is limited. Further, holders of ADSs may not exercise those limited rights unless they surrender their ADSs and become registered holders of the underlying common shares.

Holders of the ADSs have limited recourse if we or the depositary fail to meet our respective obligations under the deposit agreement. Further, holders of ADSs have no right to require the depositary to initiate any legal proceeding on their behalf.

The deposit agreement pursuant to which the ADSs will be issued expressly limits the obligations and liability of us and the depositary. Neither we nor the depositary will be liable to the extent that we or the depositary:

- are prevented or hindered in performing any obligation by circumstances beyond our or its control;
- exercise or fail to exercise discretion under the deposit agreement;
- perform our or its obligations without negligence or bad faith;
- take any action based upon advice of or information from legal counsel, accountants, any person presenting shares for deposit, any holder of the ADSs or any other qualified person; or
- rely on any documents we or it believe in good faith to be genuine and properly executed.

In addition, neither we nor the depositary has any obligation to participate in any action, suit or other proceeding in respect of the ADSs. These provisions of the deposit agreement will limit the ability of holders of the ADSs to obtain recourse if we or the depositary fails to meet our respective obligations under the deposit agreement or if they wish to involve us or the depositary in a legal proceeding.

Takeover provisions in the national law of Belgium may make a potential takeover difficult.

Public takeover bids in Belgium on our shares and other voting securities, such as subscription rights (warrants) or convertible bonds, if any, are subject to the Belgian Act of April 1, 2007 on public takeover bids, as amended and implemented by the Belgian Royal Decree of April 27, 2007, or Royal Decree, and to the supervision by the Belgian Financial Services and Markets Authority, or FSMA. Public takeover bids must be made for all of our voting securities, as well as for all other securities that entitle the holders thereof to the subscription to, the acquisition of or the conversion into voting securities. Prior to making a bid, a bidder must issue and disseminate a prospectus, which must be approved by the FSMA. The bidder must also obtain approval of the relevant competition authorities and foreign direct investment approval from the Belgian Inter-federal Screening Commission, where such approval is legally required for the acquisition of our company. However, as the Company does not qualify as a "listed company" within the meaning of the Belgian Companies and Associations Code (as mentioned above), the requirement, provided for by the Belgian Act of April 1, 2007, to launch a mandatory bid for all of our outstanding shares and securities giving access to shares if a person, as a result of its own acquisition or the acquisition by persons acting in concert with it or by persons acting on their account, directly or indirectly holds more than 30% of the voting securities in a company that has its registered office in Belgium and of which at least part of the voting securities are traded on a regulated market or on a multilateral trading facility designated by the Royal Decree does not apply. This may allow existing shareholders or new investors to acquire significant influence or control over the Company by acquiring the shares in the market without being required to acquire the other outstanding voting securities, as well as for all other securities that entitle the holders thereof to the subscription to, the acquisition of or the conversion into voting securities.

In addition, there are several provisions of Belgian company law and certain other provisions of Belgian law, such as merger control, that may apply to us and which may make an unfriendly tender offer, merger, change in management or other change in control, more difficult. These provisions could discourage potential takeover attempts that third parties may consider and thus deprive the shareholders of the opportunity to sell their shares at a premium (which is typically offered in the framework of a takeover bid). These provisions may also have the effect of depriving the holders of ADSs of the potential opportunity to sell their ADSs at a premium.

Holders of ADSs may be subject to limitations on the transfer of their ADSs and the right to surrender ADSs for the purpose of withdrawing the underlying common shares.

ADSs, which may be evidenced by American Depositary Receipts, or ADR, are transferable on the books of the depositary. However, the depositary may close its books at any time or from time to time when it deems expedient in connection with the performance of its duties. The depositary may refuse to deliver, transfer or register transfers of ADSs generally when our books or the books of the depositary are closed, or at any time if we or the depositary think it is advisable to do so because of any requirement of law, government or governmental body, or under any provision of the deposit agreement, or for any other reason. Temporary denials of the right to surrender ADSs for the purpose of withdrawal of the underlying common shares may arise because the depositary has closed its transfer books or we have closed our transfer books, in connection with voting at a shareholders' meeting or we are paying a dividend on our common shares. In addition, a holder of ADSs may not be able to surrender his or her ADSs and withdraw the underlying common shares when he or she owes money for fees, taxes and similar charges and when it is necessary to prohibit withdrawals in order to comply with any laws or governmental regulations that apply to ADSs or to the withdrawal of common shares or other deposited securities. See "Description of American Depositary Shares."

Holders of ADSs may not be able to participate in equity offerings and exercise pre-emption rights, and, as a result, may experience substantial dilution upon future issuances of ADSs or grants of rights to subscribe for shares.

In accordance with Belgian corporate law, our restated articles of association provide for waivable and cancellable pro rata preferential subscription rights to be granted to our existing shareholders to subscribe on a pro rata basis for any issue for cash of new shares, convertible bonds or warrants that are exercisable for cash, unless such rights are cancelled or limited by resolution of our shareholders' meeting or the board of directors. Our shareholders' meeting or board of directors may cancel or restrict such rights in future equity offerings. In addition, certain shareholders (including those in the United States, Australia, Canada or Japan) may not be entitled to exercise such rights even if they are not cancelled (on the basis of applicable law, practice or other considerations) unless the rights and related shares are registered or qualified for sale under the relevant legislation or regulatory framework. Under the deposit agreement, we and the depositary are not obligated to extend any pre-emption rights to holders of ADSs and, in any case, those rights would not be extended to ADS holders unless we comply with registration or qualification requirements under the securities laws in which ADS holders are located or exemptions from those requirements are available. In particular, we may not be able to establish an exemption from registration under the Securities Act of 1933, as amended, or the Securities Act, and we are under no obligation to file a registration statement with respect to any such preferential subscription rights or underlying securities or to endeavor to have a registration. As a result, there is the risk that investors may suffer dilution of their shareholding should they not be permitted to participate in preference right equity or other offerings that we may conduct in the future. We may also limit the exercise of rights by shareholders in certain jurisdictions if we distribute rights in connection with other changes to our capital structure, like a distribution of rights to tender our shares to us for redemption in connection with an issuer tender offer, resulting in such shareholders being unable to participate in such transactions.

If rights are granted to our shareholders and those rights are not extended to ADS holders, the depositary would endeavor to sell the rights for the benefit of ADS holders, but if, by the terms of such rights offering or other transaction, or for any other reason, the depositary may not either make such rights available to any ADS holders or dispose of such rights and make the net proceeds available to such ADS holders, then the depositary would allow the rights to lapse, in which case ADS holders would receive no value for such rights.

Finally, our board of directors are authorized for a period of five years from February 26, 2026, to issue shares or grant rights to subscribe for shares up to our authorized share capital from time to time and to limit or exclude pre-emption rights in connection therewith. This could cause existing shareholders to experience substantial dilution of their interest in us.

While the ADSs are on Nasdaq, the underlying shares are not listed on any securities exchange, and transfers of the underlying shares require registration in our share register. This may adversely affect liquidity and settlement of the underlying shares, and may result in the absence of a market for the underlying shares.

The ADSs representing the underlying shares are listed on Nasdaq, however, our underlying shares themselves are not listed on any securities exchange or quoted on any interdealer market. To date, we also have no intention to list the underlying shares. Consequently, there is currently no established trading market for the underlying shares, and there can be no assurance that any such market will ever develop. In addition, any transfer of the underlying shares must be recorded in the issuer's share register, which may involve administrative procedures that could delay or complicate the settlement of transactions. As a result, holders of ADSs that withdraw the underlying shares may experience limited liquidity and may be unable to effect transactions in the underlying shares or realize the market value of their investment through direct transfers of such shares.

We may not be able to complete equity offerings without cancellation or limitation of the preferential subscription rights of our existing shareholders, which may as a practical matter preclude us from timely completing offerings.

In accordance with Belgian corporate law, our restated articles of association provide for waivable and cancellable pro rata preferential subscription rights to be granted to our existing shareholders to subscribe on a pro rata basis for any issue for cash of new shares, convertible bonds or warrants that are exercisable for cash, unless such rights are cancelled or limited by resolution of our shareholders' meeting or the board of directors. Our board of directors are authorized for a period of five years from February 26, 2026, to issue shares or grant rights to subscribe for shares up to our authorized share capital from time to time and to limit or exclude pre-emption rights in connection therewith. Absent renewal by our shareholders of this authorization of the board or absent cancellation or limitation by our shareholders of the preferential subscription rights of our existing shareholders, the requirement to offer our existing shareholders the preferential right to subscribe, pro rata, for new shares being offered may as a practical matter preclude us from timely raising capital on commercially acceptable terms or at all.

We and the depositary may agree to amend the deposit agreement and to change the rights of ADS holders under the terms of such agreement, and we may initiate termination of the deposit agreement, in each case without the prior consent of the ADS holders.

We and the depositary may agree to amend the deposit agreement and to change the rights of the ADS holders under the terms of such agreement, without the prior consent of the ADS holders. We and the depositary may agree to amend the deposit agreement in any way we decide is necessary or advantageous to us or to the depositary. Amendments may reflect, among other things, operational changes in the ADS program, legal developments affecting ADSs or changes in the terms of our business relationship with the depositary. In the event that the terms of an amendment are materially disadvantageous to ADS holders, ADS holders will only receive 30 days' advance notice of the amendment, and no prior consent of the ADS holders is required under the deposit agreement. Furthermore, we may decide to direct the depositary to terminate the ADS facility at any time for any reason. For example, terminations may occur when we decide to list our common shares on a non-U.S. securities exchange and determine not to continue to sponsor an ADS facility or when we become the subject of a takeover or a going-private transaction. If the ADS facility terminates, ADS holders will receive at least 90 days' prior notice, but no prior consent is required from them. Under the circumstances that we decide to make an amendment to the deposit agreement that is disadvantageous to ADS holders or terminate the deposit agreement, the ADS holders may choose to sell their ADSs or surrender their ADSs and become direct holders of the underlying common shares, but will have no right to any compensation whatsoever.

ADS holders may not be entitled to a jury trial with respect to claims arising under the deposit agreement, which could result in less favorable outcomes to the plaintiffs in any such action.

The deposit agreement governing the ADSs representing our common shares provides that, to the fullest extent permitted by law, ADS holders waive the right to a jury trial of any claim they may have against us or the depositary arising out of or relating to our shares, the ADSs or the deposit agreement, including any claim under the U.S. federal securities laws.

If we or the depositary opposed a jury trial demand based on the waiver, the court would determine whether the waiver was enforceable based on the facts and circumstances of that case in accordance with the applicable state and federal law. To our knowledge, the enforceability of a contractual pre-dispute jury trial waiver in connection with claims arising under the federal securities laws has not been finally adjudicated by the United States Supreme Court. However, we believe that a contractual pre-dispute jury trial waiver provision is generally enforceable, including under the laws of the State of New York, which govern the deposit agreement, by a federal or state court in the City of New York, which has non-exclusive jurisdiction over matters arising under the deposit agreement. In determining whether to enforce a contractual pre-dispute jury trial waiver provision, courts will generally consider whether a party knowingly, intelligently and voluntarily waived the right to a jury trial. We believe that this is the case with respect to the deposit agreement and the ADSs. It is advisable that you consult legal counsel regarding the jury waiver provision before entering into the deposit agreement.

If you or any other holders or beneficial owners of ADSs bring a claim against us or the depositary in connection with matters arising under the deposit agreement or the ADSs, including claims under federal securities laws, you or such other holder or beneficial owner may not be entitled to a jury trial with respect to such claims, which may have the effect of limiting and discouraging lawsuits against us and the depositary. If a lawsuit is brought against either or both of us and the depositary under the deposit agreement, it may be heard only by a judge or justice of the applicable trial court, which would be conducted according to different civil procedures and may result in different outcomes than a trial by jury would have, including results that could be less favorable to the plaintiffs in any such action.

Nevertheless, if this jury trial waiver provision is not permitted by applicable law, an action could proceed under the terms of the deposit agreement with a jury trial. No condition, stipulation or provision of the deposit agreement or ADSs serves as a waiver by any holder or beneficial owner of ADSs or by us or the depositary of compliance with U.S. federal securities laws and the rules and regulations promulgated thereunder.

Concentration of ownership of our common shares among our existing executive officers, directors and principal shareholders may prevent new investors from influencing significant corporate decisions.

As of the closing of our initial public offering, our executive officers, directors and shareholders who owned more than 5% of our outstanding common shares, in the aggregate, beneficially own shares representing approximately 44% of our outstanding common shares. If our executive officers, directors and shareholders who owned more than 5% of our outstanding common shares acted together, they may be able to significantly influence all matters requiring shareholder approval, including the election and removal of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. The concentration of voting power and transfer restrictions could delay or prevent an acquisition of our company on terms that other shareholders may desire or result in the management of our company in ways with which other shareholders disagree.

If research analysts do not publish research or reports, or publish inaccurate or unfavorable research or reports, about us, our business or our market, our share price and trading volume could decline.

The trading market for the ADSs will be influenced by the research and reports that industry or financial analysts publish about us or our business. We do not currently have, and may never obtain, research coverage by industry or financial analysts. Equity research analysts may elect not to provide research coverage of the ADSs, and such lack of research coverage may adversely affect the market price of the ADSs. In the event we do have equity research analyst coverage, we will not have any control over the analysts or the content and opinions included in their reports. The price of the ADSs could decline if one or more equity research analysts downgrade the ADSs or issue other unfavorable commentary or research about us. If one or more equity research analysts cease coverage of us or fail to publish reports on us regularly, demand for the ADSs could decrease, which in turn could cause the trading price or trading volume of the ADSs to decline.

Raising additional capital may cause dilution to our shareholders, restrict our operations or require us to relinquish rights to our product candidates.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through public or private equity or debt financings, third-party funding, marketing and distribution arrangements, as well as other collaborations, strategic alliances and licensing arrangements, or any combination of these approaches. We do not have any committed external source of funds. To the extent that we raise additional capital (as the case may be, at a discount from the trading price of the ADSs), if available, through the sale of equity or convertible debt securities, your ownership interest in our company may be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a shareholder. Debt and equity financings, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as redeeming our shares, making investments, incurring additional debt, making capital expenditures, declaring dividends or placing limitations on our ability to acquire, sell or license intellectual property rights.

If we raise additional capital through future collaborations, strategic alliances or third-party licensing arrangements, we may have to relinquish valuable rights to our intellectual property, future revenue streams, research programs or product candidates, or grant licenses on terms that may not be favorable to us, if at all. If we are unable to raise additional capital when needed, we may be required to delay, limit, reduce or terminate our product candidate development or future commercialization efforts, or grant rights to develop and market product candidates that we would otherwise develop and market ourselves.

Because we do not anticipate paying any cash dividends on our common shares in the foreseeable future, capital appreciation, if any, will be your sole source of gain.

Investors should not rely on an investment in the ADSs to provide dividend income. We have never declared or paid cash dividends on our common shares. We currently intend to retain all of our future earnings, if any, to finance the expansion and development of our business. In addition, the terms of any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of the ADSs will likely be your sole source of gain for the foreseeable future.

A significant portion of our total outstanding common shares are restricted or will be restricted from immediate resale but may be sold into the market in the near future, which could cause the market price of the ADSs to drop significantly, even if our business is performing well.

Sales of a substantial number of ADS in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of ADSs intend to sell ADSs, could reduce the market price of the ADSs. As of March 31, 2026, upon the completion of our IPO and the underwriters' partial exercise of their overallotment option, we had 49,247,975 outstanding common shares. The 12,982,967 shares sold in our IPO (including the underwriters' partial exercise of their overallotment option) and 17,836 shares created as a result of the exercise of ESOP warrants in March 2026 may be resold in the public market immediately. The resale of 36,247,172 shares is currently restricted under securities laws or as a result of lock-up or other agreements, but will be able to be sold after the expiration of the lock-up on August 4, 2026 and termination of restrictions under securities laws. Moreover, holders of an aggregate 33,626,042 shares have rights, subject to conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. We have also registered all shares of common stock that we may issue under our equity compensation plans or that are issuable upon exercise of outstanding options. These shares can be freely sold in the public market upon issuance and once vested, subject to volume limitations applicable to affiliates and lock-up agreements. If any of these additional shares are sold, or if it is perceived that they will be sold, in the public market, the market price of our ADSs could decline.

In addition, in the future, we may issue additional shares of common stock or other equity or debt securities convertible into common stock in connection with a financing, acquisition, litigation settlement, employee arrangements or otherwise. Any such issuance could result in substantial dilution to our existing stockholders and could cause our stock price to decline.

As a foreign private issuer, we are permitted to, and do, follow certain home country corporate governance practices instead of otherwise applicable Nasdaq requirements, and we will not be subject to certain U.S. securities laws including, but not limited to, U.S. proxy rules and the filing of certain Exchange Act reports.

As a foreign private issuer, we are permitted to, and do, follow certain home country corporate governance practices instead of those otherwise required by Nasdaq for domestic U.S. issuers. Following our home country governance practices as opposed to the requirements that would otherwise apply to a U.S. company listed on Nasdaq may provide less protection to you than what is accorded to investors under the listing rules of Nasdaq applicable to domestic U.S. issuers.

As a foreign private issuer, we are exempt from the rules and regulations under the Exchange Act related to the furnishing and content of proxy statements, including the applicable compensation disclosure requirements. Our officers, directors and principal shareholders are exempt from short-swing profit recovery provisions contained in Section 16 of the Exchange Act. In addition, we are not required under the Exchange Act to file reports and financial statements with the SEC as frequently or as promptly as U.S. domestic companies whose securities are registered under the Exchange Act and we are exempt from filing quarterly reports with the SEC under the Exchange Act. Moreover, we are not required to comply with Regulation FD, which restricts the selective disclosure of material information, although we have voluntarily adopted a corporate disclosure policy substantially similar to Regulation FD. These exemptions and leniencies reduce the frequency and scope of information and protections to which you may otherwise have been eligible in relation to a U.S. domestic issuer.

We may lose our foreign private issuer status, which would then require us to comply with the Exchange Act's domestic reporting regime and cause us to incur significant legal, accounting and other expenses.

As a foreign private issuer, we are not required to comply with all the periodic disclosure and current reporting requirements of the Exchange Act and related rules and regulations. The determination of foreign private issuer status will be made annually on the last business day of our most recently completed second fiscal quarter. Accordingly, we will next make a determination with respect to our foreign private issuer status on June 30, 2026. There is a risk that we will lose our foreign private issuer status in the future.

We would lose our foreign private issuer status if a majority of our shares are owned by U.S. residents and a majority of our directors or executive officers are U.S. citizens or residents or we fail to meet additional requirements necessary to avoid loss of foreign private issuer status. The regulatory and compliance costs to us under U.S. securities laws as a U.S. domestic issuer may be significantly higher. If we are not a foreign private issuer, we will be required to file periodic reports and registration statements on U.S. domestic issuer forms with the SEC, which are more detailed and extensive than the forms available to a foreign private issuer. We may also be required to modify certain of our policies to comply with accepted governance practices associated with U.S. domestic issuers. Such conversion and modifications will involve additional costs. In addition, we would lose our ability to rely upon exemptions from certain corporate governance requirements on U.S. stock exchanges that are available to foreign private issuers.

We are a Belgian limited liability company but are not a "listed company" within the meaning of the Belgian Companies and Associations Code, and shareholders of our company may have different and, in some cases, more limited shareholder rights than shareholders of such "listed company" in Belgium or of a U.S. listed corporation.

We are organized as a limited liability company (*naamloze vennootschap / société anonyme*) under the laws of Belgium. Our corporate affairs are governed by Belgian corporate law. From a Belgian corporate law point of view, we do not qualify as a "listed company" (*genoteerde vennootschap / société cotée*) within the meaning of the Belgian Companies and Associations Code because none of our securities are listed on any regulated market in the EEA. The Belgian corporate law provisions that are applicable to Belgian listed companies do therefore not apply to us. Furthermore, we are not subject to most of the disclosure obligations applicable to Belgian listed companies. As a result, shareholders of our company may not enjoy certain of the rights and protection generally afforded to shareholders of a Belgian listed company. You should also be aware that the rights provided to our shareholders under Belgian corporate law and our restated articles of association differ in certain respects from the rights that you would typically enjoy as a shareholder of a U.S. corporation under applicable U.S. federal and state laws.

Under Belgian corporate law, except in certain limited circumstances, our shareholders may not ask for an inspection of our corporate records, while under Delaware corporate law any shareholder, irrespective of the size of his or her shareholdings, may do so. Shareholders of a Belgian corporation are also unable to initiate a derivative action, a remedy typically available to shareholders of U.S. companies, in order to enforce a right of our company, in case we fail to enforce such right ourselves, other than in certain cases of director liability under limited circumstances. In addition, a majority of our shareholders may release a director from any claim of liability we may have, including if he or she has acted in bad faith or has breached his or her duty of loyalty, provided, in some cases, that the relevant acts were specifically mentioned in the convening notice to the shareholders' meeting deliberating on the discharge. In contrast, most U.S. federal and state laws prohibit a company or its shareholders from releasing a director from liability altogether if he or she has acted in bad faith or has breached his or her duty of loyalty to the company. Finally, Belgian corporate law does not provide any form of appraisal rights in the case of a business combination, except that in certain cross-border mergers, de-mergers and conversions dissenting shareholders may have a cash-out right. For additional information on these and other aspects of Belgian corporate law and our restated articles of association, see Item 10.B: "Memorandum and Articles of Association". As a result of these differences between Belgian corporate law and our restated articles of association, on the one hand, and U.S. federal and state laws, on the other hand, in certain instances, you could receive less protection as a shareholder of our company than you would as a shareholder of a U.S. corporation.

In addition, as referred to below in the Item 10.B: "Memorandum and Articles of Association", the Belgian Companies and Associations Code includes a cap on liability for directors as well as persons in charge of daily management, such as our chief executive officer, for any damage they cause due to mismanagement, including breaches of the articles of association and/or the Belgian Companies and Associations Code. This liability cap applies towards the company and third parties. For our directors and management, the cap will be EUR 12,000,000. The cap applies irrespective of the number of claimants or defendants for the same (set of) facts. However, the cap does not apply to repetitive minor misconduct, serious error or cases of fraud. Furthermore, the cap does not apply to directors' liability under the special liability regimes relating to payment of withholding tax, value added tax and social security contributions. Under Delaware corporate law, companies may choose to exculpate directors from personal liability for monetary damages in connection with breaches of their fiduciary duty of care. However, exculpation does not extend to breaches of the duty of loyalty, acts or omissions not in good faith, or transactions from which they derive an improper personal benefit. Officer exculpation is not permitted in connection with claims brought by or in the right of the corporation, including shareholder derivative claims, while director exculpation is not subject to that limitation. As a result, in certain instances, the liability of our directors and officers to shareholders may be less than the liability they would have had if we were a Delaware company.

Certain of our significant shareholders may have different interests from us and may be able to control us, including the outcome of shareholder votes.

Our directors, officers and affiliated shareholders collectively own a significant percentage of our common shares. As a result, these shareholders will be able to exercise a significant level of control over all matters requiring stockholder approval, including the election of directors, amendment of our articles of association and approval of certain significant corporate transactions. This control could have the effect of delaying or preventing a change of control of the Company or changes in management, in each case, which other shareholders might find favorable, and will make the approval of certain transactions difficult or impossible without the support of these significant shareholders.

Risks related to taxation

If we are classified as a passive foreign investment company, there could be adverse U.S. tax consequences to U.S. Holders.

Under the Internal Revenue Code of 1986, or the Code, as amended, we will be a "passive foreign investment company" as defined under section 1297 of the Code for U.S. federal income tax purposes, or a PFIC, for any taxable year in which (1) 75% or more of our gross income consists of passive income or (2) 50% or more of the average quarterly value of our assets consists of assets that produce, or are held for the production of, passive income. Passive income includes, among other things, dividends, interest, certain non-active rents and royalties, and gains from certain property transactions. If we are a PFIC for any taxable year during which a U.S. Holder (as defined below in Item 10.E: "Material U.S. federal income tax considerations for U.S. Holders") holds the ADSs, the U.S. Holder may be subject to adverse tax consequences regardless of whether we continue to be a PFIC, including ineligibility for any preferred tax rates on capital gains or on qualified dividends (whether actual or deemed), interest charges on certain taxes treated as having been deferred and additional reporting requirements.

There is a significant risk that we may be a PFIC for any taxable year prior to the commercialization of our drug candidates. It is currently uncertain whether we will be treated as a PFIC for the 2026 taxable year. A separate determination must be made after the close of each taxable year as to whether we are a PFIC for that year. As a result, our PFIC status may change from year to year. Any U.S. Holder who held our ADSs during any time when we were a PFIC will continue to be subject to adverse tax consequences unless certain elections (as described in- Item 10.E: "Material U.S. federal income tax considerations for U.S. Holders - PFIC rules") are made. The total value of our assets (including intangibles) for purposes of the asset test may be calculated by reference to our market capitalization, which may fluctuate considerably, particularly prior to the commercialization of any of our drug candidates. Because we currently hold a substantial amount of cash (which is a passive asset), fluctuations in the market price of the ADSs may result in our being or becoming a PFIC for the current or any other taxable year. In addition, the composition of our assets will also be affected by how, and how quickly, we spend our current cash. Our income and PFIC status for a taxable year will also be affected by the amount of positive interest earned on our bank deposits and the characterization of other sources of gross income that we may receive. To date, our only active income has been income from government grants, but there can be no assurance that we will continue to receive governmental grants. Therefore, prior to the commercialization of any of our drug candidates we may be a PFIC if our interest and other investment income is substantial in comparison to our total gross income. Each U.S. Holder is strongly urged to consult his, her or its tax advisor regarding the application of these rules and the availability of any potential elections.

Changes to applicable tax laws and regulations or exposure to additional tax liabilities could adversely affect our business and future profitability.

We conduct operations, directly and through our subsidiaries, within the EU and the United States, and therefore are subject to income taxes in such jurisdictions. We may also in the future become subject to income taxes in other foreign jurisdictions. Our effective income tax rate could be adversely affected by a number of factors, including changes in the valuation of deferred tax assets and liabilities, changes in tax laws, changes in accounting and tax standards or practices, changes in the composition of operating income by tax jurisdiction, changes in our operating results before taxes, and the outcome of income tax audits in the jurisdictions in which we operate. We will regularly assess all of these matters to determine our anticipated tax liabilities. If any of our assessments are ultimately determined to be incorrect, our business, results of operations, or financial condition could be materially adversely affected.

Governments in the various jurisdictions in which we operate continue to review, reform and modify tax laws, regulations, treaties, interpretations, policy initiatives and tax authority practices, and how we are treated for tax purposes is subject to changes. For example, on July 4, 2025, OBBBA was signed into law and changed a number of key U.S. federal income tax provisions, including the restoration of 100% bonus depreciation, immediate expensing for domestic research and experimental expenditures and the ability to make elective adjustments for prior years, changes to the Section 163(j) interest limitations, updates to "net CFC tested income" (formerly "GILTI") and "FDII" rules, amendments to energy credits, and expanded Section 162(m) aggregation requirements. We are unable to predict whether tax reform may be proposed or enacted in the future in any jurisdiction (including with retroactive effect) or whether such changes would have a significant impact on our business, but such changes could result in material changes to the taxes that we are required to provide for and pay in various jurisdictions.

Due to the complexity of multinational tax obligations and filings, we and our subsidiaries may have a heightened risk related to audits or examinations by federal, state, provincial, and local taxing authorities in the jurisdictions in which we operate. Outcomes from these audits or examinations could have a material adverse effect on our business, results of operations, or financial condition.

The tax laws of the jurisdictions in which we operate, as well as potentially any other jurisdiction in which we may operate in the future, have detailed transfer pricing rules that require that all transactions with related parties satisfy arm's length pricing principles. Although we believe that our transfer pricing policies have been reasonably determined in accordance with arm's length principles, the taxation authorities in the jurisdictions where we carry on business could challenge our transfer pricing policies.

International transfer pricing is a subjective area of taxation and generally involves a significant degree of judgment. If any of these taxation authorities were to successfully challenge our transfer pricing policies, we could be subject to additional income tax expenses, including interest and penalties, as well as transfer pricing mismatches. Any such increase in our income tax expense and related interest and penalties could have a material adverse effect on our business, results of operations, or financial condition. We may also be adversely affected by changes in relevant tax laws and tax rates, treaties, regulations, administrative practices and principles, judicial decisions, and interpretations thereof, in each case, possibly with retroactive effect.

General risk factors

Exchange rate fluctuations or abandonment of the euro currency may materially affect our results of operations and financial condition.

Potential future expense and revenue may be incurred or derived in currencies other than the U.S. dollar, particularly in Europe. As a result, our business and share price may be affected by fluctuations in foreign exchange rates between the U.S. dollar and other currencies, particularly the Euro and British Pound, which may also have a significant impact on our reported results of operations and cash flows from period to period. In addition, the abandonment of the euro by one or more members of the EU could lead to the re-introduction of individual currencies in one or more EU Member States, or in more extreme circumstances, the dissolution of the European Union. The effects on our business of the abandonment of the euro as a currency, the exit of one or more EU Member States from the European Union (such as Brexit) or a potential dissolution of the European Union, are impossible to predict with certainty, and any such events could have a material adverse effect on our business, financial condition and results of operations.

Unstable global economic or political conditions, inflation, increases in interest rates, natural disasters, public health crises, political crises, geopolitical events such as the crisis in Ukraine, the Iran-US-Israel conflict and the Israel-Hamas war, tensions in U.S.-China relations, or other macroeconomic conditions, could adversely affect our business, financial condition or results of operations.

Our business is susceptible to general conditions in the global economy and in the global financial markets. A global financial crisis or a global or regional political disruption could cause extreme volatility in the capital and credit markets. There can be no assurance that deterioration in credit and financial markets and confidence in economic conditions will not occur. If the current equity and credit markets deteriorate, or do not improve, it may make any necessary debt or equity financing more difficult, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and share price and could require us to delay, scale back or discontinue the development and commercialization of one or more of our product candidates or delay our pursuit of potential in-licenses or acquisitions.

A severe or prolonged economic downturn, or political disruption or public health crisis could result in a variety of risks to our business and operations, or those of the third parties on which we rely, including delays or disruptions to our clinical trials, weakened demand for our current or future product candidates, if approved, and our ability to raise additional capital when needed on acceptable terms, if at all.

A weak or declining economy or political disruption, such as the tensions in U.S.-China relations, the ongoing military conflicts between Russia and Ukraine, between Iran and the United States and Israel, or between Hamas and Israel, could also strain our manufacturers or suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our potential drugs, if approved. Any of the foregoing could materially and adversely affect our business, financial condition, results of operations and prospects, and we cannot anticipate all of the ways in which the political or economic climate and financial market conditions could adversely impact our business.

The United States Congress included as part of its 2026 National Defense Appropriations Act a provision commonly known as the BIOSECURE Act, which was signed into law on December 18, 2025. The BIOSECURE Act establishes prohibitions on the U.S. government's ability to procure or purchase–or to enter contracts with or provide grants or loans to entities that procure or purchase–certain biotechnology equipment and services produced or provided by named Chinese "biotechnology companies of concern," to be explicitly identified by the U.S. government. While the U.S. government has not yet identified any biotechnology companies of concern, to the extent that the government names any of our Chinese partners from whom we purchase products or services, or with whom we otherwise collaborate, this could have a negative impact on our ability to contract with or receive funding from the U.S. government. Such restrictions could have an adverse impact on our operations.

It may be difficult for investors outside Belgium to serve process on or enforce foreign judgments against us or our directors and members of our executive committee.

We are a Belgian limited liability company. A majority of the members of our board of directors and members of our executive committee are not resident of the United States. All or a substantial portion of the assets of such non-resident persons and most of our assets are located outside the United States. As a result, it may not be possible for investors to effect service of process upon such persons or on us or to enforce against them or us a judgment obtained in U.S. courts. Original actions or actions for the enforcement of judgments of U.S. courts relating to the civil liability provisions of the federal or state securities laws of the United States are not directly enforceable in Belgium.

The United States and Belgium do not currently have a multilateral or bilateral treaty providing for reciprocal recognition and enforcement of judgments, other than arbitral awards, in civil and commercial matters. In order for a final judgment for the payment of money rendered by U.S. courts based on civil liability to produce any effect on Belgian soil, it is accordingly required that this judgment be recognized or be declared enforceable by a Belgian court in accordance with Articles 22 to 25 of the 2004 Belgian Code of Private International Law. Recognition or enforcement does not imply a review of the merits of the case and is irrespective of any reciprocity requirement. A U.S. judgment will, however, not be recognized or declared enforceable in Belgium, unless (in addition to compliance with certain technical provisions) the Belgian courts are satisfied of the following:

- the effect of the recognition or enforcement of judgment is not manifestly incompatible with Belgian public order;
- the judgment did not violate the rights of defense of the defendant;
- the judgment was not rendered in a matter where the parties did not freely dispose of their rights with the sole purpose of evading the application of the law applicable according to Belgian private international law;
- the judgment is not subject to further recourse under U.S. law;
- the judgment is not incompatible with a judgment rendered in Belgium or with a prior judgment rendered abroad that might be recognized in Belgium;
- the claim was not filed outside Belgium after a claim was filed in Belgium, if the claim filed in Belgium relates to the same parties and the same subject and is still pending;
- the Belgian courts did not have exclusive jurisdiction to rule on the matter;
- the U.S. court did not accept its jurisdiction solely on the basis of the presence of the plaintiff or the location of goods not directly linked to the dispute in the United States;
- the judgment did not concern the deposit or validity of intellectual property rights when the deposit or registration of those intellectual property rights was requested, done or should have been done in Belgium pursuant to international treaties;
- the judgment did not relate to the validity, operation, dissolution, or liquidation of a legal entity that has its main seat in Belgium at the time of the petition of the U.S. court;
- if the judgment relates to the opening, progress or closure of insolvency proceedings, it is rendered on the basis of the European Insolvency Regulation or, if not, that (a) a decision in the principal proceedings is taken by a judge in the state where the most important establishment of the debtor was located or (b) a decision in territorial proceedings was taken by a judge in the state where the debtor had another establishment than its most important establishment; or
- the judgment submitted to the Belgian court is authentic under the laws of the state where the judgment was issued; in case of a default judgment, it can be shown that under locally applicable laws the invitation to appear in court was properly served on the defendant; a document can be produced showing that the judgment is, under the rules of the state where it was issued, enforceable and was properly served on the defendant.

In addition to recognition or enforcement, a judgment by a federal or state court in the United States against us may also serve as evidence in a similar action in a Belgian court if it meets the conditions required for the authenticity of judgments according to the law of the state where it was rendered. The findings of a federal or state court in the United States will not, however, be taken into account to the extent they appear incompatible with Belgian public order.

Based on the lack of a treaty as described above, U.S. investors may not be able to enforce against us or members of our board of directors or our executive management any judgments obtained in U.S. courts in civil and commercial matters, including judgments under the U.S. federal securities laws. See also below under "Enforcement of civil liabilities."

Item 4: Information on the Company

A. History and Development of the Company

We are a clinical-stage biopharmaceutical company focused on developing novel disease-modifying therapies for fibro-inflammatory diseases with high unmet medical need.

We have assembled an executive team with deep scientific and clinical development expertise and a track record of strong business leadership. Tim Knotnerus, our Chief Executive Officer, has extensive experience in corporate development and venture capital and previously held the position of Vice President of Corporate Development at AM-Pharma, where he and his team secured a $600.0 million option-to-buy deal with Pfizer. Philippe Wiesel, M.D., our Chief Medical Officer, served as Chief Medical Officer at Genkyotex where he led clinical development of several anti-inflammatory and anti-fibrotic compounds for various fibrotic disorders including liver, lung, and kidney fibrosis. Dr. Wiesel also previously led the late-stage development and marketing approval for Raptiva® at EMD Serono. Pierre Kemula, our Chief Financial Officer, joined us in 2024 from CureVac, N.V., where he successfully contributed as Chief Financial Officer to the company's initial public offering on Nasdaq and several follow-on offerings during his eight-year tenure. Andrea Sáez, Ph.D., our Chief Development Officer, previously served as Chief Operating Officer and Chief Scientific Officer at Origo Biopharma, S.L., where both ontunisertib (AGMB-129) and AGMB-447 were discovered. Our Chief Business Officer, Paul van der Horst, Ph.D., and General Counsel, Ellen Lefever, bring broad experience in corporate development and capital raisings, including leadership roles at Galapagos during negotiations with Gilead regarding their $5.0 billion strategic collaboration, and Galapagos' initial public offering on Nasdaq and subsequent secondary public offerings.

We are headquartered in Antwerp, Belgium, with chemistry laboratory facilities in Touro, Spain and a growing presence in the United States with an office in Cambridge, Massachusetts. Our ADSs have been listed on the Nasdaq Global Select Market under the ticker "AGMB" since February 6, 2026. We raised total gross proceeds of $207.7 million dollars in our initial public offering in February 2026. In addition, we have received grants, loans and other funding from patient organizations and government institutions supporting our programs, including from the Flemish and Belgian governments under respective innovation grant programs.

Our legal and commercial name is AgomAb Therapeutics NV. We were initially incorporated under the laws of Belgium on April 13, 2017 as a Belgian private limited liability company (besloten vennootschap) and were converted under the laws of Belgium into a Belgian limited liability company (naamloze vennootschap) on March 14, 2019. Our principal executive offices are located at Posthoflei 1/6, 2600 Antwerpen, Belgium. Our telephone number at this address is +32 3 318 91 70. Our Spanish subsidiary, Agomab Spain, S.L.U., is headquartered at Parque Empresarial de Touro Fonte Diaz, A Coruña, Galicia, Spain. Our U.S. subsidiary, Agomab US, Inc. is headquartered in Cambridge, Massachusetts.

The SEC maintains an internet site that contains reports, proxy and information statements, and other information regarding issuers like Agomab that file electronically with the SEC. The address of that website is www.sec.gov. We maintain a corporate website at www.agomab.com. Information found on, or accessible through, our website is not incorporated by reference into and should not be considered a part of this Annual Report, and the reference to our website in this Annual Report is an inactive textual reference only.

The Company acquired 100% of Agomab Spain on December 14, 2021 for a total consideration of €24.3 million, which included a contingent earn-out component with a fair value at acquisition date of €3.95 million. The acquisition resulted in the recognition of €18.55 million of in-process research and development intangible assets and €8.6 million of goodwill, both of which remain fully on the balance sheet as at December 31, 2025 with no impairment recorded to date. The earn-out is payable to Agomab Spain's former equity holders upon the achievement of specified development milestones, with a maximum total contingent payment of €20 million if all targets are achieved. During 2025, the Company signed an amendment to the Share Purchase Agreement relating to this acquisition, restructuring the first earn-out milestone.

Capital expenditure on property, plant and equipment was modest across the three-year period, reflecting the Group's nature as a clinical-stage company without manufacturing infrastructure. No PP&E was held at the start of 2023; during 2024, the Group invested €675 thousand in leasehold improvements, IT equipment, furniture and other assets as it built out its physical infrastructure. Capital expenditure in 2025 was minimal at €4 thousand (furniture and fixtures). As at December 31, 2025, the net carrying amount of PP&E was €503 thousand (2024: €619 thousand).

The Group made no divestitures of businesses, subsidiaries or material asset portfolios during the three financial years ended December 31, 2023, 2024 and 2025.

B. Business Overview

Agomab is a clinical-stage biopharmaceutical company focused on developing novel disease-modifying therapies for fibro-inflammatory diseases with high unmet medical need. Agomab's product candidates are designed to target established potent pathways and utilize organ-restricted approaches, with the aim of increasing efficacy while minimizing safety liabilities. Fostering a culture of excellence, Agomab's mission is to pioneer therapeutics that aim to resolve fibro-inflammation and restore organ function to enable people with these disorders to live fuller and healthier lives.

We are advancing a pipeline of novel product candidates for chronic fibro-inflammatory disorders with well-validated targets, significant unmet medical needs and large commercial potential. Our pipeline includes:

- **Ontunisertib (AGMB-129):** Our lead product candidate, ontunisertib (AGMB-129), is a selective and potent oral, gastrointestinal-restricted small molecule inhibitor of ALK5, or TGFβR1, in development for the treatment of Fibrostenosing Crohn's Disease, or FSCD. FSCD is a severe complication of Crohn's Disease, or CD, that is associated with significant morbidity. There are approximately 1.4 million patients under treatment for CD in the seven major markets of the United States, France, Germany, Italy, Spain, the United Kingdom and Japan, and approximately 620,000, or 46%, of these patients have FSCD. The emergence of burdensome symptomatic strictures is considered to be an inevitable consequence of long-term inflammation for the large proportion of patients with CD who progress to FSCD and eventually require surgery. There are no approved pharmacologic therapies for FSCD. We believe ontunisertib has the potential to change the paradigm for treating FSCD patients and provide the first pharmacologic treatment for strictures. Ontunisertib is designed to act locally in the gastrointestinal tract, enabling high exposure in the target tissue. Then, following absorption, ontunisertib is rapidly inactivated in the liver to avoid potential toxicities associated with systemic TGFβ signaling inhibition. In November 2025, we announced topline results of the global randomized, double-blind, placebo-controlled Phase 2a trial of ontunisertib, or the STENOVA trial, in 103 FSCD symptomatic patients with at least one ileal stricture. Part A of the STENOVA study achieved its primary endpoint of assessing the safety and tolerability of ontunisertib 100mg QD and 200mg BID in FSCD patients. The severity and incidence of adverse events were balanced across all treatment arms, including the placebo. Pharmacokinetic results confirmed the GI-restricted profile of ontunisertib with high local and low systemic exposure of ontunisertib in FSCD patients. We also observed positive signals on several exploratory clinical endpoints. The 48-week open-label treatment extension of the STENOVA trial with ontunisertib is currently ongoing and we expect to report the results of such open-label treatment extension in the second half of 2026. Based on the results observed in the STENOVA study to date and our positive interactions with the U.S. Food and Drug Administration, or the FDA, we are preparing to initiate a Phase 2b trial of ontunisertib in patients with symptomatic FSCD in the second half of 2026.

- **AGMB-447:** AGMB-447, our second clinical-stage product candidate, is an inhaled small molecule inhibitor of ALK5, or TGFβR1, in development for the treatment of idiopathic pulmonary fibrosis, or IPF. IPF is a rare progressive fibrotic lung disease that has a poor prognosis for patients with a median life expectancy of less than five years. IPF affects approximately 240,000 people in the United States, Japan, the United Kingdom, and the four largest European markets (France, Germany, Spain, and Italy), with 30,000 to 40,000 new cases being diagnosed each year in the United States alone. AGMB-447 is designed to have a high local exposure in the lung tissue, and then upon absorption into the bloodstream, AGMB-447 is hydrolyzed and substantially inactivated in order to avoid potential toxicities associated with systemic inhibition of ALK5 signaling. Direct delivery to the lung through inhalation and subsequent lung restriction are designed to confer high efficacy and a favorable safety profile for AGMB-447. We believe AGMB-447 also has the potential to demonstrate a low potential for drug-drug interactions that could make it well-suited for use as a single-agent and in combination with current standard of care therapies. We completed an interim analysis of the SAD and MAD B1-6 stages in 108 healthy participants where we observed positive topline interim results and expect to report data from IPF patients in the second half of 2026. We received positive scientific advice from the UK Medicines and Healthcare products Regulatory Agency (MHRA), supporting our planned Phase 2 trial in IPF patients. We are on track to initiate a Phase 2 proof-of-concept study with AGMB-447 in IPF patients in the second half of 2026.
- **Discovery and preclinical portfolio:** We have a robust discovery pipeline including several programs in the early stages of development. AGMB-101, our most advanced preclinical asset, is a hepatocyte growth factor-, or HGF-, mimetic monoclonal antibody that acts through agonism, or stimulation, of the MET receptor and has demonstrated both antifibrotic and regenerative activity in preclinical models. We have concluded IND-enabling studies for AGMB-101 and received regulatory clearance to proceed with a Phase 1 single ascending dose trial in healthy participants and patients with liver cirrhosis. We are assessing initiation of further development of AGMB-101 as we explore strategic options for the candidate and its related intellectual property.

Fibrosis TGFβ and HGF

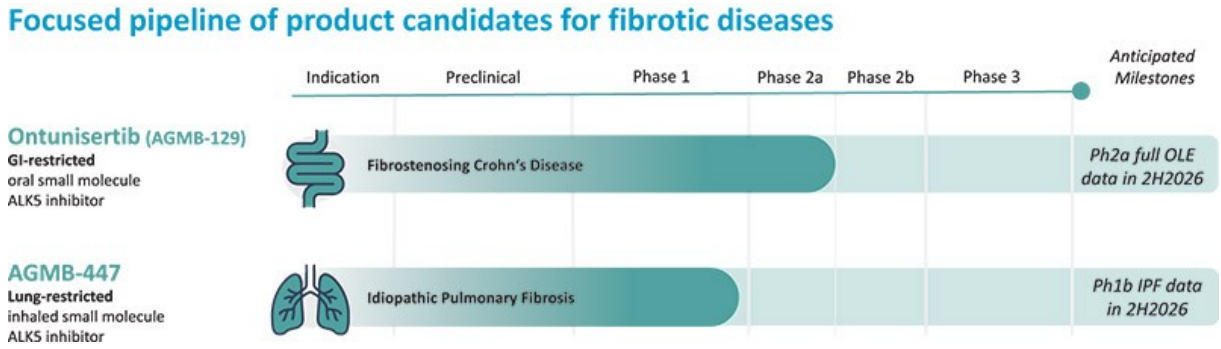
Fibrosis represents an aberrant response of a tissue to injury, leading to progressive tissue scarring that may be triggered by trauma, inflammation, infection, cell injury or cancer, amongst others. As a result, fibrosis can lead to organ dysfunction and failure. The body's normal response to injury involves the activation of cells that produce collagen and other components of the extracellular matrix, or ECM, that are part of the healing process for the tissue. Under normal physiological circumstances, scarring is self-limited and the resulting scar resolves itself, leaving behind a tissue architecture similar to what was present before the injury. However, in certain chronic disease states, this process of healing becomes both prolonged and excessive, resulting in fibrotic remodeling which interferes with organ function. Fibrosis can occur in many organ systems throughout the body including the lungs, liver, kidneys, gastrointestinal tract, skin and muscles. While the exact pathologies for diseases in these organs differ, fibrosis involves many of the same cell types and signaling pathways across different organs and tissue.

Signaling by TGFβ has been shown to play a central role in the pathophysiology of fibrosis. The well understood role of the TGFβ pathway, including through the ALK5 receptor, in driving multiple aspects of fibrosis, has made it an attractive target for antifibrotic drug development. In healthy tissue, TGFβ's physiological role is to initiate healing after injury. In fibrotic diseases, however, TGFβ signaling remains continuously activated in response to prolonged insults such as inflammation, leading the surrounding tissue to deposit excess ECM, which eventually leads to tissue fibrosis. There is strong preclinical evidence and encouraging preliminary clinical evidence that TGFβ inhibition could be effective in multiple indications; however, development of previous ALK5 inhibitors has been limited due to safety concerns as systemic inhibition of TGFβ causes toxicity in the heart and large vessels. We believe our programs have the potential to overcome these systemic toxicity challenges by acting locally within tissue of interest and avoiding systemic exposure while allowing us to leverage the well-described role of TGFβ in fibrosis.

The HGF pathway, like TGFβ, has also been established to be a key modulator of fibrosis and represents a promising target for progressive liver cirrhosis, as well as gastrointestinal, pulmonary, and renal disorders. In contrast to TGFβ, however, the HGF pathway possesses anti-fibrotic activity. The HGF pathway is a critical modulator of the proliferation, survival, motility, and differentiation of epithelial cells and has a strong regenerative effect. We have an HGF-mimetic monoclonal antibody in our development pipeline that we believe has the potential to act as an agonist of the MET receptor in a robust, stable, specific, and convenient fashion, something which has not been possible with putative small molecule agonists or native HGF.

Our pipeline

We have built a focused pipeline of novel small molecule and antibody product candidates designed to act against well-validated and potentially disease-modifying targets for the treatment of fibrotic diseases with high unmet need and large commercial potential. We retain exclusive, worldwide development and commercialization rights to all of our product candidates and preclinical programs.



ALK5, activin receptor-like kinase 5; GI, gastrointestinal; OLE, Open Label Extension

We have a robust discovery pipeline including several programs in the early stages of development.

Ontunisertib (AGMB-129): Potential treatment for Fibrostenosing Crohn's Disease

Ontunisertib (AGMB-129), our lead product candidate, is a selective and potent oral, gastrointestinal-restricted small molecule inhibitor of ALK5 in development for the treatment of FSCD. FSCD is a severe complication of CD that is associated with significant morbidity. There are approximately 1.4 million patients under treatment for CD in the seven major markets of the United States, France, Germany, Italy, Spain, the United Kingdom and Japan, and approximately 620,000, or 46%, of these patients have FSCD. FSCD is caused by a narrowing, or stricturing, of the intestinal lumen due to fibrosis. Over time, these strictures can lead to abdominal pain, cramping, and vomiting after meals, and often require dietary modifications which can lead to malnutrition. There are no approved pharmacologic therapies for FSCD and currently approved therapies for CD mainly target inflammation but have not demonstrated efficacy in FSCD. Therefore, nearly all patients with intestinal strictures will require bowel surgery, which makes FSCD the leading cause of surgery in CD patients.

Ontunisertib is designed to avoid toxicities that arise from systemic inhibition of ALK5 signaling by limiting exposure to the gastrointestinal tract. Ontunisertib takes advantage of liver metabolism which substantially inactivates the drug before it can enter systemic circulation. In preclinical studies in rodents, oral administration of ontunisertib resulted in high local exposure in the gastrointestinal tract with no or minimal systemic exposure (AUC not calculable). Ontunisertib has shown the ability to prevent and treat fibrosis in preclinical mouse models and showed downregulation of expression of both pro-fibrotic and pro-inflammatory genes in a preclinical study, assessing *ex vivo* patient-derived cells from gastrointestinal biopsies of inflammatory bowel disease, or IBD, patients. Furthermore, we have not observed cardiac valve toxicities commonly associated with systemic TGFβ inhibition in our toxicology studies to date. In a Phase 1 trial, oral administration of ontunisertib to healthy human study participants was generally well-tolerated following both single and multiple ascending doses and demonstrated high levels of ontunisertib in the gastrointestinal tract with low systemic exposure in the bloodstream. Ontunisertib received Fast Track Designation for the treatment of FSCD from the FDA in 2023.

We conducted a global randomized, double-blind, placebo-controlled STENOVA Phase 2a trial of ontunisertib. We enrolled 103 FSCD patients with non-critical symptomatic strictures. The primary endpoint of the study was assessing the safety and tolerability of ontunisertib 100mg QD and 200mg BID in FSCD patients. The co-secondary endpoints were the pharmacokinetics (PK) and target engagement of ontunisertib 100mg QD and 200mg BID in FSCD patients. In STENOVA, we are also exploring novel potential efficacy endpoints in FSCD. These include Clinical Outcome Assessment, or COA, instruments evaluating the clinical benefit to patients, such as a specific patient-reported outcome, or PRO, instrument, named S-PRO (Stricturing Patient-Reported Outcome). We also assess radiological improvement by several imaging modalities, including magnetic resonance enterography, or MRE, and the Simple Endoscopy Score in Crohn's Disease (SES-CD). MRE provides information about structural severity criteria including stricture length, bowel wall thickness, and the presence and diameter of any associated pre-stenotic dilation. The SES-CD provides information about luminal disease activity and evaluates inflammatory changes as well as narrowing and is used as co-primary endpoint for luminal CD. We announced topline data from the STENOVA trial in November 2025. We reported that Part A of the STENOVA study achieved its primary endpoint of assessing the safety and tolerability of ontunisertib 100mg QD and 200mg BID in FSCD patients. The severity and incidence of adverse events were balanced across all treatment arms, including the placebo. Pharmacokinetic results confirmed the GI-restricted profile of ontunisertib with high local and low systemic exposure of ontunisertib in FSCD patients. We also observed positive signals on several exploratory clinical endpoints. We expect to report the results of the 48-week open-label treatment extension of the STENOVA trial in the second half of 2026. Based on the results observed in the STENOVA study to date and our positive interactions with the FDA, we are preparing to initiate a Phase 2b trial of ontunisertib in patients with symptomatic FSCD in the second half of 2026.

AGMB-447: Potential treatment for IPF

AGMB-447, our second clinical-stage product candidate, is an inhaled small molecule inhibitor of TGFβR1 in development for the treatment of IPF. IPF is a rare progressive fibrotic lung disease that has a poor prognosis for patients with a median life expectancy of less than five years. IPF affects approximately 240,000 people in the United States, Japan, the United Kingdom, and the four largest European markets (France, Germany, Spain, and Italy), with 30,000 to 40,000 new cases being diagnosed each year in the United States alone. There are currently three FDA-approved therapies for IPF: pirfenidone, initially marketed as Esbriet® by Roche and nintedanib, marketed as Ofev®, and nerandomilast, marketed as Jascayd®, both by Boehringer Ingelheim. These drugs have shown modest slowing of disease progression in certain patients; however, these products do not enable recovery of lost lung function and are associated with severe safety and tolerability concerns which can be further complicated by drug-drug interactions. Despite the limitations of available treatments, the aggregate annual revenue for these therapies was approximately $4.1 billion in 2024 across IPF and other fibrosing interstitial lung diseases.

We engineered AGMB-447 to be active in the lung but avoid significant systemic exposure. AGMB-447 is administered directly to the lungs via inhalation and then rapidly hydrolyzed and substantially inactivated in the bloodstream. Preclinical studies in rodents have demonstrated that administration of AGMB-447 leads to high exposure in lung tissue, with systemic plasma exposure approximately 800 to 1,000 times lower than in the lung. Antifibrotic activity was observed with AGMB-447 in a rodent model of IPF, as well as in human lung tissue from both non-IPF and IPF patients where AGMB-447 was observed to lead to dose-dependent reductions in a number of fibrosis and inflammation markers based on gene expression data. We have not observed any of the cardiac valve toxicities commonly associated with systemic TGFβ inhibition in our toxicology studies to date. AGMB-447 received Orphan Drug Designation for the treatment of IPF from the FDA in May 2024.

We are conducting a randomized, double-blind, placebo-controlled Phase 1 clinical trial intended to evaluate the safety, PK, PD and target engagement of AGMB-447. The trial is a single center, 3-part, double-blind, randomized, placebo-controlled single ascending dose (SAD; Part A) and multiple ascending dose (MAD; Part B) study in healthy participants and multiple dose study in IPF participants (Part C). AGMB-447 is administered via nebulization, over 7 days in Part B and over 14 days in Part C. The trial is being conducted in the United Kingdom.

We enrolled 108 healthy participants in the SAD and MAD B1-B6 portions of the trial. We also initiated the IPF cohort of the study and are currently enrolling patients. We plan to enroll up to 12 IPF patients in the Phase 1b study with AGMB-447.

We completed an interim analysis of the SAD and MAD B1-6 stages in healthy participants where we observed positive topline interim results and expect to report results of the Phase 1b in IPF patients in the second half of 2026.

We received positive scientific advice from the UK Medicines and Healthcare products Regulatory Agency (MHRA), supporting our planned Phase 2 trial in IPF patients. We are on track to initiate a Phase 2 proof-of-concept study with AGMB-447 in IPF in the second half of 2026.

Discovery and preclinical portfolio

We have a robust discovery pipeline including several programs in the early stages of development. AGMB-101, our most advanced preclinical asset, is an HGF-mimetic monoclonal antibody that acts through agonism, or stimulation, of the MET receptor and has demonstrated both antifibrotic and regenerative activity in preclinical models. We have concluded IND-enabling studies for AGMB-101 and received regulatory clearance to proceed with a Phase 1 single ascending dose trial in healthy participants and patients with liver cirrhosis. We are assessing initiation of further development of AGMB-101 as we explore strategic options for the candidate and its related intellectual property.

Our approach and strategy

We have built a strong scientific foundation in immunology and inflammation, or I&I, targeting growth factors and modulating related molecular pathways through novel small molecules and monoclonal antibodies to resolve fibrosis, regenerate tissue and restore organ functionality. Our approach to drug development is focused on the identification of underlying biological processes that drive disease pathology. We leverage our core end-to-end research and development capabilities to develop therapies focused on established and clinically validated targets to overcome the limitations of previous therapeutic approaches with the aim to fundamentally de-risk a program's clinical development. Combining our scientific insights into growth factor biology along with robust drug development expertise, we are working to build differentiated programs with disease modifying potential in fibrotic diseases. Our approach is target-led, therefore we are modality-agnostic and will select a small molecule or antibody approach to achieve an optimal profile and treat the underlying cause of disease.

We are focused on internal research and development capabilities as well as the identification of promising external innovation opportunities with our proven track record of executing business development transactions. Our lead programs, ontunisertib and AGMB-447, were acquired through our acquisition of Origo Biopharma, S.L.

In October 2021, we entered into an agreement to acquire all outstanding shares of Origo Biopharma, S.L., a Spanish clinical stage biotechnology company developing organ-restricted small molecule drug candidates targeting the TGF-β pathway for the treatment of fibrosis-related disorders. The acquisition closed on December 14, 2021. The purchase price consisted of a cash payment of €20 million, subject to certain customary purchase price adjustments, and potential additional milestone payments of up to €20 million, which Origo shareholders are eligible to receive upon the achievement of specified milestones. The first milestone payment of €3 million was paid in the second quarter of 2025 upon signature of an amendment to the initial share purchase agreement.

The remaining milestone events are the following:

- €7 million upon the first dosing of the first subject with the first Agomab Spain product in either a Phase 2 or proof-of-concept clinical trial that (A) has safety and efficacy as its primary and/or secondary endpoints and (B) meets the other contractually agreed criteria, on or before December 31, 2030;
- €5 million upon the first dosing of the first subject in the first qualifying Phase 3 clinical trial with the first Agomab Spain product on or before December 31, 2035; and
- €5 million upon obtaining regulatory approval for the first Agomab Spain product in the United States on or before December 31, 2040.

The Origo acquisition and seamless integration demonstrates the strength of our business development capabilities and our corporate agility. Our strategy of selecting validated targets, with an emphasis on the underlying biology in which we have expertise, provides us with a broader yet selective range of potential opportunities to assess. We aim to continue to leverage our strong team with differentiated experience in assessing and executing business development transactions to broaden our pipeline to drive long-term value creation.

We are focused on developing therapies for diseases in the areas of I&I, with an initial focus in fibrotic diseases in which there is significant unmet medical need and large commercial potential, utilizing well-understood biology and validated pathways and modalities. Despite the significant toll that fibrotic disease has on human health and the amount of research undertaken to understand and characterize the fibrotic process, there has been limited progress towards developing highly effective pharmacological treatments that can prevent and reverse fibrosis. Our approach is comprised of the following characteristics:

- ***Focusing on I&I with an initial nexus in fibrosis****:* We are focused on the discovery and development of disease modifying approaches to treat I&I disorders to transform the treatment paradigm for patients with these diseases. Our initial focus is on fibrotic diseases which can be attenuated by growth factor biology, given the significant potential of these targets in mediating fibrotic pathways and the high unmet need of patients suffering from fibrotic diseases.
- ***Targeting indications with large commercial potential and significant unmet medical need****:* We pursue indications with large commercial potential where there is a significant unmet need driven by the limitations of existing treatment options. We are currently focused on fibrotic indications, including FSCD and IPF, that represent large commercial opportunities. Current therapies that are approved or in development for these diseases are symptomatic treatments and do not modify the underlying disease. This can leave a significant proportion of the patient population with severe symptoms, poor quality-of-life and ongoing progression of the disease. For example, of the approximately 1.4 million CD patients treated globally, approximately 46% have FSCD, while existing marketed therapies treat inflammation and are ineffective in addressing the fibrosis.
- ***Well-understood biology and validated pathways****:* We aim to directly address the underlying molecular pathways and drivers of a given disease. Our approach involves targeting established and validated pathways to improve the likelihood of clinical impact. Our lead programs ontunisertib (AGMB-129) and AGMB-447, for example, target TGFβ, a key regulator of fibrosis and the primary biochemical factor that drives fibrosis, thereby representing a well-validated and potentially disease-modifying approach for addressing FSCD and IPF. We believe that this approach has the potential to allow us to mediate underlying fibrosis of the diseases by targeting molecular pathways which were previously considered challenging to target, and deliver the drug in a manner that maximizes potential efficacy while reducing the risk of safety concerns.
- ***Utilizing validated modalities****:* We utilize both small molecules and antibodies that are validated modalities in drug discovery and development and plan to utilize the modality that maximizes the potential for a therapy to be safe and effective. Our lead programs, ontunisertib (AGMB-129) and AGMB-447, are small molecules leveraging our in-house medicinal chemistry expertise that are designed to maximize exposure of the drug to key tissue areas while being rapidly inactivated systemically to avoid systemic toxicity effects.
- ***Leveraging early evidence of proof-of-mechanism to inform clinical development decisions***: We perform thorough preclinical analyses, collection of target engagement data based on biomarkers at the key sites of tissue exposure, and detailed analyses of drug metabolism and circulating metabolites following administration that can provide early proof-of-mechanism and inform clinical development decisions.
- ***Utilizing a collaborative approach to facilitate clinical development***: Due to the novel disease modifying nature of our therapies, we are working closely with regulatory agencies, including the FDA and EMA, and key patient advocacy groups and consortia to inform the selection of biomarkers and clinical endpoints for assessing the therapeutic impact of a drug candidate. The Fast Track Designation granted by FDA for ontunisertib in FSCD allows us to have more frequent interactions with the FDA, and to actively work with the FDA to receive ongoing guidance about the evaluation of clinical and radiological responses. We are also working with the *Stenosis Therapy and Anti-Fibrotic Research Consortium*, or STAR Consortium, which was founded by leading gastroenterologists, to develop and validate measures of clinical responses, including through patient reported outcomes and radiological responses. We have incorporated these in our STENOVA Phase 2a trial design for ontunisertib in FSCD patients.
- ***Maximizing the commercial potential of our product candidates***: We retain exclusive, worldwide development and commercialization rights to all of our product candidates and discovery programs. We aim to develop and commercialize our product candidates by building a fully-integrated company focused on fibrotic diseases. We may seek strategic partnerships where we believe that external resources and expertise could accelerate the clinical development or maximize the market potential of our product candidates, or candidates, or where such collaborations could expand our internal capabilities.

To achieve our mission and through the implementation of our approach, we are building a differentiated and robust pipeline of novel therapies for immunology and inflammatory diseases, with an initial focus on chronic fibrotic indications. Our current development strategy includes:

- ***Advance ontunisertib as a potentially disease-modifying therapy for the treatment of FSCD.*** We believe that by selectively and potently inhibiting ALK5 and by avoiding systemic toxicity through localized activity in the gastrointestinal tract and rapid metabolization in the liver, ontunisertib has the potential to transform the treatment paradigm for FSCD and unlock the significant unmet need of the currently underserved FSCD patient population. We have reported topline data on the safety, PK, PD and exploratory clinical endpoints of ontunisertib in 103 patients in November 2025.

- ***Advance AGMB-447 as a potentially disease-modifying therapy for the treatment of IPF***. We believe that through targeted delivery of AGMB-447 in the lung and inactivation upon absorption into the bloodstream, we can achieve potent antifibrotic effects in IPF while avoiding toxicities associated with systemic TGFβ inhibition. We expect to report data in IPF patients in the second half of 2026.

Fibrosis background

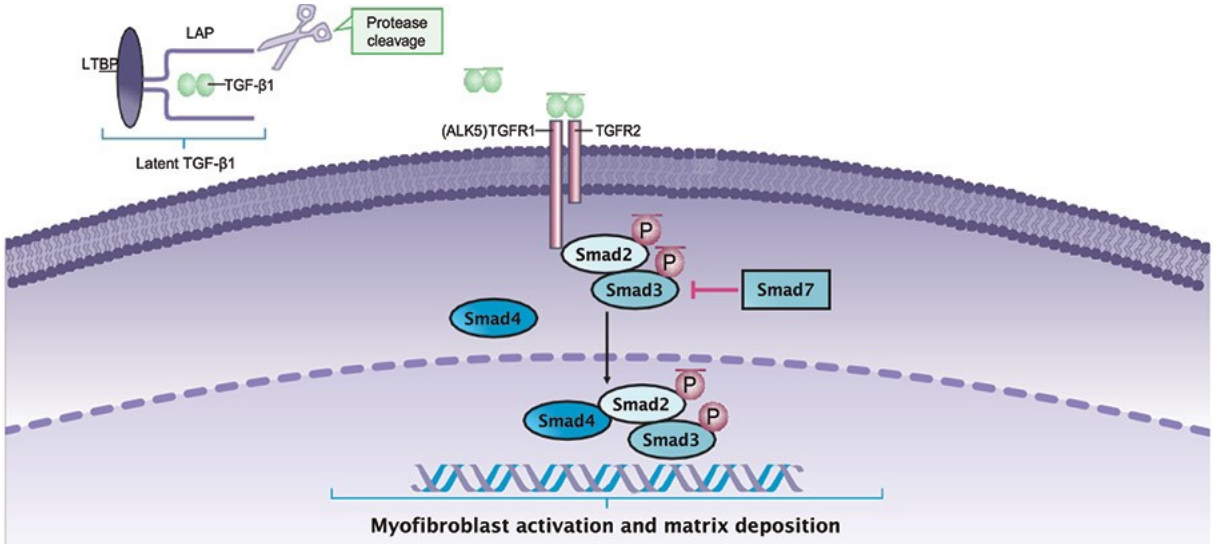
Fibrosis represents an aberrant response of a tissue to injury leading to progressive tissue scarring that may be triggered by trauma, inflammation, infection, cell injury or cancer, amongst others. As a result, fibrosis can lead to organ dysfunction and failure. The body's normal response to injury involves the activation of cells that produce collagen and other components of the ECM that are part of the healing process for the tissue. This process helps to do several things at once, including to fill in tissue voids created by the injury or damage, to segregate the damage and to facilitate healing and strengthening of the recovering tissue. Under normal physiological circumstances, scarring is self-limited and the resulting scar resolves itself, leaving behind a tissue architecture similar to what was present before the injury. However, in certain chronic disease states, this process of healing becomes both prolonged and excessive, resulting in fibrotic remodeling which interferes with organ function. Fibrosis can occur in many organ systems throughout the body including the lungs, liver, kidneys, gastrointestinal tract, skin and muscles. While the exact pathologies for diseases in these organs differ, fibrosis involves many of the same cell types and signaling pathways across different organs and tissue.

TGFβ is a master regulator of fibrosis

TGFβ is referred to as a master regulator of fibrosis and the primary biochemical factor that drives fibrosis. TGFβ is secreted by nearly all cells and organs in humans and is stored in large amounts outside of cells in an inactive form located in the ECM. In healthy tissue, TGFβ's physiological role is to initiate healing after injury, so when there is damage to the tissue, TGFβ is transiently activated in response. This activation initiates a powerful response, a cascade that results in the expression of genes encoding key components of the ECM such as collagens and fibronectin as well as genes that help stabilize the ECM and prevent its degradation. In a process referred to as epithelial-mesenchymal transformation, or EMT, TGFβ is able to transform epithelial cells, fibroblasts and endothelial cells into mesenchymal cells, such as myofibroblasts, which further promote fibrosis. In fibrotic diseases, however, TGFβ signaling remains continuously activated in response to prolonged insults such as inflammation, leading the surrounding tissue to deposit excess ECM, which eventually leads to tissue fibrosis.

The central role of TGFβ in fibrosis is well-established and has been evaluated extensively in both *in vitro* and *in vivo* studies, making it an attractive target for pharmacological intervention. In rodent models, continuous activation of TGFβ has been shown to be sufficient to induce fibrosis in the absence of any other stimuli, while its inhibition has been shown to prevent or attenuate fibrosis. It has been observed that TGFβ signaling can be blocked by inhibiting the Type I TGFβ receptor, a receptor referred to as ALK5. This receptor is a protein kinase and when bound by TGFβ, becomes activated, enabling it to add phosphate groups, known as phosphorylation, to downstream targets. Once triggered by TGFβ, ALK5 phosphorylates a protein family of transcription factors, or SMADs. The phosphorylation of SMADs is a key biochemical signal that leads to the relocation of SMADs into the nucleus, resulting in the activation of a series of genes that promote fibrotic processes such as collagen formation.

Overview of TGFβ and SMAD signaling in tissue fibrosis



TGFβ: the master regulator of fibrosis, Xiao-ming Meng, David J. Nikolic-Paterson and Hui Yao Lan, Nature Reviews, Nephrology, Volume 12, June 2016.

SMADs and TGFβ-responsive genes represent promising indicators to assess the modulation of the TGFβ pathway. Therefore, by measuring the transcription of these and related biomarkers, one can assess the level of target engagement and ultimately the pharmacological activity of ALK5 inhibitors in fibrotic diseases. These biomarkers can be analyzed in biopsies of organ tissue affected by fibrosis.

Beyond its role in the underlying biochemical pathways driving fibrosis, TGFβ plays an important role in immune homeostasis, with effects which have been shown to be context-dependent. In an environment of existing inflammation, and in conjunction with inflammatory cytokines, such as IL-6, high levels of TGFβ have been described to enhance the inflammatory response through increased cytokine signaling, such as IL-23 and activation of pro-inflammatory T cells subtypes, such as Th17 cells.

Challenges to targeting TGFβ signaling

The TGFβ signaling pathway has been under investigation as a key therapeutic target in fibrosis and oncology for over 30 years. There is strong preclinical evidence and encouraging preliminary clinical evidence that TGFβ inhibition could be effective in multiple fibrotic indications. However, use of this pathway for therapeutic interventions has been limited due to safety concerns as systemic inhibition of TGFβ causes toxicity in the heart and large vessels. In particular, development of previous systemic ALK5 inhibitors has been hampered by observations of cardiac toxicity in preclinical toxicology studies, which were characterized by the appearance of severe damage to the cardiac valves. These effects were apparent early on in toxicology programs for different classes of ALK5 inhibitors (as early as three days after dosing in rat and after one month in dog). These findings were considered target-related and due to the essential role of TGFβ in ECM remodeling processes that occur in the valves of the heart. Thus, cardiac toxicity is a major concern that has limited the potential of systemic ALK5 inhibitors to treat fibrosis, which requires chronic treatment. These observations and the lack of a safe and effective therapeutic window led to the discontinuation of several of these programs before they reached the clinic, and only two ALK5 inhibitors, galunisertib and vactosertib, have been evaluated in clinical trials in oncology patients using intermittent dosing regimens to avoid cardiac toxicity. Limiting systemic toxicity is a critical factor for any therapy being developed to inhibit TGFβ signaling.

Despite these challenges, TGFβ inhibition represents a promising therapeutic approach for the potential treatment of different fibrotic indications, and we believe that an optimal approach to modulating the TGFβ pathway is by inhibiting ALK5 locally in the tissue of interest, thereby avoiding systemic exposure. With this strategy, we aim to circumvent the safety concerns associated with ALK5 inhibitors, such as cardiac toxicity, while leveraging the key role of TGFβ in fibrosis and develop therapies for the chronic treatment of fibrotic diseases.

Ontunisertib (AGMB-129) for the potential treatment of Fibrostenosing Crohn's disease

Ontunisertib (AGMB-129), our lead product candidate, is a selective and potent oral, gastrointestinal-restricted small molecule inhibitor of ALK5 in development for the treatment of FSCD. Ontunisertib is designed to avoid toxicities that arise from systemic inhibition of ALK5 signaling by limiting its exposure to the gastrointestinal tract. In a Phase 1 trial, we evaluated the safety and pharmacokinetics of ontunisertib after oral administration of both single and multiple ascending doses to healthy human study participants. In the Phase 1 study, ontunisertib was observed to be generally well tolerated across all study stages and tested doses. We observed high levels of ontunisertib in the ileum, with low systemic exposure observed in the bloodstream, demonstrating the GI-restricted profile of ontunisertib. Ontunisertib received Fast Track Designation for the treatment of FSCD from the FDA in 2023. In November 2025, we announced topline results of the global randomized, double-blind, placebo-controlled Phase 2a trial of ontunisertib, or the STENOVA trial, with ontunisertib in 103 FSCD symptomatic patients with at least one ileal stricture. Part A of the STENOVA study achieved its primary endpoint of assessing the safety and tolerability of ontunisertib 100mg QD and 200mg BID in FSCD patients. The severity and incidence of adverse events were balanced across all treatment arms, including the placebo. Pharmacokinetic results confirmed the GI-restricted profile of ontunisertib with high local and low systemic exposure of ontunisertib in FSCD patients. We also observed positive signals on several exploratory clinical endpoints. The 48-week open-label treatment extension of the STENOVA trial with ontunisertib is currently ongoing and we expect to report the results of such open-label treatment extension in the second half of 2026. Based on the results observed in the STENOVA study to date and our positive interactions with the FDA, we are preparing to conduct a Phase 2b trial of ontunisertib in patients with symptomatic FSCD.

Fibrostenosing Crohn's disease background

FSCD involves a narrowing of the intestinal lumen due to fibrosis and is a severe complication of CD that is associated with significant morbidity. CD is a type of IBD that involves any part of the gastrointestinal tract from mouth to anus but most commonly affects the end of the small intestine, referred to as the ileum, and the colon.

Inflammatory injury to the intestinal mucosa causes erosions and ulcers that in turn cause symptoms which typically include diarrhea, fever, fatigue, abdominal pain and cramping, bloody stool, mouth sores, reduced appetite and weight loss. At diagnosis, most CD patients present with an inflammatory event; however 10% of patients already display a fibrotic phenotype. Over time, build-up of scar tissue in the intestine will continue and as a result, 46% of CD patients present with clinically apparent stricturing disease, or FSCD. Strictures mainly develop in the terminal ileum in the vicinity of the ileocecal valve which connects the ileum and the colon.

There are approximately 1.4 million patients under treatment for CD in the seven major markets of the United States, France, Germany, Italy, Spain, the United Kingdom and Japan, and approximately 620,000 of these patients have FSCD. In CD, the sustained immunological activation and inflammatory injury drive both excessive and prolonged activation of TGFβ-driven fibrosis and excessive production of ECM components. At discrete locations along the gastrointestinal, or GI, tract, most often in the ileum, excessive ECM can result in a significant intestinal stricture characterized by an increased bowel wall thickness, reduced luminal diameter and dilation of the upstream section of the intestine.

Strictures can impede the passage of intestinal contents and cause burdensome obstructive symptoms including severe pain, cramping, and vomiting after meals. This often requires FSCD patients to follow profound dietary restrictions, limiting the amount and/or type of food they can eat, which for some patients requires liquid diets or skipping meals altogether, which is of particular concern since approximately 70% of CD patients already have some degree of malnutrition. Strictures also drive the development of fistulae, which are alternate intestinal paths that form as an attempt to bypass a stricture. Fistulae can connect the intestine to the skin or other hollow organs, causing complications which often require surgery and have a detrimental impact on patients' quality of life. While our planned clinical trials will initially focus on symptom reduction and radiological improvement of strictures, we believe it is possible that addressing strictures may have beneficial effects on fistula formation. FSCD patients have two to four times more inpatient visits, five to eight times more surgical visits and two to three times more endoscopic procedures than CD patients without fibrostenosis. The additional costs associated with treating a patient with FSCD are estimated to be more than $80,000 per year.

FSCD treatment

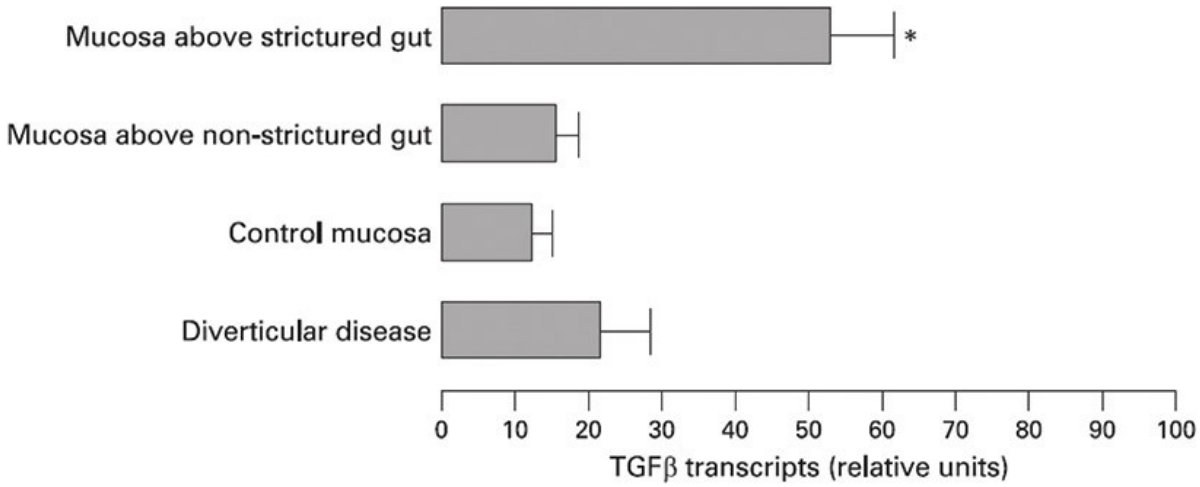
The current treatment paradigm for luminal, or inflammatory, CD is focused on anti-inflammatory agents, which include steroids and small molecule and biological anti-inflammatory therapies such as anti-TNFα and anti-IL-12/23 antibodies, or integrin α4β7 and Janus kinase, or JAK, inhibitors. Inflammation is the initial trigger for intestinal fibrotic remodeling and also directly contributes to intestinal narrowing through infiltrated inflammatory cells, increased vascularity, and edema. As a result, intensification of anti-inflammatory therapy or a steroid pulse is sometimes attempted to control stricture-related obstructive symptoms. However, these strategies have not shown efficacy against strictures in placebo-controlled clinical trials. Furthermore, the cumulative risk of developing stricturing or fistulae remains despite the widespread use of anti-inflammatory therapies. While inflammation plays an important role as an initial trigger of fibrogenesis, intestinal fibrosis becomes independent of inflammation as it progresses. As a result, there are currently no approved therapies specifically indicated for the treatment of FSCD, or for targeting the underlying intestinal fibrosis. Therefore, when symptoms can no longer be tolerated, mechanical interventions including endoscopic balloon dilation, strictureplasty, a surgical procedure that widens a narrowed section of the intestine, to relieve bowel obstruction, or intestinal resection are frequently the only option. Having to potentially undergo bowel resection surgery, especially if associated with a permanent stoma, poses significant risk to CD patients. Furthermore, bowel resection surgery, especially when it involves colectomy, can result in short bowel syndrome with serious complications including intestinal failure requiring parenteral nutrition.

Balloon dilation and surgical procedures only relieve local strictures and, in the case of balloon dilation, the benefits are only temporary. Following such procedures, most patients require re-dilation or surgery within two years. The need for surgical intervention has been reported to be close to 50% if the symptom-free interval between treatments is less than eight months. For endoscopic balloon dilation, re-dilation is needed in 74% and surgery is needed in 43% of patients after 24 months. For bowel resection surgery, the surgical recurrence rate is 24% after 5 years and 35% after 10 years. Finally, for strictureplasty, the recurrence rate is 28-36% after 1-5 years. Complications from surgery include infections, bleeding, bowel obstruction and anastomotic leaks or leaks that occur at the location where the cut ends of the bowel are surgically joined.

TGFβ is a potential target for FSCD

TGFβ signaling is believed to be a primary driver of fibrosis in FSCD, both due to its role as a master regulator of fibrosis and based on direct evidence of TGFβ overexpression in CD strictures. As shown in the figure below, analyses of TGFβ expression from sections of mucosa taken from FSCD patients found that there was a significant upregulation of TGFβ in tissue samples taken immediately above stricture sites compared to comparable samples from sites lacking strictures.

TGFβ expression is significantly elevated at sites of intestinal strictures in CD patients



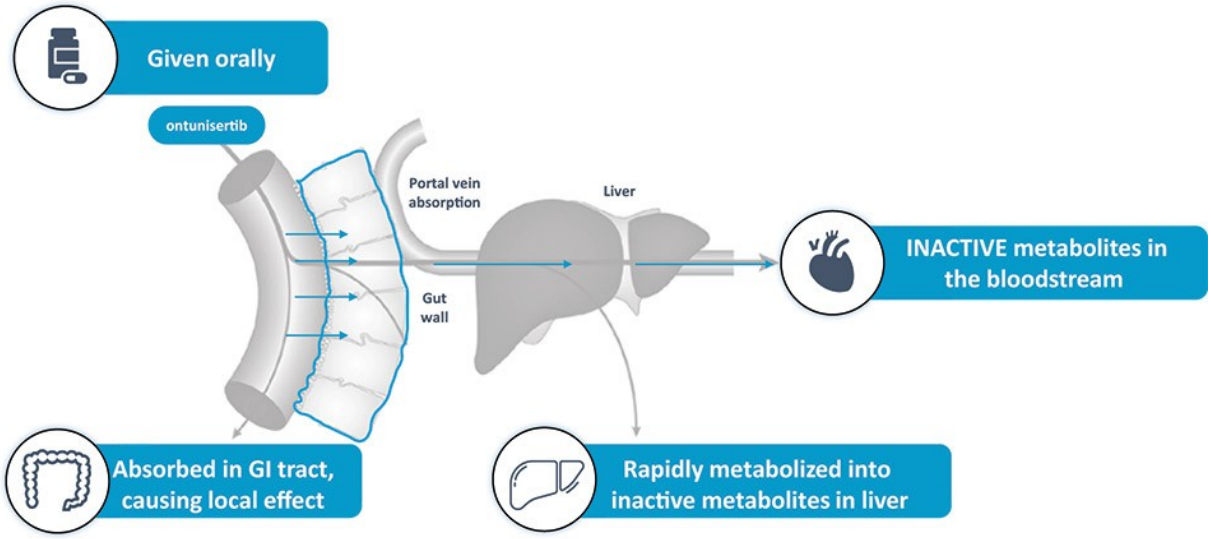
The role of TGFβ in gastrointestinal fibrosis has also been validated in several different kinds of animal models. Overexpression of TGFβ1 in the colon of mice led to spontaneous colonic fibrosis and severe gastrointestinal obstruction. Conversely, blocking the TGFβ pathway in mice conferred resistance to gastrointestinal fibrosis in fibrosis models. This was due both to a reduction in ECM production and accumulation as well as to a significant reduction in intestinal muscle layer thickness. Altogether, the key role of TGFβ on gastrointestinal fibrosis has been widely recognized in the scientific literature.

Our potential solution, ontunisertib

Ontunisertib (AGMB-129) is a selective and potent oral, gastrointestinal-restricted small molecule inhibitor of ALK5, in development for the treatment of FSCD. Due to the known safety liabilities associated with systemic ALK5 inhibition, we engineered ontunisertib to be rapidly metabolized and inactivated by the liver following absorption from the gastrointestinal tract, thereby avoiding systemic exposure of ontunisertib outside of the tissue of interest.

Following oral administration, ontunisertib passes along the gastrointestinal tract to the ileum in the small intestine where it is absorbed through the intestinal wall, thereby exposing the target tissue to the active molecule. Material absorbed from the gastrointestinal tract, including ontunisertib, is then transported directly to the liver via the portal vein before entering the systemic circulatory system, enabling ontunisertib to be metabolized in the liver into inactive metabolites before entering the systemic circulatory system. A similar strategy of local gastrointestinal targeting with limited systemic exposure has been previously employed for the corticosteroid, budesonide, which is marketed as Entocort® for the treatment of mild to moderate CD.

Ontunisertib (AGMB-129) was designed to expose the gastrointestinal tract to high levels of active drug while minimizing systemic exposure



Preclinical development of ontunisertib

Summary of preclinical findings for ontunisertib (AGMB-129)

Preclinical findings	Observations
Preclinical pharmacokinetics Ontunisertib (AGMB-129) resulted in high exposure to the gastrointestinal tract and ileum, with minimal systemic exposure	• In a preclinical rat model, area under the curve was 10,000-fold higher in the ileum compared to plasma • Ontunisertib (AGMB-129) shown to have very short half-life *in vitro* in human hepatocytes and in hepatocytes from several animal species
Activity in in vivo DSS mouse model Ontunisertib (AGMB-129) showed the ability to prevent and treat fibrosis in dextran sodium sulfate, or DSS, mouse model with evidence of potential impact on inflammation	• DSS model is one of the most widely used preclinical models of IBD* • Preventive setting: ontunisertib (AGMB-129) prevented an increase in both collagen staining and histological score compared to control • Therapeutic setting: ontunisertib (AGMB-129) led to decreases in both collagen staining and histological score compared to control • Significant change in histological score observed at highest dose largely due to a reduction in immune infiltration

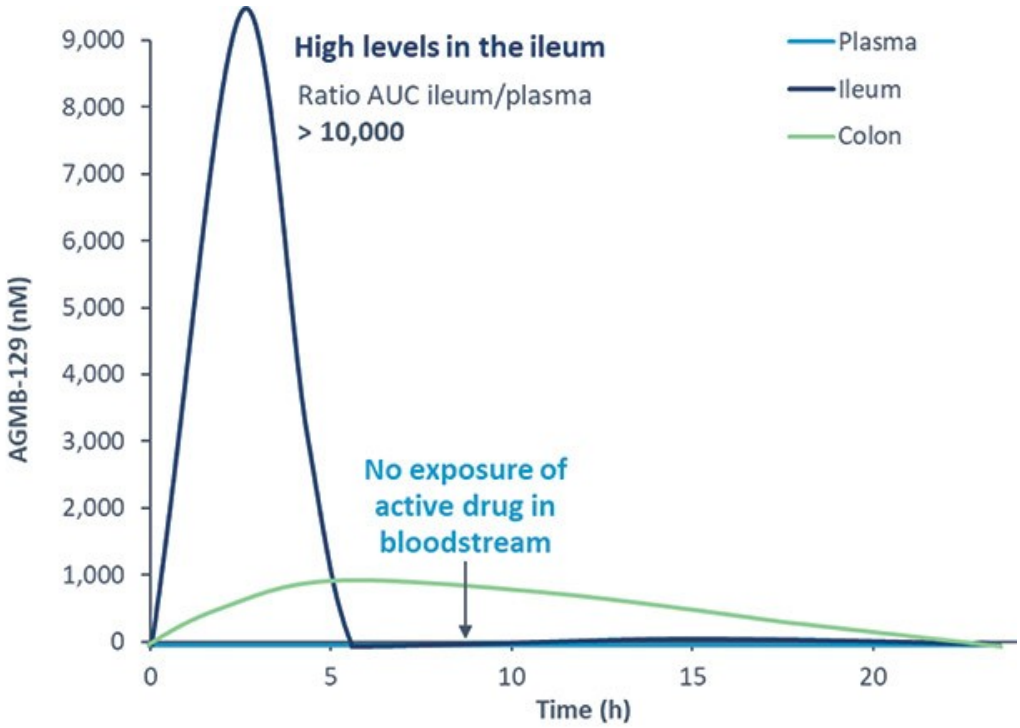
Preclinical findings	Observations
Activity in ex vivo IBD biopsies Ontunisertib (AGMB-129) led to downregulation of expression of both fibrotic and inflammatory genes in a preclinical study	• Patient-derived gastrointestinal biopsies from IBD patients were treated *ex vivo* • Ontunisertib (AGMB-129) led to significant reductions in fibrotic genes, as well as in certain inflammatory genes • RNA sequencing of IBD biopsies showed a high proportion of genes related to fibrosis were downregulated by ontunisertib (AGMB-129)
Activity in primary cell cultures ***Ontunisertib (AGMB-129) showed in vitro inhibition of TGFβ pathway activation and expression of collagen***	• Primary intestinal fibroblast cells isolated from ileal resections from stricture surgery of CD patients were analyzed in vitro • Ontunisertib (AGMB-129) demonstrated significant inhibition of both (a) TGFβ-induced phosphorylation of SMAD2-3, a downstream biomarker of TGFβ pathway activation; and (b) expression of collagen A1, or ColA1, a key fibrotic protein
Toxicology studies ***No cardiac valve lesions observed with ontunisertib (AGMB-129)***	• No cardiac valve lesions have been observed in good laboratory practice, or GLP, toxicology studies of AGMB-129 to date, including chronic toxicology studies in rodents and non-rodents

* See below for a discussion on the value and limitations of this model in relation to FSCD.

Oral dosing in rats demonstrated high exposure of ontunisertib (AGMB-129) in the gastrointestinal tract and ileum, with minimal systemic exposure

Ontunisertib (AGMB-129) is designed to undergo rapid liver metabolism and has been shown to have very short half-life *in vitro* in human hepatocytes as well as in hepatocytes from several animal species. The ileum is the target tissue for ontunisertib since it is the section of the gastrointestinal tract in FSCD patients where most of the strictures develop. In preclinical studies with ontunisertib, we demonstrated that oral dosing resulted in high exposure in the ileum and progressively decreased along the colon. We found that the total exposure to ontunisertib, represented as the area under the curve, was 10,000-fold higher in the ileum compared to plasma.

Oral dosing of ontunisertib (AGMB-129) in rats resulted in high exposure to the gastrointestinal tract with minimal plasma exposure



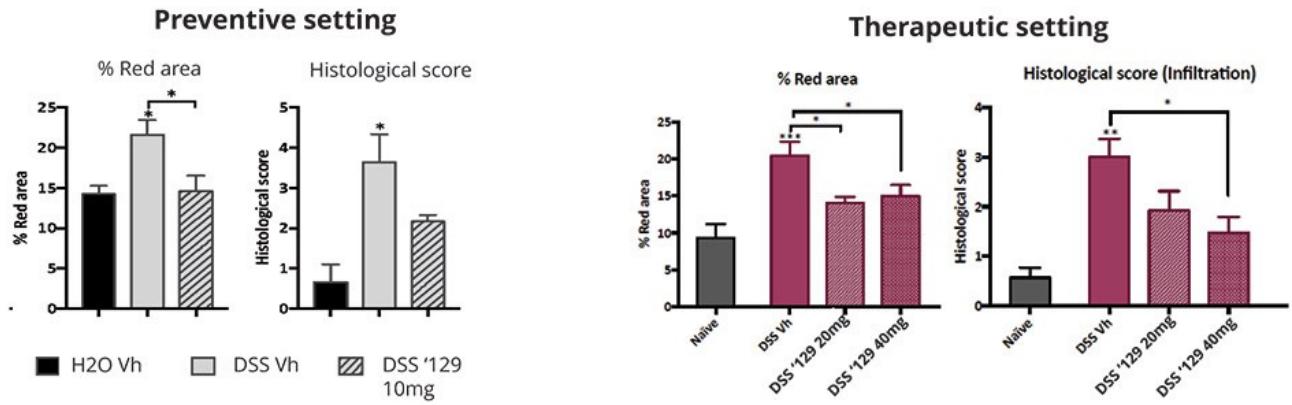
AUC, area under the curve

Ontunisertib was able to prevent and treat fibrosis in the DSS mouse model

We evaluated ontunisertib in a DSS mouse model in both the preventive and therapeutic setting. The DSS model is one of the most widely used preclinical models of IBD. In this model, DSS induces intestinal inflammation resulting in intestinal damage that reproduces key features of IBD including both (a) upregulation of markers of inflammation and fibrosis and (b) fibrogenesis in all layers of the intestinal wall.

In the preventive setting, treatment of mice with 10 mg/kg of ontunisertib from day 1 through day 34 prevented both the increase in staining for collagen and the increase in histological score compared to control. In the therapeutic setting, treatment with 20 mg/kg or 40 mg/kg from day 18 through day 51 of the study led to decreases in both collagen staining and histological scores compared to control. Although ontunisertib is not expected to directly target inflammatory pathways, the significant decrease in the histological score observed at a dose level of 40 mg/kg ontunisertib was believed to be largely due to a reduction in immune infiltration, suggesting that ontunisertib may have the potential to address multiple key drivers of FSCD pathology, including both fibrosis and inflammation.

Ontunisertib (AGMB-129) had *in vivo* activity in the DSS model in both the preventive and therapeutic settings



The DSS model has certain limitations in its applicability to FSCD because it induces inflammation in the colon while FSCD is characterized by fibrotic changes in the ileum. Furthermore, ontunisertib levels are highest in the ileum and decreased along the colon. Particular emphasis has therefore been placed on using patient-derived models for preclinical studies, including fresh biopsies from IBD patients and fibroblasts isolated from stenotic resections.

Ontunisertib has demonstrated ex vivo antifibrotic activity in IBD biopsies

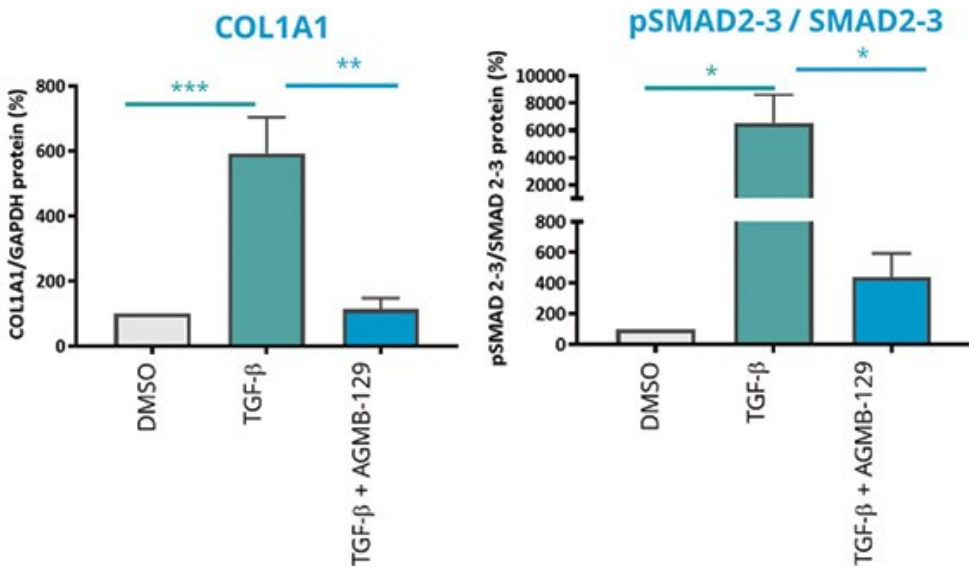
To evaluate the antifibrotic potential of ontunisertib in patient-derived cells, we used gastrointestinal biopsies from IBD patients and treated them *ex vivo* to explore the effect of ontunisertib on pro-fibrotic and pro-inflammatory genes. Treatment with ontunisertib led to significant reductions in multiple pro-fibrotic genes such as Serpine-1 which codes for PAI-1 protein, an inhibitor of ECM degradation that contributes to excessive accumulation of collagen. Notably, the reduction of Serpine-1 was shown to correlate with reduction of skin fibrosis in humans. Treatment with ontunisertib also led to reduction in certain inflammatory genes. The observation that ontunisertib led to downregulation of both pro-fibrotic and pro-inflammatory genes in this study is consistent with the *in vivo* results observed in the DSS model.

We also analyzed the biopsies from IBD patients treated *ex vivo* with ontunisertib by RNA sequencing to evaluate the impact of ontunisertib on the transcription of the full genome. We found that, among the genes downregulated by ontunisertib in IBD samples, there was a high proportion of genes related to fibrosis, including genes associated with TGFβ signaling, ECM biology, epithelial biology and growth factor biology. In addition, RNAseq analyses found evidence that ontunisertib may also have the potential to dampen the intestinal inflammation in IBD.

Ontunisertib demonstrated in vitro antifibrotic activity in primary cell cultures

We assessed the effects of ontunisertib in primary intestinal fibroblast cells isolated from ileal resections obtained from stricture surgery of CD patients. Ontunisertib demonstrated significant *in vitro* inhibition of both (a) expression of collagen A1, or COL1A1, a key fibrotic protein; and (b) TGFβ-induced phosphorylation of SMAD2-3, a downstream biomarker of TGFβ pathway activation.

Ontunisertib (AGMB-129) inhibited TGFβ signaling in primary fibroblasts from CD patients as determined by significant inhibition of COL1A1 production and pSMAD phosphorylation



Ontunisertib (AGMB-129) showed a potentially differentiated preclinical safety profile

We completed the general toxicology program for ontunisertib with chronic toxicology studies in rodents and non-rodents. Previous ALK5 inhibitors have historically caused severe heart valve lesions in rats and dogs in early toxicology studies of short duration. In contrast, no cardiac valvular lesions were detected in any of the ontunisertib toxicology studies carried out to date in any of the species tested, and we have been able to define a therapeutic window with large safety margins for clinical evaluation. No head-to-head studies have been conducted against previous systemic ALK5 inhibitors.

Clinical development of ontunisertib

Completed Phase 1 trials

We completed a Phase 1 SAD/MAD, food effect, drug-drug interaction clinical trial and oral bioavailability trial as well as an additional MAD trial to test higher doses of ontunisertib in healthy study participants. A total of 125 healthy male and female participants received oral ontunisertib as part of the Phase 1 program, with no safety signals observed and no dose limiting toxicities reported. The Phase 1 data supported prior key preclinical findings for ontunisertib, suggesting ontunisertib has the potential to be a differentiated drug for FSCD. Key attributes of ontunisertib observed in the Phase 1 trial, as summarized in the table below, include high exposure of ontunisertib in the ileal mucosa, very low systemic exposure of the active parent compound, main ontunisertib metabolites observed to be functionally inactive, low potential for drug-drug interaction, and food effect impact.

Summary of Phase 1 clinical findings for ontunisertib (AGMB-129)

Clinical findings	Observations
Orally administered single-and multiple-dose ontunisertib was observed to be generally well tolerated, with no dose limiting toxicities	● A total of 125 healthy participants received oral ontunisertib as part of the Phase 1 trial ● No safety signals were observed and there were no dose limiting toxicities in this Phase 1 trial with ontunisertib
Ontunisertib observed to have very low systemic exposure consistent with rapid first-pass liver metabolism	● Single ascending-dose (SAD) and multiple ascending-dose (MAD) trials confirmed that ontunisertib has a short half-life in plasma and very low systemic exposure to the active parent compound ● Plasma levels of the main human metabolite of ontunisertib were found to be thousands of times higher than levels of ontunisertib, indicating efficient absorption and metabolization of ontunisertib ● Repeat exposure to ontunisertib in the MAD trial showed that systemic levels of ontunisertib remained low with no relevant accumulation, while the inactive metabolite MET-158, which is produced in the liver, was identified as the most predominant human metabolite
Main human ontunisertib metabolites are functionally inactive	● Main human metabolites of ontunisertib identified by metabolite profiling of clinical samples were found to be inactive against ALK5 ● The ALK5 IC50 was 75nM with ontunisertib. By contrast, the IC50 of MET-158, the major metabolite observed in the Phase 1 trial, was too high to be determined in the assays
High exposure of ontunisertib demonstrated in the ileal mucosa	● Local drug levels were measured in the ileal mucosa of nine healthy participants receiving oral ontunisertib at 200mg BID for ten days, and three healthy subjects receiving matching placebo ● The concentration of ontunisertib in these tissue samples was at micromolar level for all participants, well above the 75nM IC50 for ALK5 inhibition determined in cellular assays and consistent with concentrations achieved in the ileum at pharmacological doses in mice

Clinical findings	Observations
Food effect analysis suggests ontunisertib can be administered with food	• Ontunisertib was administered as a single 400mg dose in fasted or fed conditions to evaluate the effect of food intake on the pharmacokinetics of ontunisertib • In the presence of food, ontunisertib absorption is higher, less variable and delayed compared to fasted conditions • We believe ontunisertib can be taken with meals, which may result in more thorough and consistent absorption and greater convenience for the patient
Lack of drug-drug interaction suggests potential for ontunisertib as an add-on treatment	• A total of 14 healthy participants were included in a dedicated drug-drug interaction trial to evaluate the potential of ontunisertib to cause drug-drug interactions through CYP3A4, a metabolizing enzyme involved in the degradation of many drugs • The trial indicated that ontunisertib is a weak inhibitor of CYP3A4 in humans and therefore does not require specific precautions when used with drugs known to be metabolized by CYP3A4
An oral bioavailability study did not reveal a benefit of a new tablet formulation compared to the capsule formulation used to date	• A total of 25 healthy participants received single-dose ontunisertib 200mg in the reference capsule formulation in the fed state, as well as a new tablet formulation in the fed and fasted states, in a sequential design • No safety signals were observed for single-dose ontunisertib administered in either capsule or tablet formulation, consistent with prior single dose trials • The relative oral bioavailability of AGMB-129 was higher in terms of Cmax (1.70-fold) and AUC0-t (1.25-fold) when AGMB-129 200mg was administered as a tablet formulation compared to a capsule formulation (both administered following a high-fat breakfast)

The Phase 1 trial has not been powered for statistical significance.

Phase 1 trial

We completed a Phase 1 SAD/MAD food effect trial of ontunisertib in healthy participants. This trial was designed to assess the safety, tolerability and pharmacokinetics of single- and multiple-dose ontunisertib. As part of this trial, we also evaluated the effect of food intake on the pharmacokinetics of ontunisertib as well as the level of local exposure to ontunisertib in the intestinal mucosa of a subset of participants. Additionally, we conducted a drug-drug interaction and a bioavailability study. Finally, we also conducted an additional Phase 1 MAD study to test higher doses of ontunisertib in healthy participants.

In the SAD portion of the first-in-human trial, single doses of ontunisertib or placebo were administered orally to 32 healthy participants in a 3:1 ratio. Ontunisertib was administered across 4 dose cohorts of 200, 400, 800 and 1200mg. In the MAD portion of the trial, ontunisertib (AGMB-129) was administered orally to 18 healthy participants, once-daily over 5 consecutive days at daily doses of 100, 200 and 400mg. A further 6 healthy participants in the MAD portion of the trial received matching placebo. In the local PK cohort, 200mg twice-daily (BID) of ontunisertib was administered orally to 9 healthy subjects over 10 consecutive days, with 3 healthy participants receiving matching placebo. In the food effect stage of the trial, ontunisertib was administered to 11 healthy subjects, as a single 400mg dose with and without food, with a further two healthy participants receiving placebo. In the drug-drug interaction trial, 14 healthy subjects received 200mg BID of ontunisertib over 12 consecutive days. In the oral bioavailability trial, 25 healthy participants received single-dose ontunisertib formulated as capsule and tablet according to a sequential design. The effect of food on the pharmacokinetics of the tablet formulation was also evaluated. In the additional MAD trial conducted to explore higher doses of ontunisertib, ontunisertib was administered orally to 24 healthy participants, over 7 consecutive days at doses of 200mg twice daily, 200mg thrice daily and 400mg twice daily. A further 6 healthy participants in the additional MAD trial received matching placebo.

Summary of the 150 healthy participants enrolled in Phase 1 clinical trial with 125 healthy participants receiving ontunisertib (AGMB-129)

Study part	Number of subjects (active/placebo)	Doses tested
Single ascending dose	24/8	Single doses up to 1200mg
Multiple ascending dose	18/6	5 daily doses of 100, 200, or 400mg
Biopsy cohort (multiple doses)	9/3	10 daily doses of 200mg BID (400mg/day)
Food effect (single dose)	11/2	Single dose of 400mg
DDI Ph1 study (multiple doses)	14/0	12 daily doses of 200mg BID (400mg/day)
BA Ph1 study	25/0	Single dose of 200mg as tablet or capsule formulation
Additional multiple ascending dose	24/6	7 daily doses of 200mg BID (400mg/day), 200mg TID (600mg/day) or 400mg BID (800mg/day)

AE, adverse event; BA, bioavailability; BID, bis in die, twice a day; TID: ter in die, thrice a day

Ontunisertib observed to have a short half-life leading to very low systemic exposure and main human metabolites are functionally inactive

Low systemic exposure of ontunisertib observed in SAD/MAD pharmacokinetic analyses of drug levels in the plasma indicated that ontunisertib had a very short half-life in plasma leading to very low systemic exposure. Conversely, plasma levels of several metabolites of ontunisertib were found to be higher than ontunisertib, and, in particular, the main human metabolite of ontunisertib (MET-158) was found to be thousands of times higher than those of ontunisertib. As described further below, main ontunisertib metabolites were shown to be functionally inactive. At the higher doses, the level of metabolites compared to ontunisertib was lower, suggesting lower liver metabolism. However, even at these dose levels, systemic exposure to metabolites of ontunisertib greatly exceeded that of ontunisertib.

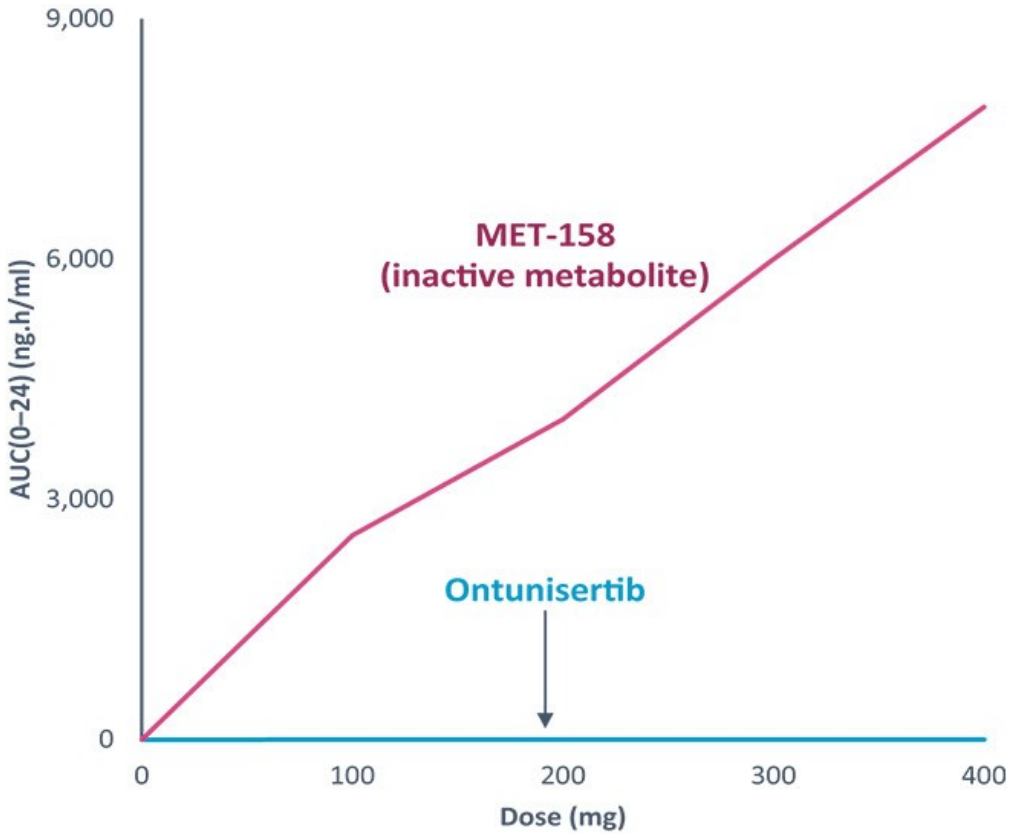
In the initial MAD portion of the Phase 1 trial, after QD dosing for 5 days, ontunisertib (AGMB-129) accumulation based on the AUC was limited (<2-fold). Ontunisertib AUC increased close to dose-proportional, and systemic exposure to ontunisertib (AGMB-129) was low across the dose range.

Metabolite ID profiling was carried out in plasma to identify the main metabolites of ontunisertib in humans. Subsequently, the proportion of the main circulating metabolites was estimated after repeated dosing of 100mg, 200mg and 400mg of ontunisertib once daily. MET-158 was found to be the main human metabolite of ontunisertib in plasma with abundance around 70%, whereas the other metabolites were around 10% or lower and ontunisertib equal or below 0.5%.

In addition, the main metabolites of ontunisertib were found to have minimal/no activity against ALK5. For ontunisertib, the IC50, or concentration at which 50% or half of the ALK5 kinase activity is inhibited, was shown to be 75 nM. By contrast, for MET-158, the IC50 could not be determined and the metabolite is thus considered inactive against ALK5. Further characterization of the main human metabolite MET-158 did not identify any relevant activity against a panel of kinases and G protein-coupled receptors related to cardiotoxicity and drug interactions. MET-158 was not found to inhibit the human Ether-à-go-go-Related Gene, cardiac ion channels or Cytochrome P450s or CYP3A4, and was not active in genotoxicity assays, supporting a potentially favorable safety profile.

The only metabolite shown to have any meaningful activity against ALK5 in cellular assays was MET-154, a metabolite that represented only 2% of the total drug-related exposure, which includes parent and all detected metabolites measured in the plasma at the 200mg dose level. Moreover, the potency of this metabolite against ALK5 was at least 10-fold weaker than that of ontunisertib.

Systemic levels of ontunisertib (AGMB-129) remained low in plasma whereas the inactive metabolite MET-158 was the major human metabolite



Metabolites of ontunisertib (AGMB-129) have minimal ability to inhibit ALK5

Inhibitory potency vs ALK5, IC50 (nM)

Compound	Enzyme	Cell	
AGMB-129	36	75	
MET-158	3% inh at 10µM	1% inh at 10µM	IC50 not determinable
MET-167	5% inh at 10µM	NA	
MET-162	6030	NA	
MET-156	12% inh at 10µM	3% inh at 10µM	
MET-154	666	302	

Summary of findings of ontunisertib (AGMB-129) in First-in-Human study in healthy participants

A total of 62 healthy male and female subjects received oral ontunisertib as part of the First-in-Human part of the Phase 1 trial. Overall, there were no observed safety signals and no dose-limiting toxicities with single- and multiple-dose oral ontunisertib. The summary table below presents the incidence and severity of adverse events for the placebo and ontunisertib groups in the single ascending dose, multiple ascending dose, food effect, and local PK study stages (Stages A, B, C, and D, respectively). The incidence and severity of adverse events were similar between subjects receiving ontunisertib and placebo. Importantly, the trial provided data supporting the 200mg BID dosing regimen as the highest dose of ontunisertib selected for the ongoing STENOVA Phase 2a trial.

The incidence and severity of adverse events were similar between subjects receiving ontunisertib (AGMB-129) and placebo in the First-in-Human Study

	Stage A			Stage B		
	AGMB-129 (N=24) n (%) E	Placebo (N=8) n (%) E	Overall (N=32) n (%) E	AGMB-129 (N=18) n (%) E	Placebo (N=6) n (%) E	Overall (N=24) n (%) E
Any TEAE	5 (20.8) 11	2 (25.0) 5	7 (21.9) 16	8 (44.4) 15	2 (33.3) 8	10 (41.7) 23
Mild	5 (20.8) 11	2 (25.0) 5	7 (21.9) 16	6 (33.3) 11	2 (33.3) 8	8 (33.3) 19
Moderate	0	0	0	2 (11.1) 4	0	2 (8.3) 4
Severe	0	0	0	0	0	0
Related TEAEs	4 (16.7) 4	2 (25.0) 5	6 (18.8) 9	8 (44.4) 14	2 (33.3) 7	10 (41.7) 21
Serious TEAEs	0	0	0	0	0	0
TEAEs leading to study discontinuation	0	0	0	0	0	0

	Stage C			Stage D		
	AGMB-129 (N=11) n (%) E	Placebo (N=2) n (%) E	Overall (N=13) n (%) E	AGMB-129 (N=9) n (%) E	Placebo (N=4) n (%) E	Overall (N=13) n (%) E
Any TEAE	9 (81.8) 20	1 (50.0) 2	10 (76.9) 22	2 (22.2) 3	1 (25.0) 6	3 (23.1) 9
Mild	6 (54.5) 17	0	6 (46.2) 18	1 (11.1) 2	0	1 (7.7) 2
Moderate	3 (27.3) 3	1 (50.0) 1	4 (30.8) 4	1 (11.1) 1	1 (25.0) 6	2 (15.4) 7
Severe	0	0	0	0	0	0
Related TEAEs	7 (63.6) 17	1 (50.0) 1	8 (61.5) 18	1 (11.1) 2	0	1 (7.7) 2
Serious TEAEs	0	0	0	0	0	0
TEAEs leading to study discontinuation	1 (9.1) 1	0	1 (7.7) 1	0	1 (25.0) 5	1 (7.7) 5

N=number of subjects; n=number of subjects with an AE; E=number of events; TEAE=treatment-emergent adverse event

If a subject experienced more than one TEAE, only the most related occurrence or the most intense occurrence was counted for the incidence rates.

(1) Stage A - Single ascending dose study in healthy young male subjects.

(2) Stage B - Multiple ascending dose study in healthy young male and female subjects.

(3) Stage C - Food-effect study to assess the interaction of ontunisertib (AGMB-129) with food in healthy young male and female subjects.
(4) Stage D - Repeated dose study in healthy young male and female subjects to evaluate local PK of ontunisertib (AGMB-129) in intestinal mucosa.

High exposure of ontunisertib demonstrated in the ileal mucosa

Local drug levels were measured in the ileal mucosa of nine healthy subjects receiving oral ontunisertib at 200mg BID for ten days, and of three healthy subjects receiving matching placebo. Mucosal biopsies were performed after two colonic preparations and approximately two hours after dosing. The concentration of ontunisertib in these tissue samples was at micromolar levels for all subjects, well above the 75nM IC50 for ALK5 inhibition determined in cellular assays and consistent with concentrations achieved in the ileum at pharmacological active doses in mice. Results we obtained from a physiologically based pharmacokinetic model refined with this data predicted that the Phase 2a dose 200mg BID would reach 80% target engagement in the ileum. We believe that these findings support the potential of ontunisertib to inhibit TGFβ signaling in the gastrointestinal tract.

Food effect analysis suggests ontunisertib can be administered with food

In the food effect part of the trial, we observed that food intake delayed the time point at which the maximal drug levels were measured (by approximately 2 hours) and increased total exposure over 24 hours (by approximately 2-fold). At the same time, food intake reduced the variability in exposure by 50%. We believe that these combined results indicated that ontunisertib can be taken with meals, which may result in more thorough and consistent absorption and greater convenience for the patient.

Lack of drug-drug interaction suggests potential for ontunisertib as an add-on treatment

14 healthy participants received ontunisertib in a dedicated drug-drug interaction trial to evaluate the potential of ontunisertib to cause drug-drug interactions through CYP3A4, a metabolizing enzyme involved in the degradation of many drugs. The trial indicated that ontunisertib is a weak inhibitor of CYP3A4 in humans and therefore is unlikely to require specific precautions when used concomitantly with drugs known to be metabolized by CYP3A4, which represent 50% of medications on the market. This result supports the potential for ontunisertib to be used as an add-on treatment on top of standard of care treatments for CD.

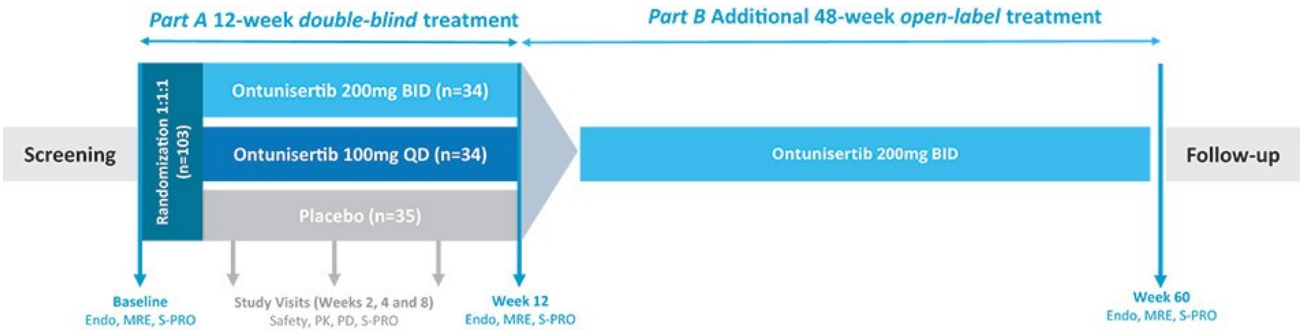
Additional MAD study confirmed safety and tolerability profile of ontunisertib for doses up to 400mg BID

To inform on dose selection for subsequent clinical trials, we conducted an additional Phase 1 MAD trial intended to evaluate the safety, tolerability, and PK of higher daily doses (>400mg per day) of ontunisertib in healthy participants. In this Phase 1 study, 24 additional healthy participants received ontunisertib over seven consecutive days at doses of 200mg twice daily, 200mg thrice daily and 400mg twice daily. The safety and tolerability profile of all dose levels evaluated in this trial was in line with previous studies. All TEAEs were mild to moderate in severity. Low systemic exposure to ontunisertib was observed for all dose levels. Based on these findings, we plan to include the 400mg BID dose level for long-term treatment evaluation in Phase 2b.

Phase 2a clinical trial of ontunisertib in FSCD

We conducted the global STENOVA Phase 2a trial of ontunisertib. The objective of STENOVA is to evaluate the safety, pharmacokinetics, and pharmacodynamics of ontunisertib in FSCD patients with non-critical symptomatic strictures. Study participants are in Part A of STENOVA for a duration of up to 19 weeks including a 5-week screening period, a 12-week double-blind, placebo-controlled treatment period, and 2-week safety follow up period. We reported positive data from Part A of STENOVA in November 2025. Participants who continue to Part B, the open-label extension part, can receive treatment for up to an additional 48 weeks, with a safety follow-up visit 2 weeks after the last dose of treatment.

The below figure gives a schematic representation of the STENOVA study design:



- 103 patients with symptomatic ileal strictures
- Ontunisertib or placebo on top of stable SoC, incl. biologics
- Sites in USA, Canada, Austria, Denmark, Germany, Italy, Poland & Spain

Endo, endoscopy, MRE, Magnetic resonance enterography: PK, pharmacokinetics; PD, pharmacodynamics; PoC, proof-of-concept; S-PRO, Stricturing Patient Reported Outcome; SoC, Standard of care

A total of 103 patients were recruited into the STENOVA study Part A across 52 sites in the United States, Canada and 6 European countries. Subjects are dosed orally at 100mg QD, 200mg BID or matching placebo for twelve weeks, on top of standard of care treatment for the underlying luminal disease. Standard of care treatment generally consists of anti-inflammatory therapies including steroids such as prednisone and budesonide for rapid symptomatic control during treatment initiation, or advanced therapies which include monoclonal antibodies targeting tumor necrosis factor alpha, interleukin-23, interleukin 12/23, or integrin α4β7, or small-molecule inhibitors targeting Janus Kinase (JAK) enzymes.

In addition to assessing safety and tolerability, pharmacokinetics, and target engagement, the study explores the effects on imaging and clinical read-outs of ontunisertib. There are currently no approved therapies, no indication-specific regulatory guidance, and no clinical development precedents to inform the selection of clinical and imaging efficacy endpoints in FSCD. Based on our interactions with FDA and EMA, and our discussions with key opinion leaders, or KOLs, we believe that it is important to explore a number of imaging assessments as well as clinical outcomes in our clinical development program to help form the basis of primary and secondary efficacy endpoints in our planned pivotal studies.

For imaging, magnetic resonance enterography, or MRE, is commonly used for the diagnosis of strictures. MRE provides information about the morphological severity of strictures, in particular stricture length, the presence and diameter of an associated pre-stenotic dilation, and bowel wall thickness. Additionally, we evaluate the SES-CD, or Simple Endoscopy Score for Crohn's Disease, as an imaging endpoint. The SES-CD provides information about luminal disease activity and evaluates inflammatory changes as well as narrowing. This endoscopic score is recommended by the FDA and other major regulators as a suitable primary efficacy endpoint for the approval of Crohn's Disease treatments, and we believe that it may also provide clinically meaningful information in the FSCD population.

We are also exploring Clinical Outcome Assessment, or COA, instruments evaluating the clinical benefit to patients, such as a Patient Reported Outcome, or PRO. To this end, we have been working alongside the STAR Consortium, an independent body founded by leading gastroenterologists. STAR has developed an initial version of a specific PRO instrument, named S-PRO, which is currently undergoing validation in a prospective observational trial in FSCD patients. The S-PRO instrument captures obstructive symptoms such as abdominal pain, cramping, bloating, and vomiting occurring after meals. Changes in diet, such as the type or amount of food, and food processing methods such as mashing or blending food are also evaluated.

Ontunisertib received Fast Track Designation for the treatment of FSCD from the FDA in 2023, which allows us to have more frequent interactions with the FDA, and to actively work with the agency to receive ongoing guidance about the clinical trial design, including evaluation of clinical and radiological responses. In an effort to achieve alignment with key regulatory bodies, we have also been involved in regulatory discussions with EMA.

We reported the full STENOVA Part A results in November 2025, and we expect to report the full results of Part B in the second half of 2026.

STENOVA Phase 2a results-Part A

In November 2025, we announced topline results of the STENOVA Phase 2a trial (Part A) with ontunisertib (AGMB-129) in 103 FSCD symptomatic patients with at least one ileal stricture. Of the 103 participants enrolled, 34 received ontunisertib 200mg BID, 34 received 100mg QD, and 35 received matching placebo, on top of stable standard of care, including biologics. The rate of study completion across all arms was high, with 85.3%, 94.1%, and 88.6% of participants completing the 12-week double-blind treatment period in the ontunisertib 200mg BID, 100mg QD, and placebo arms, respectively.

Part A of the STENOVA study achieved its primary endpoint. The severity and incidence of adverse events were balanced across all treatment arms, including the placebo. Safety signals typically reported for systemic ALK5 inhibitors were not detected in the study; in particular no cardiac toxicity signal was observed. In addition, there were no signs of pro-inflammatory effects and no clinically relevant signals in safety laboratory values, vital signs, physical exams or electrocardiograms, or ECGs. As summarized in the table below, the pharmacokinetic analysis confirmed the GI-restricted profile of ontunisertib, with very low systemic exposure to the active parent molecule and high exposure to the main inactive metabolite, MET-158, indicating extensive hepatic metabolism. In contrast, there was high local exposure to ontunisertib in intestinal mucosal samples collected at the site of the ileal strictures. We also observed consistent trends for the 200mg BID dose of ontunisertib versus placebo across multiple exploratory endpoints.

Summary of Phase 2a (Part A) clinical findings for ontunisertib (AGMB-129)

Clinical findings	**Observations**
Orally administered 200mg BID and 100mg QD of ontunisertib was observed to be generally well tolerated, with no safety signal in FSCD patients	● A total of 103 participants were included in the Phase 2a trial, with 34 receiving ontunisertib 200mg BID, 34 receiving 100mg QD, and 35 receiving matching placebo ● Severity and incidence of adverse events were balanced across treatment arms, including placebo ● No safety signals were detected in the Phase 2a trial with ontunisertib ● No safety signals of cardiac toxicity, no pro-inflammatory effects, and no other safety signals in any safety labs, vital signs, physical exams or ECGs
High local exposure to ontunisertib in the GI tract, with minimal systemic exposure	● The PK profile indicates high local exposure to ontunisertib in the GI tract, with minimal systemic exposure as measured in plasma. These results support the GI-restricted profile of ontunisertib in FSCD patients
Main human ontunisertib metabolite is functionally inactive	● Main human metabolite of ontunisertib measured in plasma confirmed to be MET-158, a metabolite previously found to be inactive against ALK5
Consistent trends across several clinical exploratory endpoints observed for 200mg BID vs placebo	● For participants receiving ontunisertib 200mg BID, we observed a greater reduction in the total Simple Endoscopic Score for Crohn's Disease (SES-CD) and a greater proportion of these participants achieved endoscopic response and endoscopic remission compared to participants receiving placebo at Week 12 ● In participants with non-passable strictures at baseline, a greater proportion of participants had strictures that became passable at Week 12 in the 200mg BID dose of ontunisertib, compared to participants receiving placebo ● Similarly, participants receiving ontunisertib 200mg BID tended to show reduced progression in stricture length, compared to those receiving placebo, as measured by magnetic resonance enterography, or MRE

Key patient inclusion and exclusion criteria

Study participants included in the STENOVA study had a diagnosis of ileal or ileocolonic Crohn's Disease, or CD, at least three months prior to screening. They had at least one passable or non-passable stricture in the terminal ileum within reach of an endoscope. Strictures were to be noncritical naive or anastomotic, caused by CD and confirmed centrally by MRE. Participants were required to have tolerable obstructive symptoms, as defined by a screening S-PRO severity score ≥2, and were expected not to require hospitalization, endoscopic balloon dilation, surgical resection, or additional therapy during Part A of the study. Participants were on a stable background therapy for CD for ≥ 3 months and agreed to stay on stable doses during the study.

Key exclusion criteria were a history or current diagnosis of ulcerative colitis, indeterminate colitis, ischemic colitis, nonsteroidal anti-inflammatory drug-induced colitis, idiopathic colitis, radiation colitis, microscopic colitis, untreated colonic mucosal dysplasia, or untreated bile acid malabsorption. Participants entering the study could not have CD-related complications such as major bowel surgery, fistulae or abscesses, anal and septic or active perianal strictures, toxic megacolon, very severe inflammation or presence of deep mucosal ulcerations, or ileitis not associated with CD. Patients with current or a history of liver cirrhosis or liver failure were also excluded.

Patients that had endoscopic balloon dilation or surgical treatment of the same small bowel stricture within the last 6 months prior to screening were also excluded, as were participants with current or history of cardiac valve or large vessel disorders or any major abnormalities documented by cardiac echocardiography.

Study disposition

The STENOVA study was conducted in 52 clinical trial sites in the Unites States, Canada, Austria, Denmark, Germany, Italy, Poland and Spain. A total of 174 patients were screened and 103 were randomized, for a screening failure rate of 41%. The enrollment of 103 participants exceeded the target of 90 participants, which we believe highlights the significant investigator and patient interest in this first-in-indication study.

The trial had a high completion rate across all arms: 92 of the 103 participants (89.3%) completed the 12-week treatment period, while 11 participants (10.7%) discontinued study treatment prior to Week 12. Seven participants discontinued treatment due to an adverse event, one participant due to non-compliance with the study schedule, and three participants discontinued the study due to consent withdrawal.

Study disposition in STENOVA *Part A*

n (%)	AGMB-129 200mg BID (N=34)	AGMB-129 100mg QD (N=34)	Placebo (N=35)	All Subjects (N=103)
Treatment disposition				
Completed	29 (85.3)	32 (94.1)	31 (88.6)	92 (89.3)
Discontinued	5 (14.7)	2 (5.9)	4 (11.4)	11 (10.7)
Adverse event	5 (14.7)	0	2 (5.7)	7 (6.8)
Non-compliance with study schedule	0	0	1 (2.9)	1 (1.0)
Withdrawal by subject	0	2 (5.9)	1 (2.9)	3 (2.9)

We believe that the efficient recruitment and study completion rate (89.3%) reflect the strong engagement of the broader IBD community, including the STAR Consortium, KOLs, patient associations, and investigators, as well as the substantial unmet medical need that currently exists in FSCD.

Patient baseline characteristics

The baseline disease characteristics, as shown in the table below, reflect a CD population with long-standing CD (mean disease duration of 16.8 years) and a high rate of prior bowel resection surgery (46.6%).

The mean scores for inflammatory luminal disease activity, including the Crohn's Disease Activity Index, or CDAI (154.1), and C-reactive protein, or CRP (4.07 mg/L), were indicative of overall disease remission or mild inflammatory Crohn's Disease.

Overall, the characteristics were well-balanced across the different treatment arms.

Parameter	AGMB-129 200mg BID (N=34)	AGMB-129 100mg QD (N=34)	Placebo (N=35)	All Subjects (N=103)
Age (years), mean (SD)	44.2 (12.6)	41.0 (13.5)	42.8 (15.3)	42.7 (13.8)
Female, n (%)	9 (26.5)	9 (26.5)	12 (34.3)	30 (29.1)
White, n (%)	32 (94.1)	31 (91.2)	30 (85.7)	93 (90.3)
BMI (kg/m^2), mean (SD)	25.9 (5.5)	26.6 (5.3)	26.7 (5.5)	26.4 (5.4)
Disease duration (years), mean (SD)	17.0 (10.4)	15.6 (10.4)	17.8 (13.9)	16.8 (11.6)
Ileocolonic disease, n (%)	15 (45.5)	19 (55.9)	25 (71.4)	59 (57.8)
Intestinal resection, n (%)	15 (44.1)	17 (50.0)	16 (45.7)	48 (46.6)
CDAI, mean (SD)	144.1 (94.6)	166.0 (74.4)	152.0 (80.6)	154.1 (83.1)
S-PRO severity, mean (SD)	6.5 (3.8)	7.1 (3.5)	6.5 (2.8)	6.7 (3.4)
CRP (mg/L), mean (SD)	3.80 (5.28)	4.20 (4.45)	4.23 (7.21)	4.07 (5.73)
FCP (mg/kg), mean (SD)	344.8 (445.5)	460.0 (696.2)	522.9 (588.5)	442.6 (583.9)
SES-CD, mean (SD)	6.9 (4.0)	7.5 (5.0)	7.9 (4.1)	7.4 (4.4)
Prior biologics, n (%)	30 (88.2)	29 (85.3)	29 (82.9)	88 (85.4)
Concomitant biologics, n (%)	26 (76.5)	25 (73.5)	27 (77.1)	78 (75.7)
Concomitant thiopurine, n (%)	3 (8.8)	3 (8.8)	4 (11.4)	10 (9.7)
Concomitant methotrexate, n (%)	1 (2.9)	3 (8.8)	0	4 (3.9)

Most participants (85.4%) had received biologic treatment prior to the study, and approximately 75% of participants were on stable anti-inflammatory biologics during the study. The main concomitant biologics used by the study participants were anti-TNFs (30.1%; adalimumab and infliximab), anti-IL-12/23 (28.2%; ustekinumab), and anti-IL-23 (16.5%; risankizumab).

Use of concomitant biologics in STENOVA *Part A*

Concomitant biologic n (%)	AGMB-129 200mg BID (N=34)	AGMB-129 100mg QD (N=34)	Placebo (N=35)	All Subjects (N=103)
Adalimumab	6 (17.6)	7 (20.6)	7 (20.0)	20 (19.4)
Infliximab	4 (11.8)	4 (11.8)	3 (8.6)	11 (10.7)
Risankizumab	6 (17.6)	5 (14.7)	6 (17.1)	17 (16.5)
Ustekinumab	10 (29.4)	8 (23.5)	11 (31.4)	29 (28.2)
Vedolizumab	0	1 (2.9)	0	1 (1.0)

Primary endpoint: safety and tolerability of ontunisertib in FSCD patients

The primary endpoint of the STENOVA study was the assessment of the safety and tolerability profile of ontunisertib in FSCD patients. The incidence and severity of adverse events were balanced across trial arms, including placebo. The proportion of participants with at least one treatment-emergent adverse event was 61.8%, 64.7%, and 71.4% in the ontunisertib 200mg BID, 100mg QD, and placebo arms, respectively. In addition, there were no safety signals observed in the safety laboratory tests, including chemistry, hematology, and markers of inflammation, or in the vital signs and physical examinations of trial participants. Specific cardiac safety monitoring was performed, including echocardiography and measurements of markers of cardiac injury and failure, as well as ECGs. No evidence of cardiac toxicity was detected at any of the doses tested. The following table summarizes an overview of adverse events observed in the different treatment arms:

Overview of safety events in STENOVA *Part A*

Subjects with any n (%)	AGMIB-129 200mg BID (N=34)	AGMB-129 100mg QD (N=34)	Placebo (N=35)
TEAE	21 (61.8)	22 (64.7)	25 (71.4)
Serious TEAE	4 (11.8)	0	4 (11.4)
Worst-case:			
Moderate TEAE	5 (14.7)	9 (26.5)	5 (14.3)
Severe TEAE	4 (11.8)	1 (2.9)	4 (11.4)
Life-threatening TEAE	0	0	1 (2.9)
Fatal TEAE	1 (2.9)	0	0
Related TEAE	8 (23.5)	2 (5.9)	4 (11.4)
Temporary treatment interruption due to TEAE	1 (2.9)	3 (8.8)	3 (8.6)
Permanent treatment interruption due to TEAE	5 (14.7)	0	2 (5.7)
Study discontinuation due to TEAE	0	0	1 (2.9)

Of the 35 participants receiving placebo, four had at least one serious adverse event (or SAE), while of the 68 participants receiving ontunisertib, four in the ontunisertib 200mg BID arm and none in the 100mg QD arm experienced at least one SAE. Of the eight participants with SAEs, one participant on placebo had a life-threatening SAE, and one participant in the ontunisertib 200mg BID arm experienced a fatal SAE.

The DSMB, did not raise any safety concerns throughout the STENOVA Part A study and recommended its continuation according to protocol following each DSMB review meeting.

The table below summarizes the SAEs in the ontunisertib 200mg BID and placebo arm.

Summary of SAEs in STENOVA *Part A*

200mg BID: 4 patients with SAEs	**Placebo: 4 patients with SAEs**

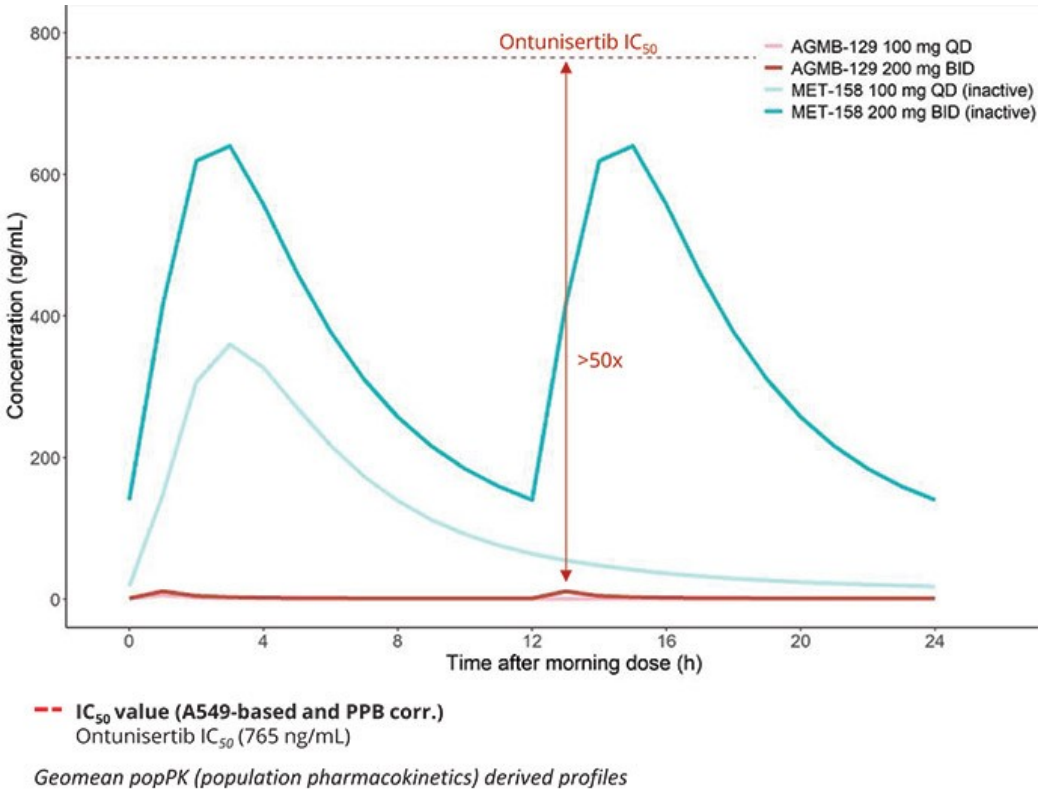
● **Atrial fibrillation and lacunar infarct** in a 75y-old male with Type 2 diabetes mellitus, hypertension, obesity, history of deep venous thrombosis, hypercholesterolemia; new fatal SAE - *Failure to thrive - not related*
● **Deep venous thrombosis and pulmonary embolism** in a 49y-old male, underweight, non-smoker, no thrombosis history, history of hypoalbuminemia - *Both events resolved - possibly related*
● **Subileus** in a 54y-old female, smoker, with prior GI resection - *Recovered with steroid course - not related*
● **Intestinal fistula** (sinus tract near ileocolonic anastomosis) - *Recovered after surgery - not related*
	● 2 cases of **Ileus:**
	  ● 35y-old male with prior GI surgery and endoscopic balloon dilations (EBD) - *Recovered (after EBD) - not related*
	  ● *30y-old male with prior GI resection - Recovered with IV steroid - not related*
	● **Small intestinal obstruction** *due to adhesions from prior urological surgery; IMP interruption; life-threatening - Resolved - not related*
	● **Herpetic radiculopathy -** *Recovered - not related*

Pharmacokinetic results with ontunisertib in FSCD patients

For the secondary endpoint of systemic pharmacokinetics (PK), plasma concentrations of ontunisertib and its metabolites were measured two hours (i.e., around Cmax) after the first dose administration at the baseline visit as well as pre-dose and two hours after the morning dose at the Week 12 visit. In addition, sparse PK concentrations were also measured after two, four, and eight weeks of dosing. The sparse PK data obtained in STENOVA were applied to a popPK model to estimate plasma exposure profiles over the 24-hour dosing interval. In the STENOVA study, low systemic exposure to ontunisertib was observed in FSCD patients at both doses. Population PK modeling showed that, around Tmax, the geomean ontunisertib plasma levels were below 30nM for both ontunisertib doses, indicating very low systemic exposure, being more than 50-fold below its IC50 at Cmax. The popPK model also indicated that systemic exposure for the ontunisertib 200mg BID dose was approximately 3.5-fold higher compared to the 100mg QD dose. The systemic exposure to the main inactive metabolite, MET-158, was substantially higher than ontunisertib, indicating efficient GI absorption and extensive hepatic metabolization of ontunisertib.

The systemic PK data observed in the STENOVA study indicates that the GI-restriction mechanism of ontunisertib was able to operate efficiently in FSCD patients and in line with what we observed in the Phase 1 trial of healthy participants.

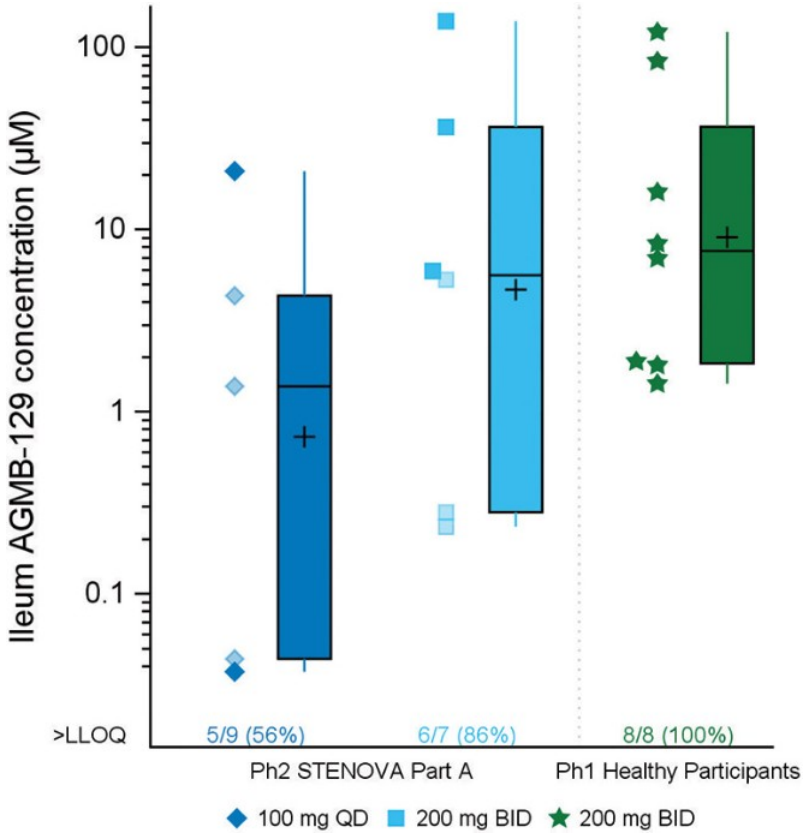
Systemic PK - High local exposure to ontunisertib, with low systemic exposure



Geomean popPK (population pharmacokinetics) derived profiles

We also measured the concentration of ontunisertib in samples from ileal biopsies in the STENOVA Part A study. Local exposure in mucosal samples collected at the site of the ileal stricture within five hours post-dose showed high and dose-dependent tissue concentrations in the ontunisertib 100mg QD and 200mg BID arms. Where measurable, we observed high average tissue levels of ontunisertib with the 200mg BID dose, at levels comparable to the ileal concentrations measured in Stage D of the Phase 1 trial in healthy participants.

Local PK - High local ileal exposure in FSCD patients



Based on observations with confirmed timing of sample collection within five hours post-dose
LLOQ: lower limit of quantification

Pharmacodynamic analysis in FSCD patients

Mucosal biopsies were collected at the site of the ileal strictures at Baseline and Week 12. RNA was extracted and RNA-Seq analysis was performed. This transcriptomics analysis did not detect a significant downregulation of disease-relevant genes in ontunisertib treatment arms as compared to placebo. The data suggest that the level of inflammatory activity at the site of the biopsy, the location of the biopsy within the ileal or colonic aspect of the stricture, and the naïve or anastomotic nature of strictures introduced significant variability which hampered the detection of a drug effect, especially if those factors varied between the Baseline and Week 12 samples.

In a post-hoc subgroup analysis of biopsies that did show active inflammation (pre- and post-treatment), we observed a statistically significant downregulation of pathways associated with inflammation and fibrosis in participants treated with high dose of ontunisertib (200mg BID) compared to placebo. For statistical analysis, the gene set analysis (GSA) model known as Generally Applicable Gene-set Enrichment (GAGE) method was used to derive p-values which were considered significant if $p<0.05$.

Clinical exploratory endpoints for ontunisertib in FSCD

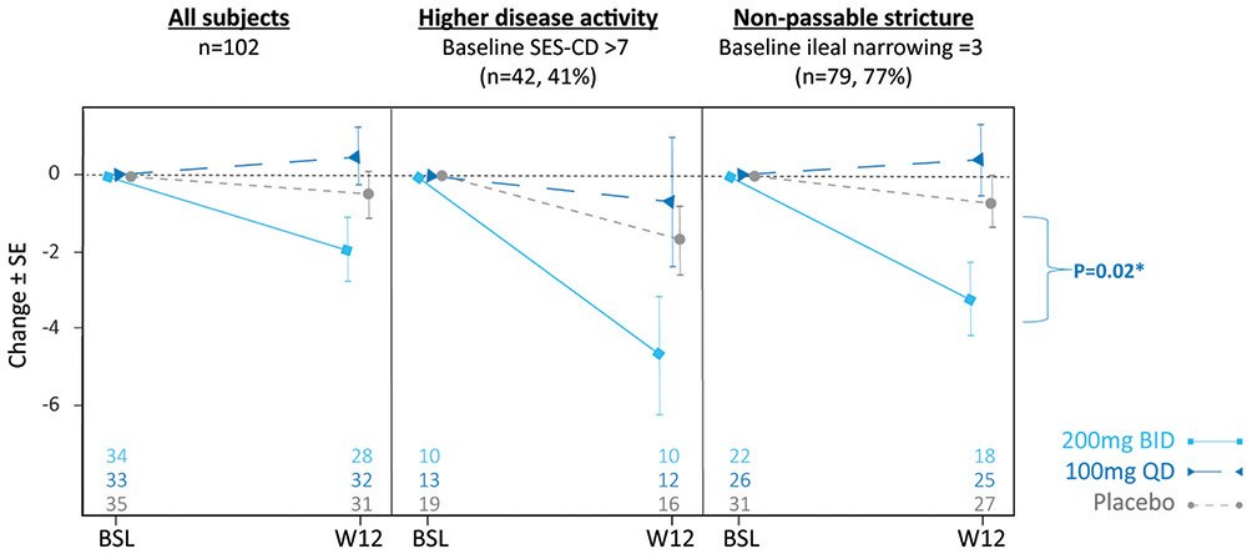
Clinical response based on established luminal endoscopic endpoint - Simple Endoscopic Score (SES-CD)

As an objective imaging endpoint assessing therapeutic response, we explored the value of the centrally read Simple Endoscopic Score for Crohn's Disease, or SES-CD. The SES-CD is an endoscopy-based scoring system that is widely used to assess both the inflammation components of luminal disease activity as well as intestinal narrowing. This score has been recommended by FDA and EMA as a validated endoscopic endpoint to support the registration of novel therapies for luminal Crohn's disease. However, the SES-CD has not yet been validated in FSCD.

At baseline, participants had a mean SES-CD of 7.4, which corresponds to the low end of the moderate range in CD patients. After 12 weeks of dosing, participants in the ontunisertib 200mg BID arm achieved an approximately two-point reduction in the total SES-CD score. Importantly, in a post-hoc analysis in participants with a baseline SES-CD score >7 (42 participants, or 41% of the total population), a larger decrease in the ontunisertib 200mg BID group of approximately five points was observed. The cut-off value of a SES-CD score of 7 was selected since it is the established threshold for moderate luminal disease activity.

While all participants had at least one stricture, 77% of participants (n=79) had a non-passable stricture at baseline, as assessed by a robust central reading process that included two blinded central readers and an adjudication mechanism in case of disagreement. In the participants with non-passable strictures at baseline, a larger reduction in the total SES-CD score was again observed in the ontunisertib 200mg BID dose arm when compared to placebo. While not powered for statistical significance, the difference between the ontunisertib 200mg BID dose and placebo arm reached statistical significance in a post-hoc analysis (p=0.02). The improvements in the ontunisertib 200mg BID arm were due to combined effects on the inflammation components of the SES-CD score (ulcer size, ulcerated surface, and affected surface) and on the narrowing component.

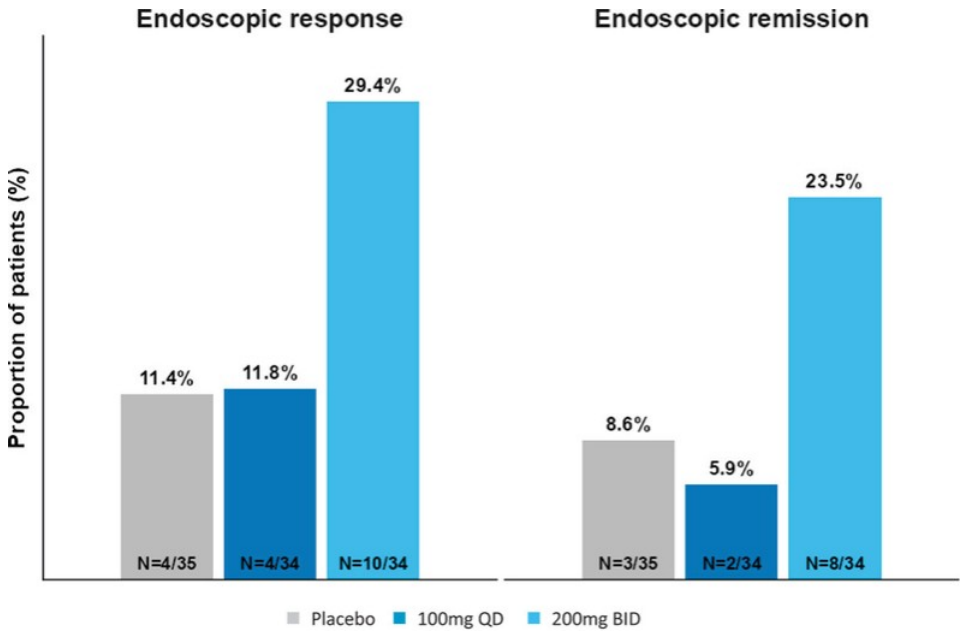
SES-CD scores in STENOVA *Part A*



** Based on post-hoc analysis; not powered for statistical significance. P-values were derived from analysis of covariance with change in SES-CD as response, and baseline SES-CD, randomization stratum, and treatment as covariates.*

A further post-hoc analysis explored the proportion of participants achieving endoscopic response and endoscopic remission. Endoscopic response, defined as a decrease from baseline in SES-CD of at least 50%, was observed in 29.4%, 11.8%, and 11.4% of participants in the ontunisertib 200mg BID, 100mg QD, and placebo arms, respectively. A higher endoscopic remission rate, defined as a total score of four or less with no item above one, was also observed for the high dose cohort (23.5%) versus the low dose cohort (5.9%) and placebo (8.6%), as shown in the bar graph below:

Endoscopic response and endoscopic remission in STENOVA *Part A*



We also assessed if strictures classified as non-passable at baseline became passable at Week 12, as this potentially indicates a clinically meaningful therapeutic benefit. We used the narrowing component of the SES-CD score to assess stricture passability. At baseline, 77% of participants had a non-passable stricture. In the placebo arm, two of the 31 non-passable strictures (6.5%) became passable at Week 12, and in the ontunisertib 100mg QD group, this was the case for two out of 26 non-passable strictures (7.7%). In contrast, in the ontunisertib 200mg BID group, seven out of 22 non-passable strictures (31.8%), became passable at Week 12. We believe that the improvement in stricture passability at Week 12 for the high dose group is an important observation.

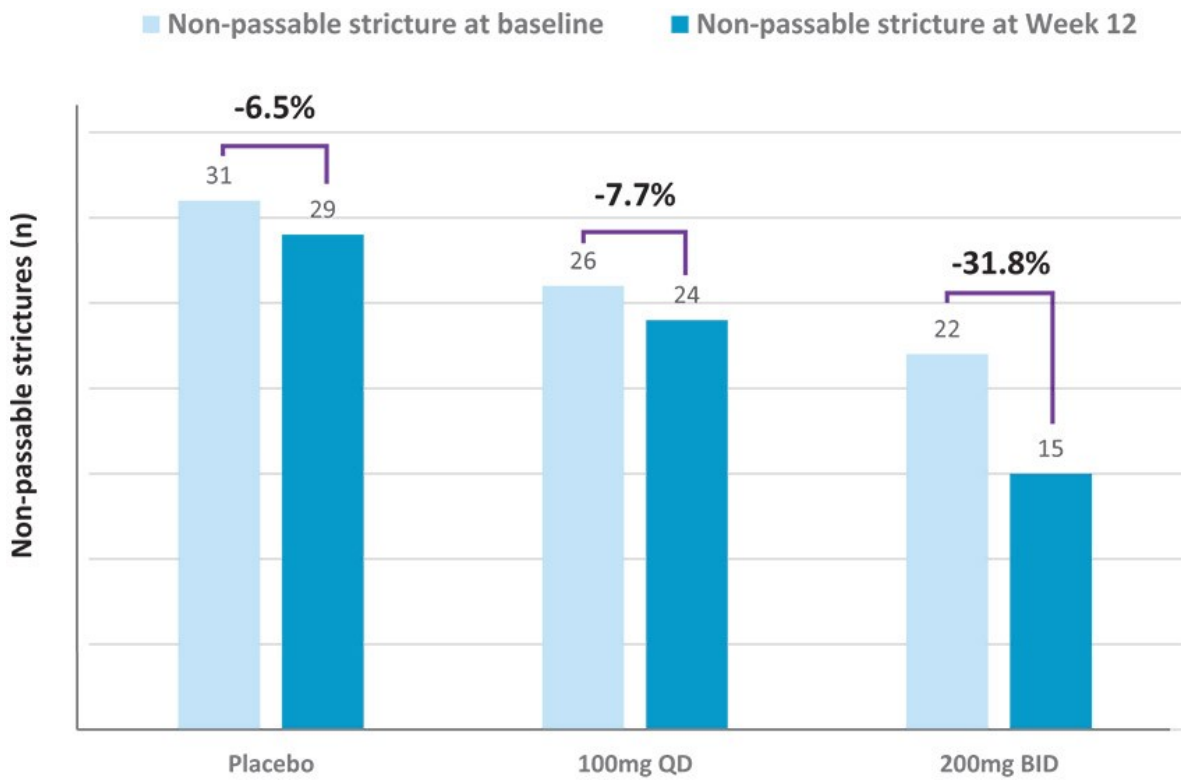
Summary of stricture passability in STENOVA *Part A*

Summary of Centrally-read Endoscopy Ileum Narrowing Changes (Full Analysis Set)

Baseline score group Week 12 change, n (%)	AGMB-129 200 mg BID (N=34)	AGMB-129 100 mg QD (N=34)	Placebo (N=35)
Ileal narrowing score < 3 at baseline	10 (29.4)	7 (20.6)	4 (11.4)
Improved	0	0	1 (25.0)
No change	4 (40.0)	4 (57.1)	0
Worsened	5 (50.0)	3 (42.9)	3 (75.0)
Missing	1 (10.0)	0	0
Ileal narrowing score = 3 at baseline	22 (64.7)	26 (76.5)	31 (88.6)
Improved	7 (31.8)	2 (7.7)	2 (6.5)
No change	11 (50.0)	23 (88.5)	25 (80.6)
Missing	4 (18.2)	1 (3.8)	4 (12.9)
Ileal narrowing score missing at baseline	2 (5.9)	1 (2.9)	0
Unknown	0	1 (100)	0
Missing	2 (100)	0	0

Week 12 denominators are based on totals within each baseline score group.

Improvement in stricture passability in STENOVA *Part A*



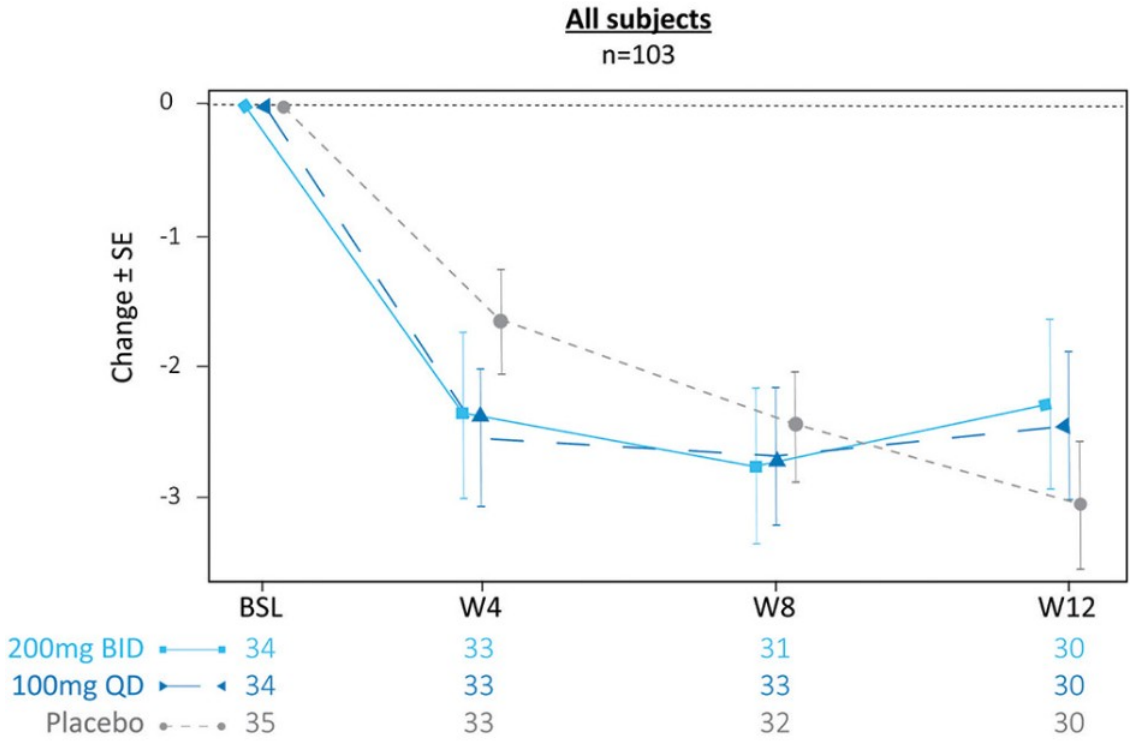
Clinical response based on novel FSCD-specific endpoints - Stricture Patient-Reported Outcome (S-PRO)

In the STENOVA study, we explored Clinical Outcome Assessment, or COA, instruments evaluating clinical benefits that are meaningful to patients, such as a Patient Reported Outcome, or PRO. To this end, we have been working alongside the STAR Consortium, an independent body founded by leading gastroenterologists. STAR has developed an initial version of a FSCD-specific PRO instrument, named S-PRO, which is currently undergoing validation in a prospective observational trial in FSCD patients conducted by a third party. The S-PRO instrument aims to capture obstructive symptoms such as abdominal pain, cramping, bloating, and vomiting occurring particularly after meals. Changes in diet, such as the type or amount of food, and food processing methods such as mashing or blending food are also evaluated.

As the graph below shows, a significant placebo effect was observed in the STENOVA Part A study, leading to a rapid symptomatic improvement for the S-PRO Severity score within four-to-eight weeks. No further benefit was observed in the ontunisertib 200mg BID and 100mg QD arms. We explored whether a drug effect could be detected in participants with higher S-PRO score at baseline. Similarly, a large placebo effect was observed in participants at or below as well as above the median value for baseline S-PRO. The data suggests that a floor effect, reached after four-to-eight weeks, hampered the detection of a drug effect.

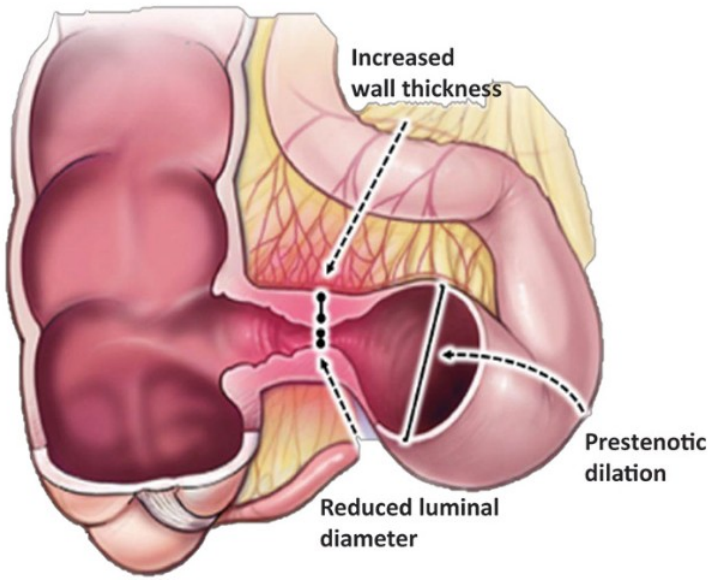
We are working with the STAR consortium on further iterations of the S-PRO instrument to improve the ability of this instrument to potentially detect drug effects. We are also exploring additional Clinical Outcome Assessments (COAs) for potential future use.

S-PRO Severity score in STENOVA *Part A*



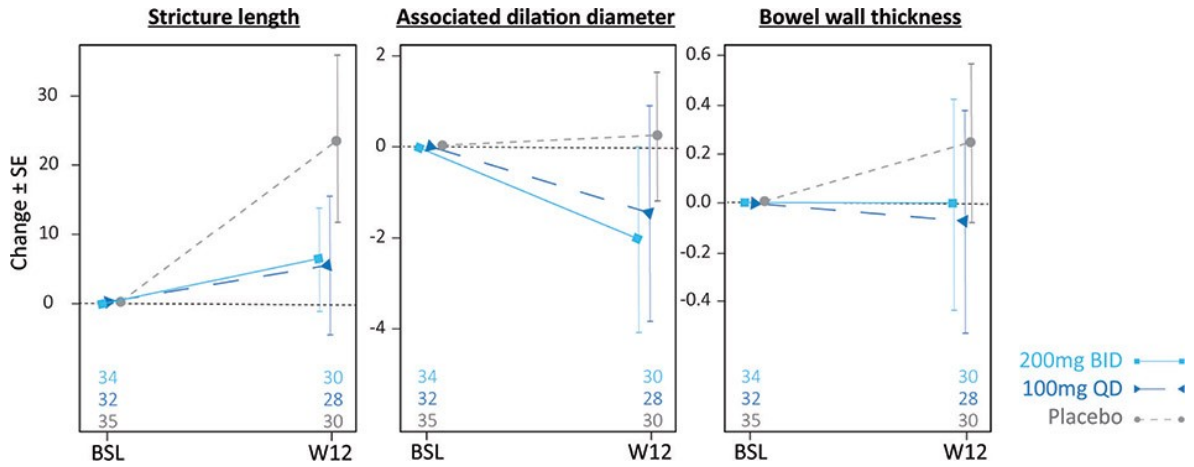
Clinical response based on novel FSCD-specific endpoints - Magnetic Resonance Enterography (MRE)

In the STENOVA trial, we also included a radiological evaluation by MRE. MRE is commonly used in clinical practice to evaluate stricture severity and provides information about structural severity criteria, including stricture length, bowel wall thickness, and the presence and diameter of any associated pre-stenotic dilation. These three parameters have been shown to be reliably measured by MRE and are considered clinically meaningful.



As shown in the graph below, we observed an early trend for both the 100mg QD and the 200mg BID dose of ontunisertib versus placebo, with the strongest trend observed for the change from baseline in stricture length at Week 12. Specifically, mean stricture length worsened in the placebo group and less so in the 100mg and 200mg BID arms. Directionally, similar findings were observed for bowel wall thickness and prestenotic dilation.

MRE subscores in STENOVA *Part A*



Mean values at baseline (in mm): Stricture length, 104mm; Associated dilation diameter, 28.3mm; Bowel wall thickness, 8.16mm.

STENOVA Phase 2a study - Part B

Part B of the STENOVA study is an ongoing open-label extension, or OLE, study, enrolling eligible participants that have completed the Week 12 study visit for Part A. The data discussed below presents an internal analysis conducted in October 2025. All eligible participants enrolled into the OLE study will receive ontunisertib 200mg BID for up to an additional 48 weeks. In the OLE, MREs are performed after 24 and 48 weeks of additional treatment, while SES-CD is assessed at Week 48.

Part B was initiated in early 2025, when Part A was already underway. Therefore, a proportion of participants had already completed the 12 weeks of dosing in Part A as well as the safety follow-up period when Part B was initiated. Only participants who finished Part A no longer than 24 weeks prior to the start of Part B were eligible. Of the participants eligible to roll over into the OLE study without treatment interruption, 94% elected to enter the OLE. Altogether, a total of 49 participants entered the OLE study, as shown in the table below. As of October 2025, 45 of those 49 participants had completed an additional 12 weeks of treatment in the OLE study, and 24 had completed 24 weeks of treatment. A total of five participants discontinued study treatment, as shown in the table below. One participant discontinued because of an adverse event, one because of non-compliance, and one withdrew consent. Two participants that were in the placebo group in the first 12 weeks discontinued the OLE because of lack of efficacy.

Study disposition in STENOVA *Part B*

	AGMB-129 200 mg BID (N=16)	AGMB-129 200 mg BID after 100 mg QD (N=19)	AGMB-129 200 mg BID after Placebo (N=14)	All subjects (N=49)
Treatment disposition				
Ongoing	15 (93.8)	17 (89.5)	12 (85.7)	44 (89.8)
Discontinued	1 (6.3)	2 (10.5)	2 (14.3)	5 (10.2)
Adverse event	0	1 (5.3)	0	1 (2.0)
Lack of efficacy	0	0	2 (14.3)	2 (4.1)
Non-compliance with study drug	1 (6.3)	0	0	1 (2.0)
Withdrawal by subject	0	1 (5.3)	0	1 (2.0)

Longer-term safety and tolerability profile of ontunisertib in FSCD

The interim data snapshot in 24 participants treated with ontunisertib 200mg BID for an additional 24 weeks in the OLE (up to 36 weeks in total) as of October 2025 supports the longer-term safety and tolerability profile of ontunisertib in FSCD patients. In the OLE, the lowest proportion of participants with at least one TEAE was observed in the participants who were already on ontunisertib 200mg BID in Part A (25.0%), compared to those switching from 100mg QD (63.2%) or placebo to the 200mg dose (50.0%; see table below). A total of four participants had at least one SAE in the OLE, including one of the participants who was already on the ontunisertib 200mg BID dose in Part A (SAE of kidney stone), two of the participants who switched from the 100mg QD to the 200mg dose of ontunisertib (SAEs of appendicitis and Crohn's colitis), and one of the participants who switched from placebo to the ontunisertib 200mg BID dose (SAE of wrist fracture). These four cases were all deemed not related to study drug by the investigators.

As of October 2025, no safety signals were detected in laboratory tests, safety biomarkers, vital signs, ECGs, and physical examinations of participants in Part B of the STENOVA study.

As of February 2026, the DSMB has not raised any safety concerns and has recommended for the study to continue as per the protocol with 200mg BID for up to 60 weeks.

Overview of safety events in STENOVA *Part B (interim data snapshot)*

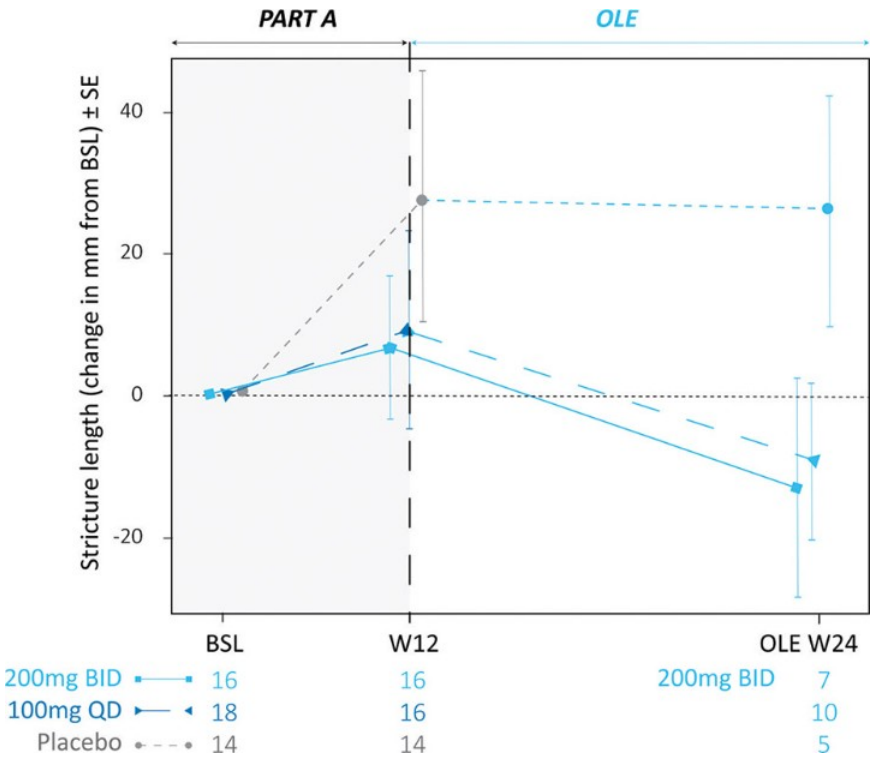
Subjects with any, n (%)	AGMB-129 200 mg BID (N=16)	AGMB-129 200 mg BID after 100 mg QD (N=19)	AGMB-129 200 mg BID after Placebo (N=14)
TEAE	4 (25.0)	12 (63.2)	7 (50.0)
Serious TEAE	1 (6.3)	2 (10.5)	1 (7.1)
Worst-case:			
Moderate TEAE	2 (12.5)	6 (31.6)	2 (14.3)
Severe TEAE	1 (6.3)	2 (10.5)	1 (7.1)
Life-threatening TEAE	0	0	0
Fatal TEAE	0	0	0
Related TEAE	1 (6.3)	0	1 (7.1)
Treatment interruption due to TEAE	1 (6.3)	2 (10.5)	2 (14.3)
Treatment withdrawal due to TEAE	0	1 (5.3)	0
Study discontinuation due to TEAE	0	0	0

MRE assessment of longer-term treatment with ontunisertib in FSCD patients

An important question of the ongoing STENOVA OLE study is to determine whether the radiological improvements observed after 12 weeks of treatment in Part A can be maintained or further enhanced with prolonged administration of ontunisertib 200mg BID. As the below graph shows, we have observed, in an initial internal analysis (based on non-cleaned, non-locked data), that for the participants who transitioned from placebo to ontunisertib 200mg BID upon entering the OLE phase, stricture length, which was previously worsening, ceased to progress and instead stabilized over the 24-week treatment period. In participants who were already receiving ontunisertib during Part A of the study, we observed an initial indication of regression in stricture length when compared to their baseline measurements.

At the time of this analysis (data cut-off: October 2025), MRE data was available for only the first 22 participants who had completed Week 24 in Part B, and these data are subject to further review. As the study progresses and more participants reach this milestone, additional data will become available, which may help to further clarify the radiological effects of longer-term treatment with ontunisertib. Furthermore, data to be collected at Week 48 may provide valuable information regarding the effect of extended treatment with ontunisertib on MRE parameters. We expect to report the results of the full 48-week open-label treatment extension in the second half of 2026.

Stricture length in STENOVA *Part B (interim data snapshot)*



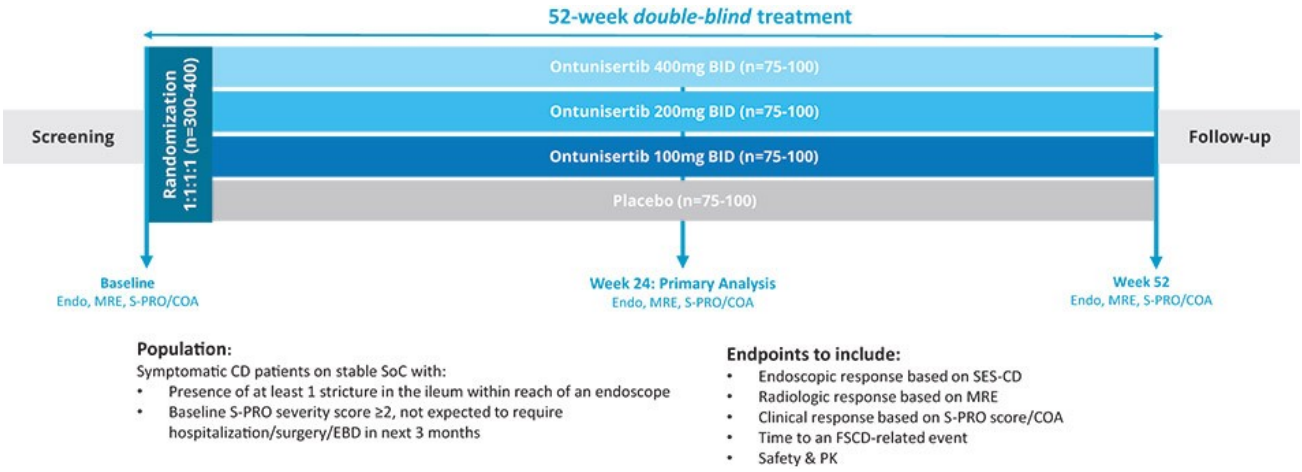
Subjects are grouped by their originally allocated arm; all receive ontunisertib 200mg BID after Week 12.
Analyses are non-validated drafts based on non-cleaned, non-locked data (EDC: 16OCT2025; ECG: 09OCT2025; MRE: 15OCT2025).

Next development steps for the ontunisertib program in FSCD

Based on the results observed in the STENOVA study to date and our positive interactions with the U.S. Food and Drug Administration, or the FDA, we are preparing to initiate a Phase 2b trial of ontunisertib in patients with symptomatic FSCD in the second half of 2026. We are currently planning to conduct a 52-week trial with a primary analysis at Week 24. The trial will compare three doses of ontunisertib versus placebo. The objective of the trial will be to further evaluate the safety and efficacy profile of ontunisertib in FSCD patients, determine the optimal dose, and inform the selection of registrational endpoints for a subsequent Phase 3 clinical program.

Pending final regulatory alignment on study design and endpoints, we are on track to initiate the Phase 2b study with ontunisertib in FSCD later this year.

Proposed Phase 2b study design with ontunisertib in FSCD



Conclusion: STENOVA, a landmark study in FSCD

STENOVA is a first-in-indication study that set out to investigate whether ontunisertib could safely target the TGFβ pathway through ALK5 inhibition in a GI-restricted fashion in FSCD patients. Ontunisertib exhibited a generally favorable safety and tolerability profile in FSCD patients in the STENOVA study, based on the balanced incidence and severity of adverse events between ontunisertib and placebo, and the absence of safety signals in patients receiving ontunisertib. The observed PK profile was consistent with the anticipated GI-restricted mode-of-action of ontunisertib, with high local and low systemic exposure in FSCD patients. We also observed improvements in strictures in the high-dose cohort, with a measurable effect on SES-CD, including inflammation and narrowing components, and MRE. While further analysis and development is needed to determine the appropriate COAs, including further work to refine and determine the utility of the S-PRO, the SES-CD and MRE parameters provide potential imaging endpoints for further studies in FSCD.

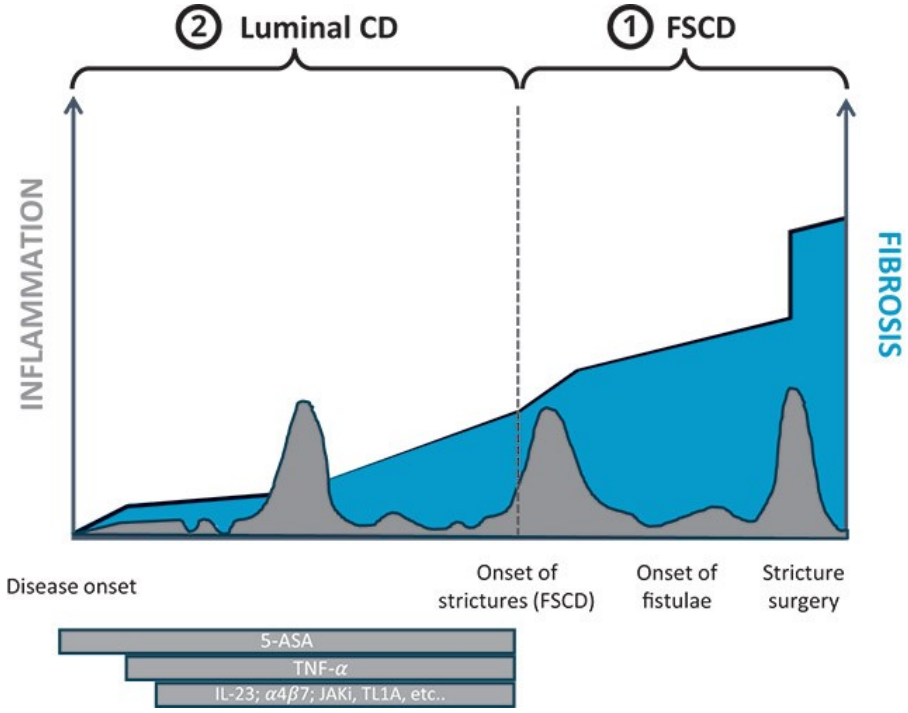
Ontunisertib, a potential solution for the main unmet medical needs in CD

We believe that ontunisertib has the potential to address the two key unmet medical needs in the current treatment of Crohn's disease.

First, for the 46% of CD patients with established strictures, no targeted treatment exists. We believe that ontunisertib, if approved, could provide the first therapeutic option to halt or reverse disease progression in these patients. The STENOVA results indicate that ontunisertib has the potential to serve as an anti-fibrotic therapy, on top of standard of care. Moreover, based on animal pharmacology studies, *ex vivo* studies in mucosal samples derived from IBD patients, and on the improvements in inflammation and narrowing components of the SES-CD score observed in the STENOVA study, data to date suggests that ontunisertib possesses both anti-fibrotic and anti-inflammatory properties. This potential dual anti-inflammatory and anti-fibrotic mode-of-action could enable monotherapy in FSCD patients.

Secondly, in the broader luminal CD population, the main medical need is to break the efficacy ceiling of current anti-inflammatory drugs. This efficacy ceiling results in sequential drug cycling and inadequate disease control, which allows for the development of strictures and fistulae that require surgery in many CD patients. We believe that ontunisertib could be positioned earlier in the treatment paradigm for CD to enhance the control of mucosal inflammation and prevent progressive GI fibrosis. In this therapeutic setting, we believe that ontunisertib could be used in combination with advanced anti-inflammatory therapies to provide an important addition to the therapeutic options available to IBD patients.

Ontunisertib could provide solution for strictures and efficacy ceiling



Conclusion

The emergence of burdensome symptomatic strictures is considered to be an inevitable consequence of long-term inflammation for the large proportion of patients with CD who progress to FSCD and eventually require surgery. We believe ontunisertib has the potential to change the paradigm for treating FSCD patients and provide the first pharmacologic treatment for strictures. We believe ontunisertib's antifibrotic effect through efficient blockade of TFGβ signaling in the gastrointestinal tract has the potential to address the underlying driver of strictures while avoiding the known toxicities associated with systemic TGFβ inhibition. We believe ontunisertib has the potential to be used as a chronic treatment for patients with symptomatic strictures not requiring immediate surgical intervention.

Outlook

We are currently progressing the open-label treatment extension part of the STENOVA study (Part B) and expect to report the results in the second half of 2026. As of February 2026, the DSMB has not raised any safety concerns and has recommended for the study to continue as per the protocol with 200mg BID for up to 60 weeks. The 48-week data may provide important insights into extended treatment with ontunisertib in FSCD patients.

We continue to have positive interactions with the FDA to align on the study design of the Phase 2b study with ontunisertib in FSCD and are on track to initiate the study in the second half of 2026.

AGMB-447 for the treatment of idiopathic pulmonary fibrosis

AGMB-447, our second clinical-stage product candidate, is an inhaled small molecule inhibitor of ALK5 in development for the treatment of idiopathic pulmonary fibrosis (IPF). AGMB-447 is designed to have high local exposure in the lung tissue and low systemic exposure. Upon absorption into the bloodstream, AGMB-447 is hydrolyzed and inactivated to avoid potential toxicities associated with systemic inhibition of ALK5 signaling. We are conducting a randomized, double-blind, placebo-controlled Phase 1 clinical trial intended to evaluate the safety, PK, PD and target engagement of AGMB-447. We completed an interim analysis of the SAD and MAD 1-6 stages of the Phase1 trial where we enrolled 108 healthy participants, and have dosed the first patients in the IPF cohort, with the aim to recruit up to 12 patients with IPF. We plan to report data in IPF patients in the second half of 2026.

IPF background

Pulmonary fibrosis is a severe chronic disease characterized by rapidly progressive scarring of connective tissue within the lung. IPF, the most common type of pulmonary fibrosis, is an age-related (i.e., usually occurring in adults over the age of 60), rare progressive fibrotic interstitial pneumonia of unknown cause. According to American Thoracic Society (ATS) guidelines, IPF diagnosis is based on exclusion of known causes of interstitial lung disease and is associated with a pattern of usual interstitial pneumonia (UIP) on high resolution computed tomography (HRCT) or surgical lung biopsy. There is a growing clinical need for improved treatment options given the limited number of approved medications. IPF has a poor prognosis for patients, with a median life expectancy of less than five years after diagnosis. Patients with IPF develop progressive shortness of breath from the scarring of the lungs and have difficulty performing routine functions, such as walking and talking. Other symptoms include chronic dry cough, fatigue, weakness, chest pain and weight loss.

IPF affects approximately 240,000 people in the United States, Japan, the United Kingdom, and the four largest European markets (France, Germany, Spain, and Italy), with 30,000 to 40,000 new cases being diagnosed each year in the United States alone.

IPF treatments

There are no approved pharmacological treatments for IPF that can cure the disease or reverse disease pathology. Patients with IPF are managed by providing supportive care such as pulmonary rehabilitation and assisted ventilation, pharmacological interventions that may slow disease progression, and lung transplantation for eligible patients. IPF is the main cause of all lung transplantations, however, mortality on the waiting list is high due to speed of disease progression. There are currently three FDA-approved anti-fibrotic therapies for the treatment of IPF, all of which are administered orally: pirfenidone, originally marketed as Esbriet® by Genentech/Roche, nintedanib, marketed as Ofev®, and nerandomilast, marketed as Jascayd®, both by Boehringer Ingelheim.

Pirfenidone, whose direct mechanism of action is not well defined, has been shown to slow disease progression as reflected by a reduced rate of lung function decline, exercise tolerance, and longer progression-free survival. Nintedanib is an inhibitor of the tyrosine kinase activity of multiple growth factor receptors. Treatment with nintedanib has been shown to reduce the annual rate of decline of pulmonary function and lead to significant delays in the time to acute disease exacerbation, with a trend towards increased survival. Both pirfenidone and nintedanib are associated with significant side effects which include persistent gastrointestinal disorders (e.g., diarrhea, nausea, abdominal pain, vomiting) and elevated liver enzymes, which may lead to temporary dose reductions or discontinuation of therapy altogether. Required monitoring of liver tests prior to initiation of treatment and at regular intervals during treatment is clinically indicated. Over 60% of patients treated with nintedanib experience diarrhea and around 5% have elevated liver enzymes. Cases of drug-induced liver injury have been reported in patients treated with nintedanib, including one patient death, with pirfenidone’s prescribing information carrying a similar warning about elevated liver enzymes. Other side effects in patients taking pirfenidone include Severe Cutaneous Adverse Reactions (SCAR) and photosensitivity and rash. However, despite the side effect profile, the aggregate annual revenue for nintedanib and pirfenidone was approximately $4.1 billion in 2024 across IPF and other fibrosing interstitial lung diseases.

Nerandomilast was recently approved by the FDA in October 2025. Nerandomilast is an orally administered, preferential inhibitor of the phosphodiesterase 4B (PDE4B) enzyme. Treatment with nerandomilast has been shown to significantly reduce the rate of lung function decline in patients with IPF. However, 41% of patients in clinical trials experienced diarrhea, and the incidence of diarrhea increased substantially in combination with nintedanib, to 62% of patients. Trial results also suggest that combining pirfenidone with nerandomilast may lead to a pharmacokinetic interaction: pirfenidone might reduce nerandomilast's plasma concentrations, potentially lowering its efficacy. Hence, nerandomilast's potential to combine with the other approved therapies for the treatment of IPF may be limited.

In conclusion, despite the availability of approved anti-fibrotic treatment options, we believe an important unmet medical need remains for patients with IPF for novel therapies demonstrating both enhanced efficacy and an optimized safety and tolerability profile.

TGFβ is a key driver of fibrosis in IPF

TGFβ is produced by a wide variety of cell types in the lung including alveolar macrophages, neutrophils, fibroblasts, endothelial cells and myofibroblasts. Repetitive injury of the alveolar epithelium is understood to be a trigger for the aberrant wound healing process that drives the development of IPF. Studies of lung tissue from patients with IPF demonstrate that TGFβ is increased in the alveolar epithelium, macrophages and fibroblastic foci, where it promotes fibroblast recruitment and proliferation via paracrine signaling. In the lung, TGFβ activates multiple pathways relevant to the pathogenesis of IPF including cell differentiation, proliferation, apoptosis, migration, and extracellular matrix, or ECM production.

Disruption of TGFβ signaling has been found to limit the development of fibrosis in both *in vitro* and *in vivo* preclinical models of IPF. In these experimental models, the expression of active TGFβ alone is sufficient to induce fibrosis, while the inhibition of epithelial activation of TGFβ or TGFβR function prevents fibrotic progression. In the lungs, TGFβ also stimulates the expression of several proinflammatory and fibrogenic cytokines, such as TNFα, PDGF, IL-1β and IL-13, thereby amplifying the fibrotic response. Additionally, TGFβ suppresses production of antifibrotic molecules, such as HGF and prostaglandin E2. Although inhibitors of the TGFβ pathway, such as inhibitors of ALK5, have potential to treat IPF, systemic toxicities of multiple organ systems have precluded their clinical development.

Our potential solution, AGMB-447

AGMB-447 is a small molecule inhibitor of ALK5 designed to be administered by inhalation, targeting the TGFβ pathway in the lung. Unlike other ALK5-targeted drug candidates, AGMB-447 was designed to be rapidly hydrolyzed and inactivated upon absorption, to limit systemic exposure and potentially reduce the risk of toxicities associated with systemic ALK5 inhibition. Additionally, AGMB-447 has the potential to reduce the risk of drug-drug interactions, making it an attractive candidate for combination with systemic therapeutics. Moreover, dosing via inhalation may offer significant advantages for IPF patients as it allows for the direct delivery of drug to the site of action maximizing local exposure with smaller doses while circumventing the need for high systemic doses. A nebulizer, rather than a dry-powder inhaler (DPI), was selected since nebulization is better suited for deep lung drug delivery and is easier for IPF patients who are generally elderly and limited in their capability to achieve the high inspiratory flow that is required for DPI.

Preclinical development of AGMB-447

The key preclinical findings for AGMB-447 are summarized in the table below.

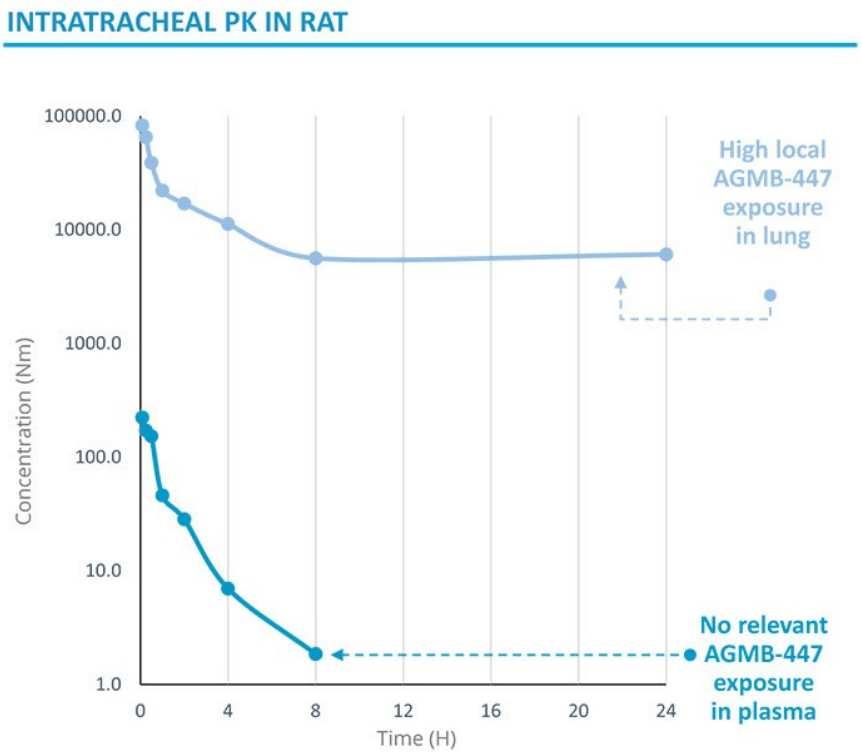
Summary of preclinical findings for AGMB-447

Preclinical findings	Observations
Preclinical pharmacokinetics AGMB-447 resulted in high exposure to the lung with fast hydrolysis in plasma	● Exposure to AGMB-447 after intratracheal administration in rodents was approximately 800 to 1,000-fold higher in the lung than in plasma ● The major metabolite of AGMB-447 in plasma, MET-093, has shown no meaningful ALK5 inhibitory activity in cellular experiments
Activity in in vivo bleomycin mouse model AGMB-447 led to dose-dependent reductions in the bleomycin model across a number of fibrosis and inflammation readouts	● Bleomycin model is the most widely used preclinical model for IPF due to its ability to reproduce many aspects of the disease ● The Ashcroft score, a histological method of quantifying fibrosis, was significantly reduced with 1 mg/kg dose of AGMB-447. AGMB-447 also led to significant reductions in inflammation as measured by immune infiltration into the tissue (assessed by histopathology scores) and the number of leukocytes in bronchoalveolar lavage fluid
Activity in ex vivo human lung fibroblasts AGMB-447 led to dose-dependent decreases in the release of COL1A1 protein	● Dose-dependent decreases in the release of COL1A1 protein were observed in fibroblasts from non-IPF and IPF patients ● Similar results were seen with other pro-fibrotic markers such as plasminogen activator inhibitor-1 (PAI-1) and fibronectin 1 (FN1)
Activity in ex vivo human precision cut lung slices AGMB-447 led to dose-dependent decreases in profibrotic genes	● Precision-cut lung slices are increasingly recognized and employed as an *ex vivo* organotypic model ● Expression of COL1A1 was decreased in a dose-dependent manner in hPCLs from non-IPF and IPF patients ● Similar effects were observed for other profibrotic genes such as SERPINE-1 (coding for PAI-1), fibronectin (FN1) and integrin beta 6 (ITGB6)
Toxicology studies No cardiac valve lesions observed with AGMB-447	● No cardiac valve lesions have been observed in GLP toxicology studies, including chronic toxicology studies of AGMB-447 in rodents and toxicology studies in non-rodents

AGMB-447 resulted in high exposure to the lung with fast hydrolysis in plasma

AGMB-447 was designed to be hydrolyzed in the bloodstream and was confirmed to have low plasma stability in human plasma *in vitro*. The ability to restrict exposure of AGMB-447 to the lungs was confirmed in preclinical studies. Exposure to AGMB-447 after intratracheal administration in rodents was approximately 800- to 1,000-fold higher in the lung than in plasma as shown in the below figure. The major metabolite of AGMB-447 in plasma, MET-093, had no meaningful ALK5 inhibitory activity in cellular experiments. Consistent with the low systemic exposure of AGMB-447, we did not observe cardiac valve lesions or other concerning systemic toxicities in the preclinical toxicology program.

AGMB-447 exposure in the lung in rats

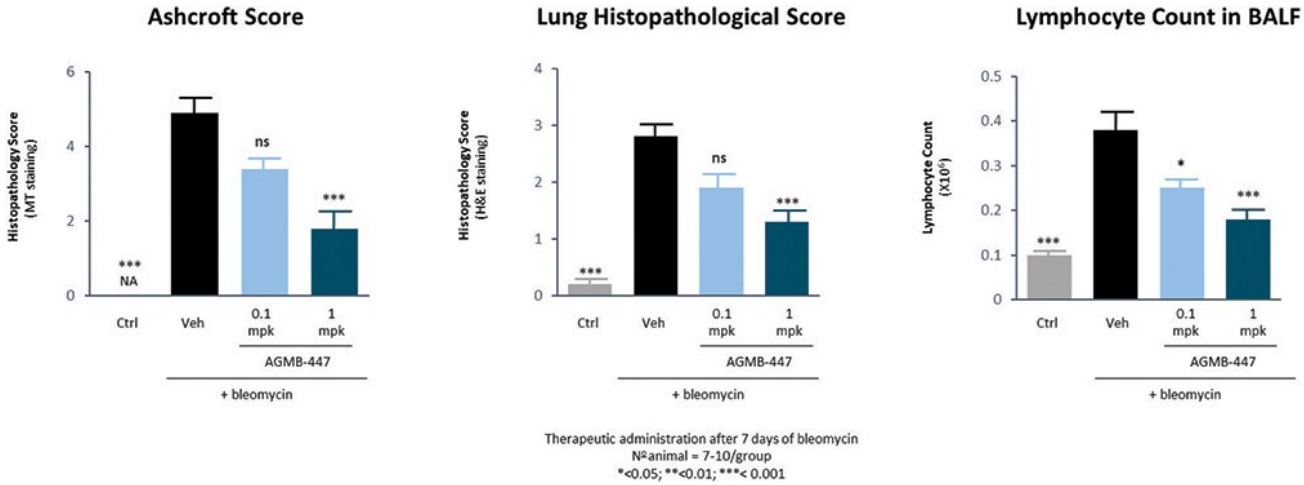


AGMB-447 - summary of dose-dependent findings in the bleomycin model across several fibrosis and inflammation readouts

The most common and best-characterized preclinical model of IPF is the bleomycin-induced lung injury model (in rodents), due to its ability to reproduce many aspects of the disease including epithelial injury, fibroblast proliferation, extracellular matrix accumulation and fibrotic remodeling of the lung tissue. As shown in the below figure, treatment with AGMB-447 led to dose-dependent reductions in the bleomycin model across a number of fibrosis and inflammation readouts. In this mouse model, treatment with AGMB-447 was initiated seven days after induction of fibrosis with bleomycin. Intratracheal doses of AGMB-447 at 0.1 mg/kg or 1 mg/kg were administered daily.

The Ashcroft score, a histological method of quantifying fibrosis, was significantly reduced with 1 mg/kg dose of AGMB-447. AGMB-447 also led to significant reductions in inflammation as measured by the number of lymphocytes in bronchoalveolar lavage fluid, or BALF and immune infiltration into the lung tissue (assessed by histopathology score).

AGMB-447 showed desired preclinical activity in the bleomycin therapeutic mice model

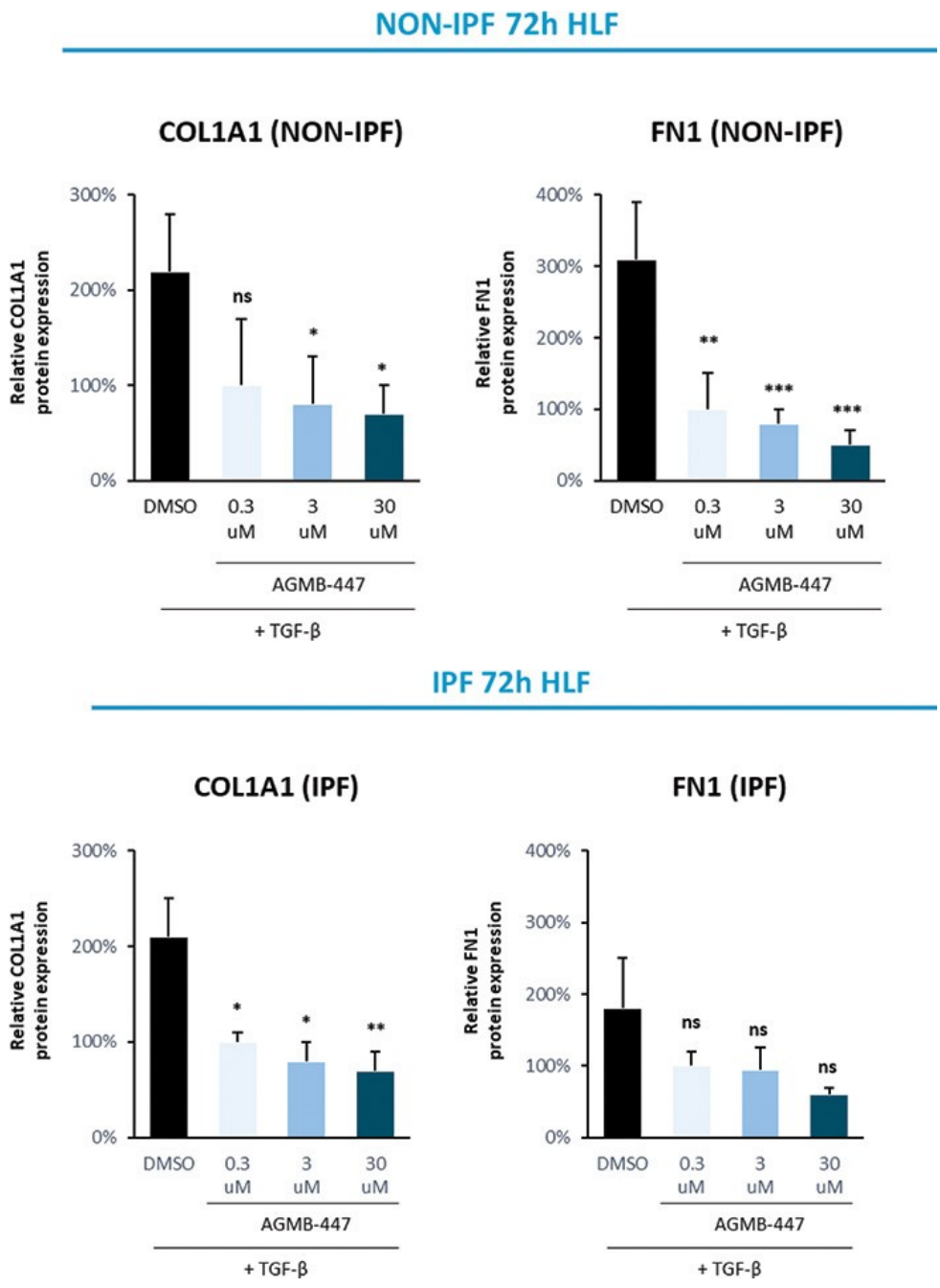


Fibrotic effect quantified by Ashcroft Score (histological method). Inflammatory effect quantified by the number of lymphocytes in bronchoalveolar lavage fluid (BALF) and histopathological score

AGMB-447 led to dose-dependent decreases in the release of COL1A1 protein

As shown in the below Figure, in *ex vivo* experiments using primary human lung fibroblasts, treatment with AGMB-447 led to dose-dependent decreases in the release of collagen type 1 alpha 1, or COL1A1, and FN1 protein, pro-fibrotic markers, into the supernatant of TGFβ treated cells. This effect was seen in fibroblasts from non-IPF human subjects and IPF patients. Similar results were obtained with another pro-fibrotic marker, PAI-1.

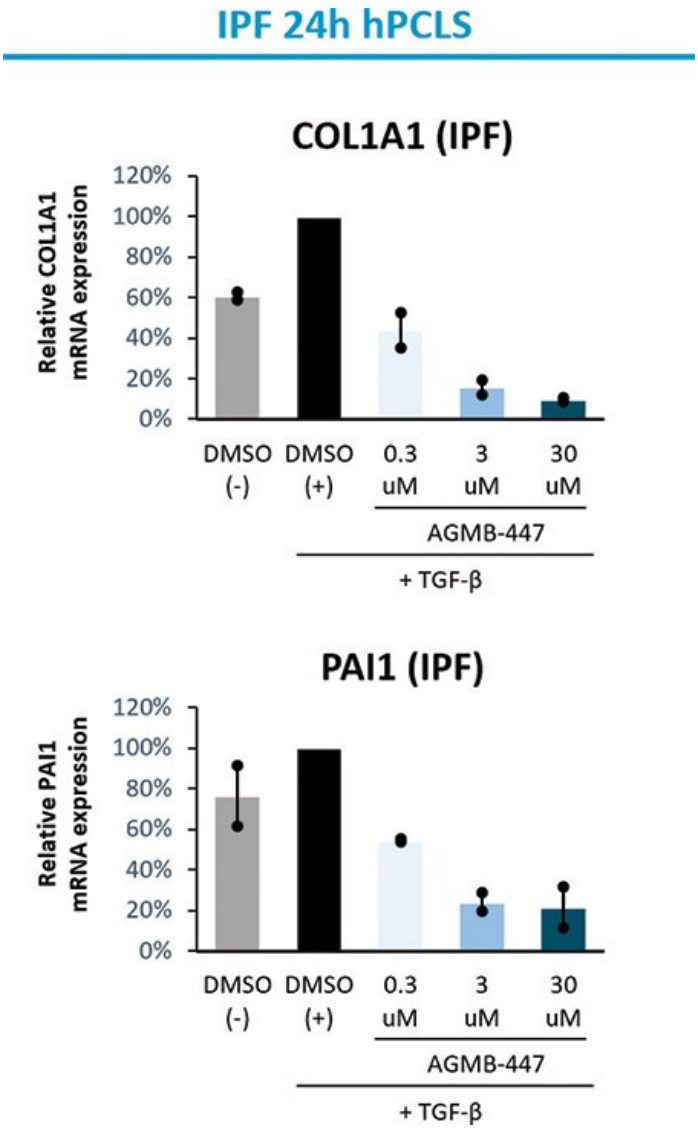
AGMB-447 reduced COL1A1 and FN1 protein in TGF-β stimulated primary human lung fibroblasts in non-IPF and IPF tissue



AGMB-447 led to dose-dependent decreases in profibrotic genes in human precision-cut lung slices

Human precision-cut lung slices, or hPCLS, which are small, uniform tissue slices generated from human lungs, are increasingly recognized and employed as an *ex vivo* organotypic model. In contrast to cell cultures, hPCLS retain the cellular complexity and the architecture of the lung, providing a platform to investigate perturbations in a near-native environment. As displayed in the below figure, we found that the expression of TGFβ-stimulated profibrotic genes, such as COL1A1, was decreased in a dose-dependent manner after treatment with AGMB-447 in hPCLS tissue from patients with IPF. Similar effects were observed for other profibrotic genes such as FN1, encoding fibronectin, integrin beta 6 (ITGB6), and SERPINE1, encoding PAI-1, and in non-IPF hPCLS.

AGMB-447 reduced COL1A1 and PAI-1 mRNA expression in hPCLS from IPF patients



AGMB-447 showed a potentially differentiated preclinical safety profile

We completed general toxicology studies up to six months in the rat and nine months in the dog with AGMB-447. Previous ALK5 inhibitors have caused severe heart valve lesions in rats after 3 to 14 days and in dogs after 1 month of treatment in early toxicology studies. In contrast, no cardiac valvular lesions were detected in any of the toxicology studies carried out to date with AGMB-447 in any of the species tested.

Histopathology findings in AGMB-447 were limited to the respiratory tract and were suggestive of nonspecific mucosal irritations for both rats and dogs. In rats, but not in dogs, laryngeal findings in the ventral cartilage were observed, consistent with the greater sensitivity of rodents to laryngeal injury in inhalation studies. However, because of the absence of ventral cartilage in humans and the known greater sensitivity of laryngeal injury in rats, these findings were not considered to be relevant to humans. Thus, while no head-to-head studies have been conducted versus systemic ALK5 inhibitors, we believe AGMB-447 has the potential for a differentiated preclinical safety profile, and we have defined a therapeutic window for clinical evaluation of AGMB-447 that supports target inhibition of ALK5 while potentially avoiding cardiotoxicity associated with systemic inhibition of ALK5 signaling.

Clinical development of AGMB-447

Phase 1 trials

AGMB-447-C101 is a Phase 1, randomized, double-blind, placebo-controlled, single ascending dose (SAD) and multiple ascending dose (MAD) clinical trial of orally inhaled AGMB-447 intended to assess its safety, tolerability, pharmacokinetics (PK), pharmacodynamics (PD) and target engagement in healthy participants and IPF patients. The trial consists of three parts: a SAD (Part A) and MAD (Part B) study in healthy participants and multiple dose study in IPF participants (Part C). AGMB-447 or placebo is administered by oral inhalation using a commercially available nebulizer as a single dose in the SAD, over 7 days in the MAD and over 14 days in the IPF cohort.

A schematic of the study design is presented in the figure below.

Part A SAD (alternating cohorts of 8 healthy participants - 6 of whom are to be randomized to AGMB-447 and 2 to be randomized to placebo): Up to 4 ascending dose levels (1mg, 3mg, 9mg, and 20mg) are planned to be evaluated in two alternating cohorts (referred to as Cohorts A1 and A2). Participants receive a single dose of AGMB-447 or placebo on one occasion for each treatment period.

Part A SAD bronchoscopy cohort (Cohort A3): A separate cohort of 12 healthy participants is planned to receive a single dose of AGMB-447 or placebo on one occasion and undergo bronchoscopy to assess PK in bronchoalveolar lavage, or BAL, and epithelial lining fluid, or ELF, as well as target engagement in BAL cells.

Part B MAD (12 healthy participants, 9 of whom are to be randomized to AGMB-447 and 3 are to be randomized to placebo); referred to as Cohorts B1 - B8: Participants receive multiple daily doses of AGMB-447 or placebo over 7 consecutive days. A blinded interim data review is conducted by the Safety Advisory Committee, or SAC, before each dose escalation to the next dose level to determine safety and tolerability. The dose levels and dosing frequency are confirmed by the SAC based on safety, tolerability, available PK data, and PD data observed at the previous dose levels (including the SAD).

Part C (up to 12 participants with IPF, 9 of whom are to be randomized to AGMB-447 and 3 to be randomized to placebo): Participants with IPF receive multiple doses of AGMB-447 or placebo over 14 days.

Schematic Overview of AGMB-447-C101 Study Design

Because AGMB-447 is a lung-restricted compound administered by inhalation, invasive procedures are required to assess the local exposure, pharmacodynamics, and target engagement of this compound in the lung. Therefore, bronchoscopies were performed in one SAD cohort and in each multiple dose cohort of the MAD at 1.5, 6, or 24 hours after the last dose, and in the IPF cohort 6 hours after the last dose on Day 14.

Target engagement is assessed by measuring the effect of AGMB-447 on TGFβ signaling through evaluation of pSMAD3 levels in cells isolated from BALF. BAL cells are collected through the above-mentioned bronchoscopies. pSMAD3 acts as signaling molecules directly downstream from the TGFβ receptor and therefore are considered reliable biomarkers for TGFβ activation.

Study Status

As of February 2026, four dosing regimens have been evaluated in the SAD in a total of 33 healthy participants, including 1mg QD, 3mg QD, 9mg QD, and 20mg QD. In the MAD, four dosing regimens have been evaluated and reported in 75 participants over seven consecutive days, including 1mg QD, 3mg QD, 9mg QD, and 4.5mg BID. Interim data from the four completed SAD cohorts, the SAD bronchoscopy cohort, and the first six cohorts of the MAD (B1 - B6) are summarized below. Data from the MAD cohorts B7 and B8 are currently under review and pending analysis. The IPF cohort (Part C) study conduct is currently ongoing, with the first patients dosed.

Participant disposition (Part A & Part B):

A total of 108 healthy participants were enrolled in the SAD and MAD 1-6 Cohorts.

SAD

A total of 33 unique participants (22 unique participants in 2 alternating cohorts (Cohorts A1 and A2) and 11 participants in the SAD bronchoscopy cohort (Cohort A3)) were randomized to receive at least one dose of study drug or placebo. Of the 22 unique participants randomized, 9 participated in more than one cohort and were counted more than once across multiple doses, accounting for 31 unique administrations.

Over 75% of the participants in the alternating cohorts completed the SAD portion of the study. In two cases, participants discontinued the study treatment early due to an AE (details provided in Safety Results below); all other early discontinuations in study treatment or early discontinuations from the study were due to withdrawal of consent or for other reasons.

In the SAD bronchoscopy cohort, all 11 healthy participants completed the study. In the AGMB447 treatment arm, two participants discontinued the study treatment (i.e., the inhalation was stopped prematurely) due to an AE (see Safety Results below for details), and one participant discontinued the study treatment (i.e., the inhalation) due to the full dose not being administered because of a technical issue with the nebulizer device.

MAD

A total of 75 healthy participants were randomized to the first 6 MAD cohorts.

All but one randomized participant (74/75) in the MAD Cohorts 1-6 completed the study; one participant in the MAD Cohort B3 (3mg QD) discontinued the study early due to Investigator’s decision. Discontinuation of study treatment was reported for 4 participants.

The table below summarizes the main findings from this interim readout of Study AGMB-447-C101.

Summary of Phase 1 interim clinical findings for AGMB-447 (SAD and MAD 1-6 in healthy participants)

Clinical findings	Observations
Safety and tolerability AGMB-447 showed no systemic safety signal and a generally favorable tolerability profile	● No systemic safety signal observed at different dose levels tested ● Most common tolerability signals were cough, wheezing and throat irritation, in line with other inhaled therapies ● Bronchospasm was observed in 6 healthy participants treated with AGMB-447
PK profile in healthy participants AGMB-447 resulted in high exposure to the lung with low systemic exposure	● Observed low systemic exposure of AGMB-447 across cohorts ● Rapid and higher exposure of inactive MET-093 confirms absorption, tissue penetration and efficient hydrolysis
Target Engagement Dose-dependent inhibition of ALK5 in BAL cells	● The 20mg SAD cohort and the 4.5mg BID and 9mg QD MAD cohorts achieved robust target engagement

Interim Safety Results

Overall, in the SAD and MAD B1-B6 cohorts, we observed a generally favorable safety profile of AGMB-447 in healthy participants. No systemic safety signals were detected, and no dose-limiting toxicities were observed. Tolerability signals including cough and additional respiratory events such as bronchospasm were observed and are described below.

Treatment-emergent adverse events, or TEAEs, were reported by almost all healthy participants across all AGMB-447 treatment arms, and in general, with a lower incidence in participants treated with placebo. All TEAEs were mild or moderate in severity. No severe or serious TEAEs or deaths were reported. The reported TEAEs were mostly respiratory in nature and were more frequently reported in the higher dose cohorts.

TEAEs leading to treatment discontinuation were reported in two participants in the SAD cohorts and in four participants in the MAD cohorts. These TEAEs were all respiratory AEs, except for a case of COVID-19 infection, and included cough, throat irritation, chest discomfort, wheezing, non-cardiac chest pain, a burning sensation, and dyspnea.

The table below provides an overview of TEAEs reported during the MAD of the study for completed Cohorts MAD 1-6.

Overview of Treatment-Emergent Adverse Events (Part B MAD)

	AGMB-447						
Subjects with n (%)	**MAD B1 1 mg QD (N=9)**	**MAD B2 3 mg QD (N=10)**	**MAD B3 9 mg QD (N=9)**	**MAD B4 4.5 mg BID (N=10)**	**MAD B5 4.5 mg BID (N=9)**	**MAD B6 9 mg QD (N=10)**	**Pooled placebo (N=18)**
TEAE	6 (66.7)	10 (100)	9 (100)	10 (100)	9 (100)	10 (100)	14 (77.8)
Serious TEAE	0	0	0	0	0	0	0
Worst-case moderate TEAE	2 (22.2)	4 (40.0)	6 (66.7)	7 (70.0)	1 (11.1)	6 (60.0)	6 (33.3)
Worst-case severe TEAE	0	0	0	0	0	0	0
Related TEAE	5 (55.6)	9 (90.0)	9 (100)	10 (100)	9 (100)	10 (100)	4 (22.2)
TEAE leading to study drug discontinuation	0	1 (10.0)*	0	1 (10.0)	0	2 (20.0)	0
TEAE leading to study discontinuation	0	0	0	0	0	0	0

* One participant in MAD B2 Cohort experienced a TEAE which led to study drug discontinuation following physician decision.

In both the SAD and MAD B1-B6 cohorts, there was a higher incidence of respiratory TEAEs in the participants receiving AGMB-447, compared to those receiving placebo. These respiratory AEs included primarily cough and throat irritation. The majority of these TEAEs were of mild intensity and were temporally associated with drug administration (inhalation) or study procedures (e.g., bronchoscopy).

Study drugs administered via inhalation are associated with certain inherent risks within the respiratory tract due to direct airway exposure. Local irritation of the airways may occur, potentially manifesting as symptoms of cough, throat irritation, increased secretions, or in some cases, bronchospasm. In this study, bronchospasm was defined as a reduction in FEV1 greater than or equal to 15%.

In the MAD part, TEAEs of cough, wheezing, and throat irritation were more frequent and of longer duration in the MAD B3 and B4 cohorts (9mg QD and 4.5mg BID, respectively) compared to other cohorts and their respective placebo control. The SAC considered these dosing regimens to be safe but not well tolerated. The SAC further commented that there were no safety concerns with the dose level as most of these AEs resolved with no or minimal medical intervention and were not associated with additional adverse manifestations.

To improve the tolerability signals that had been detected in the MAD B3 and B4 cohorts, an improved dilution method using physiological saline was developed to reduce the amount of mannitol in the final drug product. Mannitol is an excipient contained within the AGMB-447 and placebo formulations and has the potential to induce bronchospasm in participants with airway hyper-responsiveness. The improved dilution method was used in subsequent cohorts (i.e., MAD cohorts B5 onwards) and was associated with a reduced incidence and severity of bronchospasm-related AEs in the MAD B5 and B6 cohorts (4.5mg BID and 9mg QD, respectively). The availability of this improved drug preparation method allowed further dilution of the drug product in these cohorts, also resulting in substantially shorter duration of cough events.

A total of 6 healthy participants treated with AGMB-447 presented with signs or symptoms suggestive of bronchospasm, defined as wheezing and/or a drop in FEV1 greater than or equal to 15%. These participants received 200µg of salbutamol, and their symptoms were generally manageable with salbutamol use. The study protocol was also amended to allow for the prophylactic use of salbutamol in participants presenting with a first case of bronchospasm. In such cases, participants received 200µg of salbutamol 5-15 minutes prior to subsequent dose administrations. The prophylactic use of salbutamol was introduced from the MAD Cohort B5 onwards.

Altogether, dilution of the drug product with a mannitol-free solution efficiently mitigated the development of cough and bronchospasm. As a result, the SAC deemed the dosing regimens used in the MAD B5 and B6 cohorts (4.5mg BID and 9mg QD, respectively), where the improved dilution method was implemented, safe and well tolerated for use in healthy participants and participants with IPF for use in the ongoing Phase 1 trial.

Clinical laboratory tests showed no clinically relevant changes in liver enzymes nor other routine blood chemistry parameters following administration of AGMB-447 across dose levels and dosing regimens.

No findings of concern were reported in vital signs. No clinically relevant changes in ECG parameters were observed.

Pharmacokinetic Results - Low systemic exposure of AGMB-447 in healthy participants

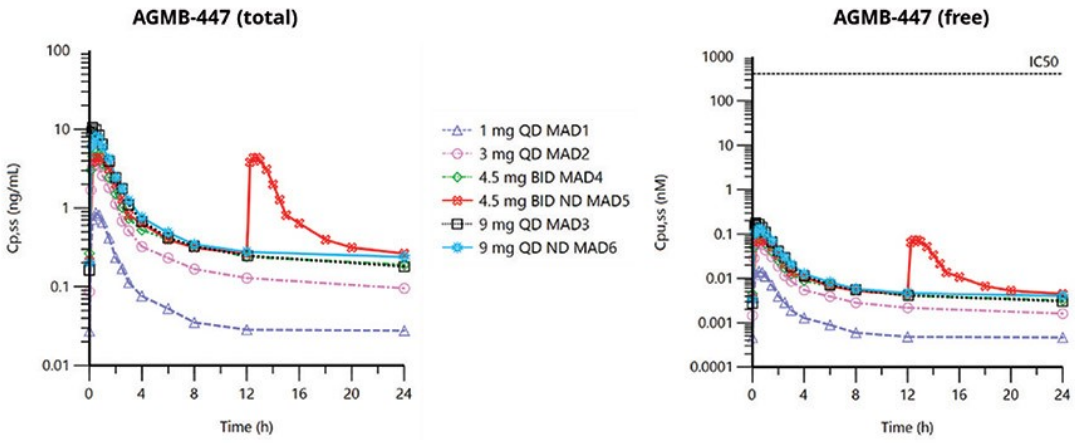
Following both single and multiple dose administrations, AGMB-447 was observed to be rapidly absorbed, with plasma peak concentrations occurring within approximately 0.25-0.74 hours. Across dose levels and regimens, systemic exposure to AGMB-447 remained low, with Cmax increasing dose-proportionally and AUC0-t showing slightly greater than dose-proportional increases. The primary metabolite, MET-093, consistently appeared within 1-1.5 hours post-dose, consistent with rapid hydrolysis of AGMB-447. Also, in keeping with the rapid and extensive metabolization of AGMB-447, exposure of the MET-093 metabolite was markedly higher than the parent compound (up to ~25-fold in SAD and ~19-fold in MAD), with stable metabolite-to-parent ratios across doses and regimens. While MET-093 Cmax rose dose-proportionally, AUC0-t tended to increase more than proportionally, supporting its contribution to overall systemic exposure.

After 7 days of dosing, AGMB-447 showed little accumulation with once daily dosing and only slightly higher, but still modest, accumulation with BID dosing. MET-093 accumulation was comparable to AGMB-447. Urinary recovery of both AGMB-447 and MET-093 was consistently low (<1%), regardless of dose or regimen. Renal clearance values for both compounds remained stable across cohorts and were below reference creatinine clearance.

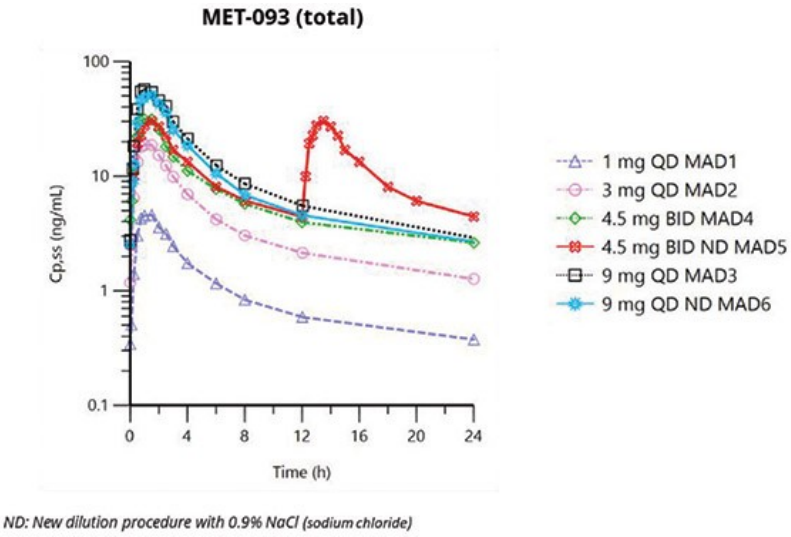
Pharmacokinetics, systemic AGMB-447 and metabolite MET-093 concentrations

As shown in the figure below, multiple dose administration of inhaled AGMB-447 achieved very low systemic concentrations of AGMB-447 (for both total levels and for the free fraction unbound to plasma proteins). After inhalation, AGMB-447 was rapidly metabolized in plasma through hydrolyzation into its main, inactive metabolite MET-093. The observed low systemic exposure of AGMB-447 and the high systemic exposure of MET-093 provide support for the hypothesized lung-restricted mode-of-action of AGMB-447. The graph also shows that the free fraction concentration of AGMB-447 was well below its IC50 (>100-1000x). We believe that this suggests that the compound could avoid the risks of toxicities associated with systemic ALK5 inhibition. Finally, nebulization of AGMB-447 with the selected inhalation device resulted in consistent and reproducible exposure profiles, as shown by the overlapping profiles of the 2 cohorts assessing 4.5mg BID, and again in the two cohorts assessing 9mg QD.

First-in-human PK profile of AGMB-447 and main metabolite MET-093 (MAD 1-6; Day 7)



Free: free fraction in plasma, considered at 1%; ND: New dilution procedure with 0.9% NaCl (sodium chloride)

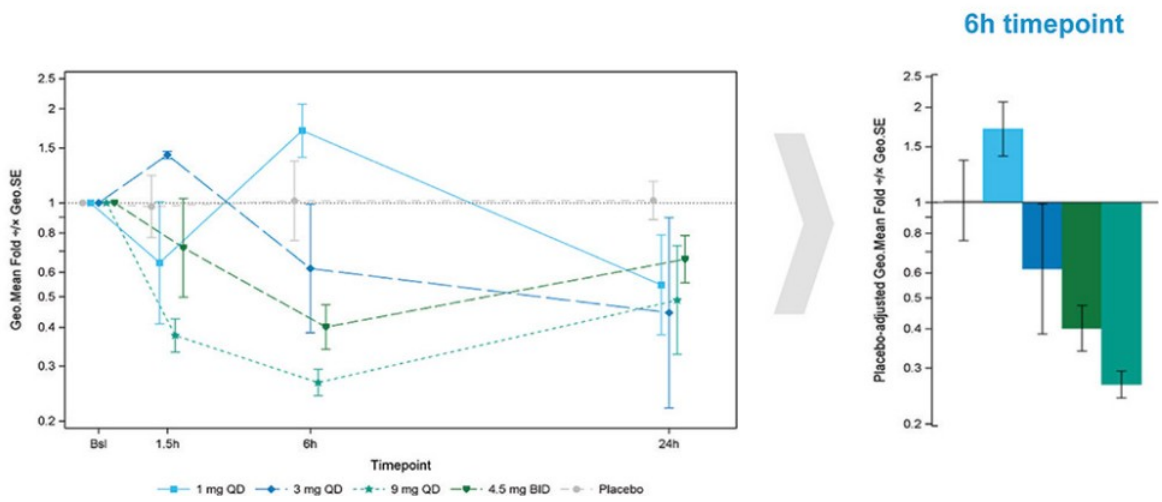


ND: New dilution procedure with 0.9% NaCl (sodium chloride)

Pharmacodynamic Results - Target engagement

To assess target engagement, we measured ALK5 inhibition by assessing pSMAD3 levels in BAL cells in the bronchoscopy cohort of the SAD portion, and in the MAD cohorts of the Phase 1 study conducted in healthy participants. SMAD3 is transcription factor which, upon the direct phosphorylation by ALK5, translocates to the cell nucleus to drive the expression of fibrogenic TGFβ-inducible genes. SMAD3 phosphorylation therefore represents a very direct and meaningful marker of target engagement. We observed a generally dose-dependent inhibition of ALK5 activity in the BAL cells, with robust target engagement observed for the 20mg SAD cohort and the 4.5mg BID and 9mg QD MAD cohorts. This indicates efficient inhibition of the TGFβ signaling pathway following local administration of AGMB-477.

pSMAD3 inhibition in BAL cells with AGMB-447 in healthy participants



Conclusion

In the ongoing Phase 1 study, the interim data support the lung-restricted PK profile of AGMB-447 in healthy participants, and no safety signals were observed. Tolerability signals commonly reported for inhaled therapies, such as cough and bronchospasm, were initially observed but efficiently mitigated by diluting the drug product with an improved dilution method.

Measurement of SMAD3 phosphorylation in BAL cells was used to assess target engagement. We observed that inhaled AGMB-447 inhibits ALK5 activity in BAL cells, indicating generally dose-dependent target engagement in the lung.

We believe that AGMB-447 has the potential to address the high unmet medical need that exists in IPF. AGMB-447 was designed to safely and potently block the key fibrogenic pathway TGFβ through local, lung-restricted ALK5 inhibition. Low systemic exposure and in particular low hepatic exposure to the active parent compound potentially limits the risk of clinically significant drug-drug interactions. Together with the observed safety profile of AGMB-447, we believe this finding potentially also makes AGMB-447 a favorable candidate for combination therapy with currently approved systemic therapies.

Outlook

The IPF cohort (Part C) study conduct is currently ongoing, with the first patients dosed. In this cohort, up to 12 participants with IPF will receive multiple doses of AGMB-447 or placebo over 14 days. We expect to report the results in IPF patients in the second half of 2026.

We received positive scientific advice from the UK Medicines and Healthcare products Regulatory Agency (MHRA), supporting our planned Phase 2 trial in IPF patients. We are on track to initiate a Phase 2 proof-of-concept study with AGMB-447 in IPF in the second half of 2026.

Discovery and preclinical portfolio

We have a robust discovery pipeline with several programs in the early stages of development, including AGMB-101, our most advanced preclinical asset.

AGMB-101 for the treatment of liver cirrhosis

AGMB-101, our third product candidate, is an HGF-mimetic monoclonal antibody that acts through agonism, or stimulation, of the MET receptor and has demonstrated both antifibrotic and regenerative activity in preclinical models. HGF is a well-characterized growth factor with key roles in homeostasis and regeneration of multiple organs and tissue. Preclinical experiments have demonstrated that AGMB-101 can mimic the activity of HGF, preventing injury and accelerating tissue regeneration. In 2025, we received regulatory authorization to conduct a Phase 1 single ascending dose trial in healthy participants and patients with liver cirrhosis. We are assessing initiation of further development of AGMB-101 as we explore strategic options for the candidate and its related intellectual property.

Liver cirrhosis background

Liver cirrhosis is an advanced stage of liver fibrosis which develops in patients with chronic liver disease. The underlying causes of cirrhosis include obesity and metabolic dysfunction, viral infection, alcohol abuse, cholestatic diseases and autoimmune hepatitis. These various insults induce liver inflammation which, over time, leads to the accumulation of fibrotic scar tissue within the liver. The scar tissue that forms replaces healthy liver tissue and can impede normal blood flow through the liver, causing increased pressure in the portal system. Both effects contribute to liver failure. One of the most serious complications of cirrhosis is portal hypertension caused by restricted blood flow in the portal vein and smaller veins that drain off of it. Portal vein hypertension is the most common cause of hospitalization and death in people with cirrhosis. Patients with cirrhosis are classified as having compensated cirrhosis or decompensated cirrhosis. Patients with compensated cirrhosis have asymptomatic disease and a median survival of up to twelve years. Progression into decompensated cirrhosis is associated with the development of overt decompensation events, including severe gastrointestinal bleeding, encephalopathy, ascites, severe systemic infections, as well as cardiac and renal failure. These patients have a median survival of approximately two years.

Worldwide it is estimated that there are 110 million to 130 million cases of cirrhosis, approximately 90% of which are compensated cirrhosis. In 2019, cirrhosis led to 1.5 million deaths worldwide. In the United States, 4.9 million people have cirrhosis. Annual direct and indirect costs for the care of cirrhosis exceed $12.0 billion in the United States alone. In 2023, chronic liver disease and cirrhosis were the tenth leading cause of death in the United States.

Liver cirrhosis treatments

Medical care for patients with liver cirrhosis focuses on treating the underlying causes of cirrhosis including antiviral therapy, anti-cholestatic agents, alcohol abstinence, and metabolic therapies for metabolic dysfunction-associated steatohepatitis. Medical management also focuses on managing symptoms and complications of cirrhosis. However, there is no specific therapy for the treatment of cirrhosis. While liver transplantation may be an option for some patients, not all are eligible due to factors such as organ availability and overall health.

Our potential solution, AGMB-101

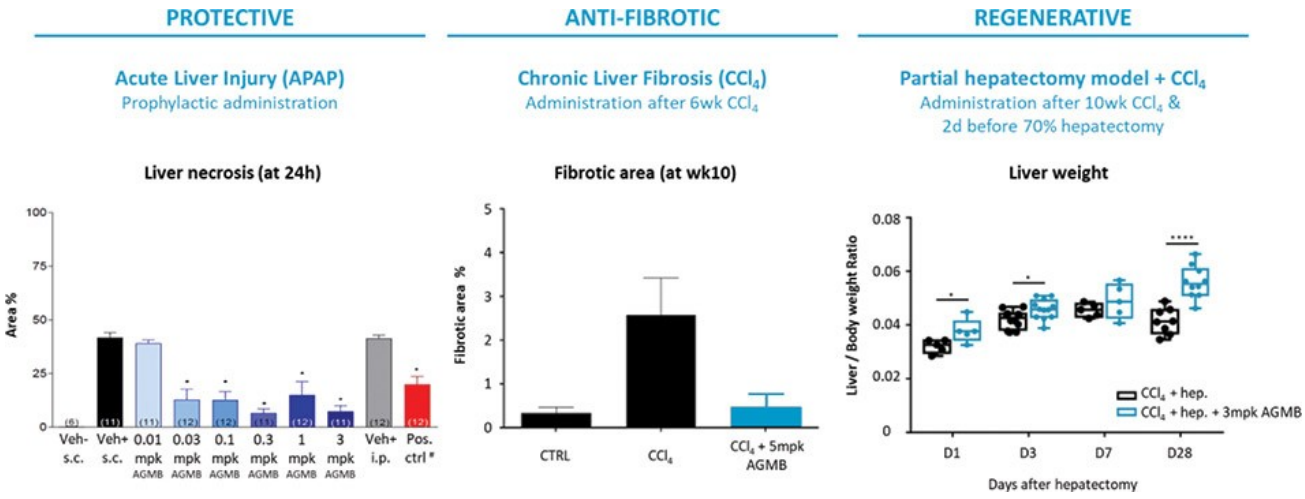
We are developing AGMB-101, an HGF-mimetic monoclonal antibody. We have generated preclinical data which suggests that activation of this receptor with AGMB-101 can mimic the effects of HGF, potentially reversing the fibrotic process in cirrhosis and stimulating the regeneration of healthy liver cells to restore hepatic function.

AGMB-101 was created on the argenx Simple® antibody platform using the antibody-binding domains of antibodies generated in llamas to the extracellular domain of the HGF receptor. These domains were humanized and combined with human IgG1 heavy chains to create AGMB-101. AGMB-101 also contains a set of mutations, referred to as LALA mutations, which decrease binding to the FcRg receptors, reducing its ability to activate the immune system.

AGMB-101 is distinct from most other antibodies in that it functions as an agonist of the HGF receptor. Incubation of HGF-receptor-expressing cells with AGMB-101 resulted in phosphorylation of the receptor and downstream proteins in the HGF signaling pathway in a dose-dependent manner. AGMB-101 treatment of cells recapitulated HGF activity in various assays such as protection against drug-induced apoptosis, epithelial cell scattering and branching morphogenesis.

In vivo, AGMB-101 mimicked the biology of HGF in models designed to measure its protective, antifibrotic and regenerative potential to treat fibrotic diseases in the liver. In an acute liver injury model (acetaminophen- or APAP-induced), prophylactic treatment with AGMB-101 reduced liver necrosis from 0.03 mg/kg. In a carbon tetrachloride, or CCl4, model of chronic liver injury, treatment with AGMB-101 for four weeks reduced fibrosis. In a partial hepatectomy model, mice with pre-existing CCl4-induced liver damage were subjected to hepatectomy in which 70% of the liver was removed. Treatment with AGMB-101 improved survival and triggered robust hepatocellular regeneration resulting in significantly higher liver weight compared to treatment with a control antibody. Based on these and other data, we believe AGMB-101 may potentially be effective in fibrotic liver disorders.

AGMB-101 treatment had *in vivo* activity in models corresponding to the prevention or treatment of liver diseases



Competition

The biotechnology and biopharmaceutical industries are characterized by rapidly advancing technologies, strong competition and an emphasis on proprietary products. While we believe that our R&D capabilities, expertise in growth factor biology, ability to execute business development transactions, agility and personnel provide us with competitive advantages, we face substantial competition from many different sources, including larger pharmaceutical companies with greater resources. Smaller specialized biotechnology and biopharmaceutical companies, academic research institutions, governmental agencies, as well as public and private institutions are also potential sources of competitive products and technologies, including through collaborative arrangements with large and established biopharmaceutical companies to (i) obtain support for their research, development and commercialization of products or (ii) combine several treatment approaches to develop longer lasting or more efficacious treatments that may potentially directly compete with our current or future product candidates. Mergers and acquisition activity in the pharmaceutical, biopharmaceutical and biotechnology sector is likely to result in greater resource concentration among a smaller number of our competitors. We also face competition in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and enrolling patients for clinical trials, and acquiring technologies complementary to, or necessary for, our programs.

We believe that the key competitive factors affecting the success of any of our product candidates will include efficacy, safety profile, convenience, method of administration, cost, level of promotional activity and intellectual property protection.

In addition to the current standard-of-care treatments to address the diseases we are targeting in therapeutic development programs, numerous commercial and academic preclinical studies and clinical trials are being undertaken by a large number of parties to assess novel technologies and product candidates.

There are a number of large biopharmaceutical companies that are currently pursuing the development of products for the treatment of various fibrosis indications. Companies that we are aware of that aim to inhibit various parts of the TGF-β pathway for the treatment of fibrosis include large companies with significant financial resources such as Merck & Co., Inc., Sanofi S.A., Roche Holding AG, Boehringer Ingelheim International GmbH, Bristol Myers Squibb Co. and Amgen Inc. We are aware of several marketed and investigational products in our leading disease areas, including but not limited to:

- Ontunisertib (AGMB-129) for FSCD: since FSCD is a subset of CD patients, we will compete with the standard-of-care for CD patients. This includes corticosteroids (e.g. budenoside, prednisone), immunomodulators (e.g. azathioprine, 6-MP, methotrexate) and approved advanced therapeutics (e.g. anti-TNF, anti-IL12/23 & IL23, anti-integrins, JAK inhibitors). Next to this, we will compete with companies currently developing novel product candidates. Our most direct competitors are the companies developing product candidates for FSCD, such as RedX Pharma Ltd, Palisade Bio and Enveda. In addition, we will compete with companies developing product candidates in CD with a potential anti-fibrotic effect (e.g. anti-TL1A and combinations, miR-124 modulators) including Merck & Co., Teva Pharma Ltd. & Sanofi S.A., Roche Holding AG, Pfizer Inc., Spyre Therapeutics Inc.,Xencor Inc, Caldera Therapeutics Inc., Boehringer Ingelheim International GmbH, Earendil Labs and Abivax SA. Finally, we will compete with companies developing product candidates in inflammatory bowel disease with gastrointestinal-restricted characteristics including Eli Lilly, AstraZeneca PLC and Spyre Therapeutics Inc.

- AGMB-447 for IPF: There are currently three approved products for the treatment of IPF: Esbriet is marketed by Roche Holding AG and Ofev is marketed by Boehringer Ingelheim International GmbH. In addition, Jascayd (nerandomilast), developed by Boehringer Ingelheim International, has recently received FDA approval to treat IPF. United Therapeutics Corporation announced positive Phase 3 results in IPF for its TETON-1 and TETON-2 study with Tyvaso, the company will file for FDA approval for Tyvaso in IPF. Also, companies currently developing product candidates in IPF using inhaled administration include Avalyn Pharma Inc., Sarepta Therapeutics Inc., and Mannkind Corporation. Finally, companies currently developing product candidates in IPF using systemic administration include Bristol-Myers Squibb Co., PureTech Health (Celea Therapeutics), RedX Pharma, Vicore Pharma Holding AB, Endeavor BioMedicines, Boehringer Ingelheim International GmbH, Lassen Therapeutics Inc., Calliditas Therapeutics AB, Roche Holding AG, RedX Pharma Ltd., InSilico Medicine Inc., Contineum Therapeutics Inc., Structure Therapeutics Inc. AstraZeneca PLC, Eli Lilly, Calluna Pharma Inc. and Daewoong Pharmaceutical Co Ltd.

- AGMB-101 for liver cirrhosis: No approved products exist to treat cirrhosis, but there are several companies focused on the development of product candidates for liver cirrhosis or liver fibrosis, such as Madrigal Pharmaceuticals, Inventiva Pharma SA, Novo Nordisk A/S (Akero Therapeutics Inc.), Glaxosmithkline PLC (Boston Pharmaceuticals Inc.), Roche Holding AG (89 Bio Inc.), Galectin Therapeutics Inc. and Alentis Therapeutics AG. In addition, companies that focus on the development of product candidates for liver-related diseases that can lead to cirrhosis, including AstraZeneca PLC, Boehringer Ingelheim International GmbH, Eli Lilly, Innovent Biologics Inc., Johnson & Johnson, Merck & Co. Inc., Novo Nordisk A/S, Pfizer Inc., Roche Holding AG, Takeda Pharmaceutical Company Limited, Altimmune Inc., Arrowhead Pharma Inc. and Viking Therapeutics, Inc.

Our commercial opportunity could be reduced or eliminated if one or more of our competitors develop and commercialize products that are safer, more effective, better tolerated, or of greater convenience or economic benefit than our proposed product offering. Our competitors also may be in a position to obtain FDA or other regulatory approval for their products more rapidly, resulting in a stronger or dominant market position before we are able to enter the market.

Human Capital Resources

As of December 31, 2025, we had 62 employees and 18 consultants providing us directly with services. 38 of our employees and consultants hold M.D. or Ph.D. degrees. 55 of our employees and consultants work in research and development or intellectual property and 25 work in management and administrative areas. We do not employ a significant number of temporary employees. 53 of our employees have an employment contract with AgomAb Therapeutics NV, six have an employment contract with Agomab Spain and three have an employment contract with Agomab US. 33 of our employees are females and 29 are males.

We believe in passion and commitment and have built a strong team from all walks of life, who are up to the challenge and committed to make a difference for the patients we serve. We actively create a caring atmosphere, in which we love to work and maintain productive and happy lives. At Agomab, we foster empowerment, self-development, creativity, and a sense of community.

As an employer, we are a true believer in the value of a workforce in which people from all backgrounds are encouraged to develop themselves both personally and professionally. This is reflected in our equal gender balanced leadership team and broader workforce. We believe that happy and energized people, working well together in an environment in which they thrive, will do phenomenal and awesome things.

We are committed to ensure that no employee, candidate, or job applicant receives less favorable treatment on the grounds of race, age, disability, pregnancy, religion, gender identity and expression, sexual orientation, marriage or civil partnership status. At Agomab, we want to create an inclusive culture where everyone can be valued for who they are and in which individual differences and the contributions in all forms are recognized and valued.

Manufacturing and Supply

We do not own or operate, and currently have no plans to establish, any manufacturing facilities. We currently rely, and expect to continue to rely, on third-party contract development and manufacturing organizations, or CDMOs, for the manufacture and supply of the active pharmaceutical ingredients, or APIs, of our product candidates for preclinical studies and clinical trials, as well as for the commercial manufacture and supply of our product candidates, if approved. We also rely on CDMOs for the manufacture and supply of the inhalation device needed to administer our AGMB-447 product candidate in clinical trials, as well as for the commercial manufacture and supply thereof, if our AGMB-447 product candidate is approved. As our development programs expand and we build new process efficiencies, we expect to continually evaluate this strategy with the objective of satisfying demand for our clinical trials and, if approved, the manufacture, sale and distribution of commercial products. We believe we maintain and will have access to sufficient supply to avoid any material disruptions in the event of any need to replace one or more of our suppliers. We plan to secure additional supply sources as our product candidates advance, including for the commercial manufacture and supply of any products we successfully develop. All of our clinical-stage product candidates are manufactured under current Good Manufacturing Practice, or cGMP, through reliable and reproducible processes using standard equipment and readily available starting materials.

Intellectual Property

Our success depends in part upon our ability to protect our technology and intellectual property. We strive to protect the proprietary technologies that we believe are important to our business by relying on patents and trade secret laws, confidentiality procedures, and employee disclosure and invention assignment agreements. Our intellectual property is critical to our business and we strive to protect it through a variety of approaches, including by obtaining and maintaining patent protection in various countries for our product candidates. This includes plans to pursue and maintain patent protection intended to cover the composition of matter of ontunisertib (AGMB-129), AGMB-447 and AGMB-101, their methods of use, and other related technologies and inventions that are important to our business. Additionally, although we have pending patent applications, we have only one issued patent in the United States for AGMB-447 and one issued patent in the United States for ontunisertib (AGMB-129). In addition to seeking patent protection, we also rely on trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. Trade secrets can be difficult to protect, and while we have confidence in the measures we take to protect and preserve our trade secrets, such measures can be breached, and we may not have adequate remedies for any such breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors.

Our commercial success depends in part upon our ability to obtain and maintain patent and other proprietary protection for commercially important technologies, inventions and know-how related to our business, defend and enforce our intellectual property rights, in particular, our patent rights, preserve the confidentiality of our trade secrets and operate without infringing valid and enforceable intellectual property rights of others. For more information regarding the risks related to our intellectual property, please see “Risk factors-Risks related to our intellectual property.”

Patent portfolio

As of March 31, 2026, our patent estate included five issued U.S. patents, three pending U.S. patent applications, thirty-two issued foreign patents, six pending Patent Cooperation Treaty (PCT) applications and fifty-one pending foreign patent applications (including six pending European patent applications).

Ontunisertib (AGMB-129)

We have two patent families relating to our ontunisertib (AGMB-129) product candidate. The first patent family includes composition of matter and method of treatment claims directed to ontunisertib (AGMB-129). This patent family includes one issued U.S. patent and eight issued foreign patents, in China, India, Israel, Japan, Russia (via the Eurasian Patent Office), Saudi Arabia, Singapore, and South Africa, a pending U.S. non-provisional patent application, and fifteen pending ex-U.S. patent applications in North America (such as Canada and Mexico), South America (such as Argentina and Brazil), Europe, Asia (such as Japan, Malaysia, and South Korea), and Australia. The patents and the pending patent applications, if issued, are expected to expire in 2040, without giving effect to any potential patent term extensions or adjustments and assuming all maintenance fees are paid. The second patent family includes a patent application under the Patent Cooperation Treaty (PCT), and a pending application in Taiwan with claims directed to certain physical forms, including salts, polymorphic forms and compositions, of ontunisertib. Any national or regional stage applications which may be filed based on this PCT application, if filed and issued, are expected to expire in 2045, without giving effect to any potential patent term extensions or adjustments and assuming all maintenance fees are paid.

AGMB-447

We have two patent families relating to our AGMB-447 product candidate. The first patent family includes composition of matter and method of treatment claims directed to AGMB-447. This patent family includes one issued U.S. patent and one pending U.S. non-provisional patent application, four issued patents in Japan, Russia (via the Eurasian Patent Office), Saudi Arabia and South Africa, and sixteen pending ex-U.S. patent applications in North America (such as Canada and Mexico), South America (such as Argentina and Brazil), Europe, Asia (such as China, India, Malaysia and South Korea), the Middle East (such as Israel), Australia and New Zealand. The patent and the pending patent applications, if issued, are expected to expire in 2041, without giving effect to any potential patent term extensions or adjustments and assuming all maintenance fees are paid. The second patent family includes a patent application under the PCT, and a pending application in Taiwan with claims directed to certain physical forms, including salts, polymorphic forms and compositions, of AGMB-447. Any national or regional stage applications which may be filed based on this PCT application, if filed and issued, are expected to expire in 2045, without giving effect to any potential patent term extensions or adjustments and assuming all maintenance fees are paid.

AGMB-101 and Back Up Molecules

We have three patent families relating to our AGMB-101 product candidate and back up molecules. The first patent family includes composition of matter claims and method of treatment claims directed to AGMB-101 and back up molecules. This patent family includes nineteen issued patents, in the United States (two issued patents), Australia, Brazil, China (two issued patents), India, Japan (two issued patents), Mexico, New Zealand (four issued patents) South Korea (three issued patents) and Russia (two issued patents), one pending U.S. non-provisional patent application, and eleven pending ex-U.S. patent applications in North America (such as Canada), Europe, Asia (such as India and Japan), Australia, and Russia. The patents and the pending patent applications, if issued, are expected to expire in 2037, without giving effect to any potential patent term extensions or adjustments and assuming all maintenance fees are paid. The second patent family is directed to the use of an anti-MET agonistic antibody such as AGMB-101 in treating diabetes by promoting pancreatic islet cell growth. This patent family includes three issued patents in Australia, China and Japan, and four pending ex-U.S. patent applications in North America (such as Canada), Europe, Asia (such as India) and New Zealand. The patent and the pending patent applications, if issued, are expected to expire in 2039, without giving effect to any potential patent term extensions or adjustments and assuming all maintenance fees are paid. The third patent family is directed to the use of AGMB-101 in treating cancer or colorectal fibrosis. This patent family includes an issued U.S. patent relating to the use of AGMB-101 in treating colorectal cancer and a pending patent application in Europe. The patent and the pending patent application, if issued, are expected to expire in 2039, without giving effect to any potential patent term extensions or adjustments and assuming all maintenance fees are paid.

We have entered into a research and commercialization license agreement with argenx BV for certain patent rights and know-how for AGMB-101 in exchange for a profit-share certificate. The license agreement includes a non-exclusive, worldwide milestone-free and royalty-free research license to certain patent rights and know-how for the sole purpose of researching certain anti-MET SIMPLE antibodies in the field. The license agreement also grants a worldwide, exclusive, sub-licensable license under such patent rights and know-how to research, develop, manufacture, use and sell certain licensed products in the field. The license agreement expires on the last to expire licensed patent right and cannot be terminated by either party other than for cause or due to insolvency.

General remarks on patent protection

The patent positions for biopharmaceutical companies are generally uncertain and can involve complex legal, scientific and factual issues. In addition, the coverage claimed in a patent application can be significantly reduced before a patent is issued, and its scope can be reinterpreted and even challenged after issuance. As a result, we cannot guarantee that our ontunisertib, AGMB-447 and AGMB-101 product candidates will be protected or remain protectable by enforceable patents, even if issued. We cannot predict whether the patent applications we are currently pursuing will issue as granted patents in any particular jurisdiction or whether the claims of any granted patent will provide sufficient proprietary protection from competitors. Any patents that we hold may be challenged, circumvented or invalidated by third parties. The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries where we may elect to file, the patent term is 20 years from the earliest date of filing a non-provisional patent application. In the United States, a patent's term may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the USPTO in granting a patent. A United States patent term may be shortened, if a patent is terminally disclaimed by its owner, over another patent.

In the United States, the term of a patent covering an FDA-approved drug may be eligible for a patent term extension under The Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, as compensation for the loss of patent term during the FDA regulatory review process. The period of extension may be up to five years beyond the expiration of the patent, but cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval. Only one patent among those eligible for an extension may be extended. Similar provisions are available in Europe and in certain other jurisdictions to extend the term of a patent that covers an approved drug. It is possible that an issued United States patent covering ontunisertib, AGMB-447 or AGMB-101 may be entitled to a patent term extension. If any of our product candidates receives FDA approval, we intend to apply for a patent term extension, if available, to extend the term of the patent that covers the approved product candidate. We also intend to seek patent term extensions in any jurisdictions where they are available. However, there is no guarantee that the applicable authorities, including the FDA, will agree with our assessment of whether such extensions should be granted, and if granted, the length of such extensions.

In addition to patent protection, we may rely on other forms of regulatory and legislative non-patent exclusivity protection that are typically triggered by marketing approval of a product. In the United States, these include orphan drug exclusivity, pediatric exclusivity, new chemical entity exclusivity for drugs such as ontunisertib and AGMB-447, and reference product exclusivity for biologics such as AGMB-101. The EU and many other key markets outside the United States, have comparable forms of such exclusivity. However, there is no guarantee that we will obtain any of these forms of exclusivity protection for ontunisertib, AGMB-447, AGMB-101 or any future product candidate.

Trade secrets and proprietary information

We also rely on trade secret protection for our proprietary information that is not amenable to, or that we do not consider appropriate for, patent protection, including, for example, certain aspects of our manufacturing processes. However, trade secrets can be difficult to protect. Although we take steps to protect our proprietary information, including restricting access to our premises and our confidential information, as well as entering into agreements with our employees, consultants, advisors, contract research organizations, contract manufacturing organizations and potential collaborators, these agreements may be breached and we may not have adequate remedies for any breach. In addition, third parties may independently develop the same or similar proprietary information or may otherwise gain access to our proprietary information or disclose our technology. As a result, we may be unable to meaningfully protect our trade secrets and proprietary information. For more information regarding the risks related to our intellectual property, see "Risk Factors-Risks Related to Our Intellectual Property."

Government regulation

Government authorities in the United States, at the federal, state and local level, and in the European Union and other countries and jurisdictions, extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, post-approval monitoring and reporting, and import and export of drug and biological products. In addition, some jurisdictions regulate the pricing of drug and biological products. The processes for obtaining marketing approvals in the United States and in foreign countries and jurisdictions, along with subsequent compliance with applicable statutes and regulations and other regulatory authorities, require the expenditure of substantial time and financial resources.

Licensure and regulation of drugs and biologics in the United States

In the United States, drug and biological products used for the prevention, treatment, or cure of a disease or condition in humans are subject to regulation under the Federal Food, Drug, and Cosmetic Act, or the FDCA, and its implementing regulations, although biologics are approved for marketing under provisions of the Public Health Service Act, or the PHSA, via biologics license applications, or BLAs. The application process and requirements for approval of BLAs are very similar to those for NDAs. The failure to comply with applicable U.S. requirements at any time during the product development process, including preclinical testing and clinical testing, the approval process or post-approval marketing may subject an applicant to delays in the conduct of a clinical trial, regulatory review and approval, and/or administrative or judicial sanctions. These sanctions may include, but are not limited to, the FDA's refusal to allow an applicant to proceed with clinical testing, refusal to approve pending applications, application or license suspension or revocation, warning or untitled letters, adverse publicity, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines and civil or criminal investigations and penalties brought by the FDA or the Department of Justice or other governmental entities.

An applicant seeking approval to market and distribute a new drug or biologic in the United States generally must satisfactorily complete each of the following steps:

- preclinical laboratory tests, animal studies and formulation studies performed in accordance with applicable regulations, which may include good laboratory practices, or GLPs;
- submission to the FDA of an IND application for human clinical testing, which must become effective before human clinical trials may begin;
- approval by an institutional review board, or IRB, or ethics committee, or EC, for each clinical site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials to establish the safety and effectiveness of the product candidate for each proposed indication, in accordance with GCPs;
- preparation and submission to the FDA of an NDA for a drug product or a BLA for a biological product requesting marketing for one or more proposed indications, including submission of detailed information on the manufacture and composition of the product and proposed labeling;
- one or more FDA inspections of the manufacturing facility or facilities, including those of third parties, at which the product, or components thereof, are produced to assess compliance with current good manufacturing practice, or cGMP, requirements and to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality and purity;
- FDA audits of certain clinical trial sites to assure compliance with GCPs, and the integrity of clinical data in support of the NDA or BLA;
- payment of user fees and securing FDA approval of the NDA or BLA; and
- compliance with any post-approval requirements, including any postmarketing studies required by the FDA.

Before testing any product candidate in humans, the product candidate must undergo preclinical testing. Preclinical tests include laboratory evaluations of product chemistry, formulation and stability, as well as animal studies to evaluate the potential for activity and toxicity. The conduct of the preclinical tests and formulation of the compounds for testing must comply with applicable regulations and requirements. The results of the preclinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND application. The IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions about the product candidate or conduct of the proposed clinical trial, including concerns that human research subjects will be exposed to unreasonable health risks, and places the proposed clinical trial on clinical hold. In that case, the IND sponsor and the FDA must resolve the FDA concerns before the clinical trial can begin.

As a result, submission of the IND may result in the FDA not allowing the clinical trial to commence or on the terms originally specified by the sponsor in the IND. If the FDA imposes a partial or complete clinical hold, this action would delay either a proposed clinical trial or cause suspension of an ongoing clinical trial, or in the case of a partial clinical hold place limitations on the conduct of the clinical trial such as duration of treatment, until all outstanding concerns have been adequately addressed and the FDA has notified the company that investigation may proceed and then only under terms authorized by the FDA. This could cause significant delays or difficulties in completing planned clinical trials in a timely manner. The FDA may impose clinical holds on a drug or biological product candidate at any time before or during clinical trials due to safety concerns or non-compliance.

Human clinical trials in support of an NDA or BLA

Clinical trials involve the administration of the product candidate to healthy subjects or patients with the disease to be treated under the supervision of a qualified principal investigator in accordance with GCPs, including informed consent requirements. Clinical trials are conducted under clinical trial protocols detailing, among other things, the objectives of the clinical trial, inclusion and exclusion criteria, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND.

A sponsor who wishes to conduct a clinical trial outside the U.S. may, but is not required to, conduct the clinical trial under an IND. If a foreign clinical trial is not conducted under an IND, the sponsor may submit data from the clinical trial to the FDA in support of the NDA or BLA so long as the clinical trial is well-designed and conducted in accordance with GCPs, including review and approval by an independent ethics committee, and the FDA is able to validate the clinical trial data through an onsite inspection, if necessary.

Further, each clinical trial must be reviewed and approved by an IRB or, if applicable, an Ethics Committee, either centrally or individually at each institution at which the clinical trial will be conducted. The IRB or the Ethics Committee will consider, among other things, clinical trial design, patient informed consent, ethical factors and the safety of human subjects. An IRB must operate in compliance with FDA regulations. The FDA, IRB, the Ethics Committee or the clinical trial sponsor may suspend or discontinue a clinical trial at any time for various reasons, including a finding that the clinical trial is not being conducted in accordance with FDA requirements or the subjects or patients are being exposed to an unacceptable health risk. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or data monitoring committee. This group may recommend continuation of the clinical trial as planned, changes in clinical trial conduct, or cessation of the clinical trial at designated check points based on access to certain data from the clinical trial.

Clinical trials typically are conducted in three sequential phases, but the phases may overlap or be combined. Additional clinical trials may be required after approval.

- Phase 1 clinical trials are initially conducted in a limited population to test the product candidate for safety, including adverse effects, dose tolerance, absorption, metabolism, distribution, excretion and PD in healthy humans or, on occasion, in patients, such as cancer patients.

- Phase 2 clinical trials are generally conducted in a limited patient population to identify possible adverse effects and safety risks, evaluate the efficacy of the product candidate for specific targeted indications and determine dose tolerance and optimal dosage. Multiple Phase 2 clinical trials may be conducted by the sponsor to obtain information prior to beginning larger Phase 3 clinical trials.

- Phase 3 clinical trials proceed if the Phase 2 clinical trials demonstrate that a dose range of the product candidate is potentially effective and has an acceptable safety profile. Phase 3 clinical trials are undertaken within an expanded patient population to gather additional information about safety and effectiveness necessary to evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis for physician labeling.

In some cases, the FDA may approve an NDA or BLA for a product candidate but require the sponsor to conduct additional clinical trials to further assess the product candidate's safety and effectiveness after approval. Such post-approval clinical trials are typically referred to as Phase 4 clinical trials. These clinical trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication and to confirm clinical benefit in the case of products approved under accelerated approval. If the FDA approves a product while a company has ongoing clinical trials that were not necessary for approval, a company may be able to use the data from these clinical trials to meet all or part of any Phase 4 clinical trial requirement or to request a change in the product labeling. Failure to exhibit due diligence in conducting required Phase 4 clinical trials could result in withdrawal of approval or other FDA enforcement action.

Progress reports detailing the results of the clinical trials, among other information, must be submitted at least annually to the FDA, and written IND safety reports must be submitted to the FDA and the investigators within 15 days after the clinical trial sponsor determines that serious and unexpected suspected adverse events or findings from other clinical trials or animal or *in vitro* testing that suggest a significant risk for human subjects qualify for reporting. The sponsor must also submit an IND safety report to the FDA for any unexpected fatal or life-threatening suspected adverse reaction as soon as possible but in no case later than seven calendar days after the sponsor's initial receipt of the information.

A product candidate being studied in clinical trials may be made available for treatment of individual patients in certain circumstances. Pursuant to the 21st Century Cures Act, the manufacturer of an investigational drug for a serious disease or condition is required to make available, such as by posting on its website, its policy on evaluating and responding to requests for expanded access to an investigational product. This requirement applies on the earlier of the first initiation of a Phase 2 or Phase 3 clinical trial of the investigational product, or as applicable, 15 days after the investigational product receives a designation as a breakthrough therapy, fast track product, or regenerative advanced therapy.

Sponsors of clinical trials of drug and biological products are required to register and disclose certain clinical trial information on the website www.clinicaltrials.gov. Information related to the product, patient population, phase of investigation, clinical trial sites and investigators, and other aspects of a clinical trial are then made public as part of the registration. Sponsors are also obligated to disclose the results of their clinical trials after completion, although disclosure of such results can be delayed in certain circumstances.

Review and approval of an NDA or BLA

The results of product candidate development, preclinical testing and clinical trials, including negative or ambiguous results as well as positive findings, are submitted to the FDA as part of an NDA or BLA requesting approval to market the product. The NDA or BLA must contain extensive manufacturing information and detailed information on the composition of the product and proposed labeling as well as payment of a user fee.

The FDA has 60 days after submission of the application to conduct an initial review to determine whether the NDA or BLA is sufficiently complete to permit substantive review. If the FDA determines the NDA or BLA is not sufficiently complete, it will refuse to file the application. Once the submission has been filed, the FDA begins an in-depth review of the application. Under the goals agreed to by the FDA under the Prescription Drug User Fee Act, or PDUFA, the FDA has 10 months from the filing date in which to complete its initial review of a standard application and respond to the applicant, and six months from the filing date for a priority review of an application, for a total review time of 12 or 8 months, respectively. The FDA does not always meet its PDUFA goal dates for standard and priority reviews. The review process and the PDUFA goal date may also be extended if the FDA so requests or if the applicant otherwise provides additional information or clarification during the review process regarding information already previously provided in the submission.

As part of the review process, the FDA typically will inspect the facility or facilities where the product candidate is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the sponsor must develop methods for testing the identity, strength, quality, potency, and purity of the final biological product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the biological product candidate does not undergo unacceptable deterioration over its shelf life.

After the FDA's evaluation of the application and accompanying information, including the results of any inspections of the manufacturing facilities and any FDA audits of clinical trial sites to assure compliance with GCPs, the FDA will issue an approval letter or a complete response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. If the application is not approved, the FDA will issue a complete response letter, which will identify the deficiencies in the application and the conditions that must be met in order to secure approval of the application, and when possible, will outline recommended actions the sponsor might take to obtain approval of the application. Sponsors that receive a complete response letter may submit to the FDA information that represents a complete response to the issues identified by the FDA, withdraw the application or request a hearing. The FDA will not approve an application until issues identified in the complete response letter have been addressed.

The FDA may also refer the application to an advisory committee for review, evaluation and recommendation as to whether the application should be approved. In particular, the FDA may refer applications for novel product candidates or product candidates that present difficult questions of safety or efficacy to an advisory committee. Typically, an advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Even if the FDA approves an NDA or BLA, it may limit the approved indications for use of the product. It may also require that contraindications, warnings or precautions be included in the product labeling. In addition, the FDA may call for post-approval studies, including Phase 4 clinical trials, to further assess the product's safety after approval. The agency may also require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms, including a Risk Evaluation and Mitigation Strategy, or REMS, to help ensure that the benefits of the product outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals and elements to assure safe use, or ETASU. ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring and the use of patent registries. The FDA may prevent or limit further marketing of a product based on the results of post-market studies or surveillance programs.

After approval, many types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval. Such regulatory reviews can result in denial or modification of the planned changes, or requirements to conduct additional tests or evaluations that can substantially delay or increase the cost of the planned changes.

Regulation of combination products in the United States

Certain products may be comprised of components, such as drug components, biologic components and device components, that would normally be regulated under different types of regulatory authorities, and frequently by different centers at the FDA. These products are known as combination products.

Under the FDCA and its implementing regulations, the FDA is charged with assigning a center with primary jurisdiction, or a lead center, for review of a combination product. The designation of a lead center generally eliminates the need to receive approvals from more than one FDA center for combination products, although it does not preclude consultations by the lead center with another FDA center. The determination of which center will be the lead center is based on the "primary mode of action" of the combination product.

A combination product with drug primary mode of action, such as a drug delivered via a nebulizer, generally would be reviewed and approved under the new drug approval process; however, FDA reviewers in the relevant drug review division could consult with their counterparts in the device center to ensure that the device component of the combination product meets applicable requirements regarding safety, effectiveness, durability and performance.

Following approval of a combination product, each component of a combination product retains its regulatory status (as a drug or device, for example) and is subject to the requirements established by the FDA for that type of component. Accordingly, under FDA regulations, drug-device combination products are subject to both the cGMP requirements for drugs and the FDA's Quality System Regulation applicable to medical devices.

Fast track, breakthrough therapy and priority review designations

The FDA is authorized to designate certain products for expedited review if they are intended to address an unmet medical need in the treatment of a serious or life-threatening disease or condition. These programs are referred to as fast track designation, breakthrough therapy designation and priority review designation.

The FDA may designate a product for fast track review if it is intended, whether alone or in combination with one or more other products, for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition. For fast track products, sponsors may have greater interactions with the FDA and the FDA may initiate review of sections of a fast track product's application before the application is complete. This rolling review may be available if the sponsor provides, and the FDA approves, a schedule for the submission of the remaining information and the sponsor must pay the applicable user fee. The FDA's review goal does not begin until the last section of the application is submitted, however. Fast Track Designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

A product may be designated as a breakthrough therapy if it is intended, either alone or in combination with one or more other products, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The FDA may take certain actions with respect to breakthrough therapies, including holding meetings with the sponsor throughout the development process, providing timely advice to the product sponsor regarding development and approval, involving more senior staff in the review process, assigning a cross-disciplinary project lead for the review team, and taking other steps to help design the clinical trials in an efficient manner.

The FDA may designate a product for priority review if it is a product that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness of the treatment, diagnosis, or prevention of such condition. The FDA determines, on a case-by-case basis, whether the proposed product represents a significant improvement when compared with other available therapies. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting product reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes and evidence of safety and effectiveness in a new subpopulation. A priority designation is intended to direct overall attention and resources to the evaluation of such applications, and to shorten the FDA's goal for taking action on a marketing application from 10 months to 6 months.

Accelerated approval pathway

The FDA may grant accelerated approval to a product for a serious or life-threatening condition that provides meaningful therapeutic advantage to patients over existing treatments based upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit or on a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality, or IMM, and that is reasonably likely to predict an effect on IMM or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. Products granted accelerated approval must meet the same statutory standards for safety and effectiveness as those granted traditional approval.

For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radio-graphic image, physical sign, or other measure that is thought to predict clinical benefit but is not itself a measure of clinical benefit. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. An intermediate clinical endpoint is a measurement of a therapeutic effect that is considered reasonably likely to predict the clinical benefit of a product. The FDA has limited experience with accelerated approvals based on intermediate clinical endpoints, but has indicated that such endpoints generally may support accelerated approval where the therapeutic effect measured by the endpoint is not itself a clinical benefit, if there is a basis for concluding that the therapeutic effect is reasonably likely to predict the ultimate clinical benefit of a product.

The accelerated approval pathway is often appropriate in settings in which the course of a disease is long and an extended period of time is required to measure the intended clinical benefit of a product, even if the effect on the surrogate or intermediate clinical endpoint occurs rapidly.

The accelerated approval pathway is generally contingent on a sponsor's agreement to conduct one or more post-approval confirmatory clinical trials or studies to verify and describe the product's clinical benefit. These confirmatory clinical trials must be completed with due diligence, and failure to conduct or confirm a clinical benefit in post-marketing studies may prompt the FDA to withdraw the product from the market on an expedited basis. Unless otherwise informed by the FDA, all promotional materials for products approved under accelerated approval are subject to prior review by the agency. Pursuant to the Food and Drug Omnibus Reform Act, or FDORA, enacted in December 2022, the FDA is authorized to require a post-approval clinical trial to be underway prior to approval or within a specified time period following approval. Under FDORA, the FDA also has increased authority for expedited procedures to withdraw approval of a drug or indication approved under accelerated approval if, for example, the confirmatory trial fails to verify the predicted clinical benefit of the product.

Post-approval regulation

If regulatory approval for marketing of a product or new indication for an existing product is obtained, the sponsor will be required to comply with all post-approval regulatory requirements as well as any post-approval requirements that the FDA has imposed as part of the approval process. The sponsor will be required to report certain adverse reactions and production problems to the FDA, provide updated safety and efficacy information and comply with requirements for advertising and promotional labeling. Manufacturers and other parties involved in the drug supply chain for prescription drug and biological products must also comply with product tracking and tracing requirements and notify the FDA of counterfeit, diverted, stolen and intentionally adulterated products or products that are otherwise unfit for distribution in the United States Manufacturers and certain of their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with ongoing regulatory requirements, including cGMPs, which impose certain procedural and documentation requirements upon manufacturers. Accordingly, the sponsor and its third-party manufacturers must continue to expend time, money and effort in the areas of production and quality control to maintain compliance with cGMPs and other regulatory requirements.

The FDA may revoke or suspend the approval of an NDA or BLA if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market.

Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information, imposition of post-market studies or clinical trials to assess new safety risks, or imposition of distribution or other restrictions under a REMS program. FDA also has authority to require post-market studies and labeling changes, where appropriate. Other potential consequences for a failure to maintain regulatory compliance include, among other things:

- restrictions on the marketing or manufacturing of the product, product recalls, or complete withdrawal of the product from the market;
- fines, untitled letters or warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending applications or supplements to approved applications;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of drug and biological products that are placed on the market. Promotional materials must be submitted to the FDA at the time of their first use, and products may be promoted only for their approved indications and in a manner that is consistent with the approved labeling. Although physicians may prescribe legally available products for unapproved uses or in patient populations that are not described in the product's approved labeling (known as off-label use), companies with approved products may not market or promote such off-label uses. The FDA and other agencies enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability, including investigation by federal and state authorities.

From time to time, legislation is drafted, introduced, passed in Congress and signed into law that could significantly change the statutory provisions governing the approval, manufacturing, and marketing of products regulated by the FDA. In addition to new legislation, FDA regulations, guidance, and policies are often revised or reinterpreted by the agency in ways that may significantly affect the manner in which pharmaceutical products are regulated and marketed.

Orphan drug designation

Orphan drug designation in the United States is designed to encourage sponsors to develop products intended for rare diseases or conditions. In the United States, a rare disease or condition is statutorily defined as a condition that affects fewer than 200,000 individuals in the United States or that affects more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making available the product for the disease or condition will be recovered from sales of the product in the United States.

Orphan drug designation qualifies a company for tax credits and market exclusivity for seven years following the date of the product's marketing approval if granted by the FDA and if it is the first FDA approval for that product for the disease for which it has such designation. An application for designation as an orphan product can be made any time prior to the filing of an application for approval to market the product. If the FDA grants orphan drug designation, the generic identity of the product and its potential orphan use are disclosed publicly by the FDA. The product must then go through the review and approval process like any other product in order to be marketed.

A sponsor may request orphan drug designation of a previously unapproved product or new orphan indication for an already marketed product. In addition, a sponsor of a product that is otherwise the same product as an already approved orphan drug may seek and obtain orphan drug designation for the subsequent product for the same rare disease or condition if it can present a plausible hypothesis that its product may be clinically superior to the first drug. In the case of a biological product, whether said biological product is the same as another product for orphan drug designation purposes is based on whether the two products have the same principal molecular structural features. More than one sponsor may receive orphan drug designation for the same product for the same rare disease or condition, but each sponsor seeking orphan drug designation must file a complete request for designation.

If orphan drug exclusivity is granted by the FDA, the period of exclusivity begins on the date that the marketing application is approved by the FDA and applies only to the indication for which the product has been designated. The FDA may approve a second application for the same product for a different use or a second application for a clinically superior version of the product for the same use. The FDA cannot, however, approve the same product made by another sponsor for the same indication during the orphan drug exclusivity period unless it has the consent of the sponsor or the sponsor is unable to provide sufficient quantities of the product.

Pediatric studies and exclusivity

Under the Pediatric Research Equity Act of 2003, or PREA, an NDA, BLA or supplement thereto must contain data that are adequate to assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric sub-populations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. During development, sponsors must also submit pediatric clinical trial plans that contain an outline of the proposed pediatric clinical trial or studies the applicant plans to conduct, including clinical trial objectives and design, any deferral or waiver requests and other information required by regulation.

The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements. Unless otherwise required by regulation, PREA does not apply to a drug or biological product for an indication for which orphan designation has been granted, except that PREA will apply to an original application for a new active ingredient that is orphan-designated if the product candidate is a molecularly targeted cancer product intended for the treatment of an adult cancer and is directed at a molecular target that FDA determines to be substantially relevant to the growth or progression of a pediatric cancer.

Pediatric exclusivity is another type of non-patent marketing exclusivity in the United States and, if granted, provides for the attachment of an additional six months of marketing protection to the term of any existing regulatory exclusivity. This six-month exclusivity may be granted if a sponsor submits pediatric data that fairly respond to a written request from the FDA for such data. The data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, and the reports of requested pediatric studies are submitted to and accepted by the FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity cover the product are extended by six months.

Generic drug competition and exclusivity

The Hatch-Waxman Amendments to the FDCA established an abbreviated regulatory framework authorizing the FDA to approve generic drugs that are shown to contain the same active ingredients as, and to be bioequivalent to, pharmaceutical products previously approved by the FDA pursuant to an NDA. To obtain approval of a generic drug, an applicant must submit an abbreviated new drug application, or ANDA, to the FDA. An ANDA is a comprehensive submission that contains, among other things, data and information pertaining to the active pharmaceutical ingredient, bioequivalence, drug product formulation, specifications and stability of the generic drug, as well as analytical methods, manufacturing process validation data and quality control procedures. ANDAs are "abbreviated" because they generally do not include preclinical and clinical data to demonstrate safety and effectiveness. Instead, a generic manufacturer may rely on the preclinical and clinical testing previously conducted for a drug product previously approved under an NDA, known as the reference-listed drug, or RLD.

For an ANDA to be approved, the FDA must find that the generic version is the same as the RLD with respect to the active ingredients, route of administration, dosage form, and strength and conditions of use of the drug. The FDA must also determine that the generic drug is bioequivalent to the RLD. Under the statute, a generic drug is bioequivalent to an RLD if the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the RLD. Upon approval of an ANDA, the FDA determines whether the generic product is "therapeutically equivalent" to the RLD in its publication "Approved Drug Products with Therapeutic Equivalence Evaluations," also referred to as the "Orange Book." Physicians and pharmacists consider a therapeutically equivalent generic drug to be fully substitutable for the RLD. In addition, by operation of certain state laws, the FDA's designation of therapeutic equivalence often results in substitution of the generic drug without the intervention of the prescribing physician.

The Hatch-Waxman Amendments also specify a period of five years of non-patent regulatory exclusivity for a new drug containing a new chemical entity, or NCE. An NCE is a drug that contains no active moiety, which is the molecule or ion responsible for the physiological or pharmacological action of the drug substance, that has previously been approved by the FDA in any other NDA. Where such NCE exclusivity has been granted, an ANDA may not be filed with the FDA until the expiration of the five-years exclusivity, unless the ANDA is accompanied by a Paragraph IV certification, which states that the proposed drug will not infringe the RLD's listed patents or that such patents are invalid or unenforceable, in which case the applicant may submit its application four years following the RLD approval.

The Hatch-Waxman Amendments also specify a period of three years of exclusivity if an NDA includes reports of one or more new clinical investigations, other than bioavailability or bioequivalence studies, that were conducted by or for the applicant and are essential to the approval of the application. This three-year exclusivity period often protects changes to a previously approved drug product, such as a new dosage form, route of administration, combination or indication. Three-year exclusivity would be available for a drug product that contains a previously approved active moiety, provided the statutory requirement for a new clinical investigation is satisfied.

Upon approval of an NDA or a supplement thereto, NDA sponsors are required to list with the FDA each patent with claims that cover the applicant's product or an approved method of using the product. Each of the patents listed by the NDA sponsor is published in the Orange Book. When an ANDA applicant files its application with the FDA, the applicant is required to certify to the FDA concerning any patents listed for the reference product in the Orange Book, except for patents covering methods of use for which the ANDA applicant is not seeking approval. To the extent that a generic applicant relies on studies conducted for an already approved product, the applicant is required to certify to the FDA with respect to each patent that:

- the required patent information has not been filed;
- the listed patent has expired;

- the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or
- the listed patent is invalid, unenforceable or will not be infringed by the new product.
- A certification that the new product will not infringe the already approved product's listed patents or that such patents are invalid or unenforceable is called a Paragraph IV certification. If the applicant does not provide a Paragraph IV certification against the listed patents or indicates that it is not seeking approval of a patented method of use, the application will not be approved until all the listed patents claiming the referenced product have expired (other than method of use patents involving indications for which the applicant is not seeking approval).

If the ANDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA application has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days after the receipt of a Paragraph IV notice automatically prevents the FDA from approving the ANDA until the earlier of 30 months after the receipt of the Paragraph IV notice, expiration of the patent, or a decision in the infringement case that is favorable to the applicant. The ANDA also will not be approved until any applicable non-patent exclusivity listed in the Orange Book for the RLD drug has expired.

Biosimilar competition and exclusivity

The Biologics Price Competition and Innovation Act, or BPCIA, established a regulatory framework authorizing the FDA to approve biosimilars. Under the BPCIA, an applicant may submit an application for licensure of a biologic product that is "biosimilar to" or "interchangeable with" a previously approved biological product, or reference product. For the FDA to approve a biosimilar product, it must find that there are no clinically meaningful differences between the reference product and proposed biosimilar product in terms of safety, purity and potency. For the FDA to approve a biosimilar product as interchangeable with a reference product, the agency must find that the biosimilar product can be expected to produce the same clinical results as the reference product, and (for products administered multiple times) that the biologic and the reference biologic may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date of approval of the reference product. The FDA may not approve a biosimilar product until 12 years from the date on which the reference product was approved. Even if a product is considered to be a reference product eligible for exclusivity, another company could market a competing version of that product if the FDA approves a full BLA for such product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product. The BPCIA also established an exclusivity period for the first biosimilar approved as an interchangeable product. Biosimilar products deemed interchangeable by the FDA may be substituted by pharmacies depending on state law.

U.S. patent term restoration

Depending upon the timing, duration and specifics of FDA approval of product candidates, some of a sponsor's U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, or Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit restoration of the patent term for an eligible patent of up to five years as compensation for patent term lost during the FDA regulatory review process. Patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date and only those claims covering such approved product, a method for using it or a method for manufacturing it may be extended. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of an NDA or BLA plus the time between the submission date of an NDA or BLA and the approval of that application, except that the review period is reduced by any time during which the applicant failed to exercise due diligence. Only one patent applicable to an approved product is eligible for the extension and the application for the extension must be submitted within sixty (60) days of approval from FDA and prior to the expiration of the patent. The USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may apply for restoration of patent term for our currently owned or licensed patents, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant NDA or BLA.

Regulation and procedures governing approval of medicinal products in the EU and the UK

In order to market any medicinal product outside of the U.S., a company also must comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of products. Whether or not it obtains FDA approval for a product, an applicant will need to obtain the necessary approvals by the comparable regulatory authorities before it can initiate clinical trials or marketing of the product in those countries or jurisdictions. Specifically, with respect to the EU, no medicinal product may be placed on the market of a respective EU Member State unless a marketing authorization has been granted by the competent authorities of that Member State, or a centralized marketing authorization has been granted by the European Commission. Similar requirements apply in Great Britain. The process governing approval of medicinal products in the EU and Great Britain generally follows the same lines as in the United States It entails satisfactory completion of pharmaceutical development, preclinical trials and adequate and well-controlled clinical trials to establish the safety and efficacy of the medicinal product for each proposed indication.

Clinical trial approval

Since January 31, 2025, all clinical trials in the EU are governed by the Clinical Trials Regulation (EU) No 536/2014, which replaces Directive 2001/20/EC and introduces a harmonized approval process via the Clinical Trials Information System (CTIS) operated by the European Medicines Agency. Despite a three-year transition period, sponsors continue to face challenges such as technical hurdles, administrative complexity, and delays in trial approvals and amendments. Targeted changes to the EU Clinical Trials Regulation may be introduced as part of the European Commission's competitiveness agenda.

Following its departure from the EU, the UK did not adopt the EU Clinical Trials Regulation. Instead, using powers under the Medicines and Medical Devices Act 2021, the UK government enacted the Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025, signed into law in April 2025 and taking effect on April 28, 2026. These reforms mark the most significant overhaul of the UK clinical trials framework in two decades, aiming to streamline approvals, reduce administrative burdens, and introduce risk-proportionate regulation, while maintaining international alignment and supporting innovation.

Marketing authorization

To obtain a marketing authorization for a product under the EU regulatory system, an applicant must submit a marketing authorization application, either to the European Medicines Agency, or the EMA, using the centralized procedure or to competent authorities in the EU Member State using the other procedures (decentralized procedure, national procedure, or mutual recognition procedure). A marketing authorization may be granted only to an applicant established in the EU. Regulation (EC) No. 1901/2006 concerning medicinal products for pediatric use provides that, in order to obtain a marketing authorization in the EU, an applicant must submit (i) either the results of all studies performed and details of all information collected in compliance with an agreed pediatric investigation plan, or PIP, or (ii) a decision of the EMA granting a product-specific waiver, class waiver, or a deferral with respect to a PIP.

The centralized procedure provides for the grant of a single marketing authorization by the European Commission that is valid for all EU Member States, and in the additional Member States of the European Economic Area, or the EEA, (Norway, Iceland and Liechtenstein). Pursuant to Regulation (EC) No. 726/2004, the centralized procedure is compulsory for specific products, including for medicines produced by certain biotechnological processes, products designated as orphan medicinal products, advanced therapy medicinal products (gene therapy, somatic cell therapy or tissue engineered products) and products with a new active substance indicated for the treatment of certain diseases, including products for the treatment of cancer and auto-immune diseases and other immune dysfunctions, viral diseases and neurodegenerative disorders. The centralized procedure is optional for products that contain an active substance for any other indications, or which are a significant therapeutic, scientific or technical innovation or whose authorization would be in the interest of public health at the EU level.

Under the centralized procedure, the EMA's Committee for Medicinal Products for Human Use, or CHMP, is responsible for conducting the assessment of a product to define its risk/benefit profile. The CHMP recommendation is then sent to the European Commission, which adopts a decision binding in all EEA Member States. Under the centralized procedure, the maximum timeframe for the evaluation of a marketing authorization application is 210 days, excluding clock stops when additional information or written or oral explanation is to be provided by the applicant in response to questions asked by the CHMP. Clock stops may extend the timeframe of evaluation of a marketing authorization application considerably beyond 210 days. Accelerated evaluation may be granted by the CHMP in exceptional cases upon request of the applicant, when a medicinal product is of major interest from the point of view of public health and, in particular, from the viewpoint of therapeutic innovation. If the CHMP accepts such a request, the time limit of 210 days will be reduced to 150 days (excluding clock stops), but it is possible that the CHMP may revert to the standard time limit for the centralized procedure if it determines that it is no longer appropriate to conduct an accelerated assessment.

As a result of the Northern Ireland Protocol, following Brexit, the EMA remained responsible for approving novel medicines for supply in Northern Ireland under the EU centralized procedure, and a separate authorization was required to supply the same medicine in Great Britain (England, Wales and Scotland). The United Kingdom government and the European Commission have since agreed to replace the Northern Ireland Protocol with a new set of arrangements, known as the "Windsor Framework". The medicines aspects of the Windsor Framework have applied since January 1, 2025. This new framework fundamentally changes the previous system under the Northern Ireland Protocol, including with respect to the regulation of medicinal products in the United Kingdom. In particular, the MHRA is now responsible for approving all medicinal products destined for the United Kingdom market (i.e., Great Britain and Northern Ireland), and the EMA no longer has any role in approving medicinal products destined for Northern Ireland under the EU centralized procedure. A single UK-wide marketing authorization is granted by the MHRA for all novel medicinal products to be sold in the United Kingdom, enabling products to be sold in a single pack and under a single authorization throughout the United Kingdom.

The MHRA has introduced changes to national licensing procedures, including procedures to prioritize access to new medicines that will benefit patients, an accelerated assessment procedure and new routes of evaluation for novel products and biotechnological products. On January 1, 2024, the MHRA put in place a new international recognition framework which means that the MHRA may have regard to decisions on the approval of marketing authorizations made by the EMA and certain other regulators when determining an application for a new UK marketing authorization.

Data and market exclusivity

In the EU, innovative medicinal products, approved on the basis of a complete and independent data package, qualify for eight years of data exclusivity upon marketing authorization and an additional two years of market exclusivity. The data exclusivity, if granted, prevents generic or biosimilar applicants from referencing the innovator's preclinical and clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar marketing authorization in the EU, for a period of eight years from the date on which the reference product was first authorized in the EU. During the additional two-year period of market exclusivity, a generic or biosimilar marketing authorization application can be submitted, and the innovator's data may be referenced, but no generic or biosimilar product can be marketed in the EU until the expiration of the market exclusivity period. The overall ten-year period will be extended to a maximum of eleven years if, during the first eight years of those ten years, the marketing authorization holder obtains a marketing authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are determined to bring a significant clinical benefit in comparison with existing therapies.

There is no guarantee that EMA will accept the significant clinical benefit of any new indication and products may not qualify for one additional year of market protection. Additionally, under the EU global marketing authorization framework, once a medicinal product is granted an initial marketing authorization, any additional strengths, pharmaceutical forms, routes of administration, or variations submitted by the same marketing authorization holder are considered part of the same authorization and do not trigger new data or market exclusivity. Only products containing a new active substance may qualify for a separate data protection period, but there is no guarantee the EMA will classify a product as such. Even if data exclusivity is granted, another company may still obtain a marketing authorization by submitting a complete and independent data package. Similar arrangements apply in the UK.

Orphan designation and exclusivity

Regulation (EC) No. 141/2000 and Regulation (EC) No. 847/2000 provide that a product can be designated as an orphan product by the European Commission if its sponsor can establish that: (1) the product is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition, (2) either (i) the prevalence of the condition is not more than five in ten thousand persons in the EU, or (ii) without incentives it is unlikely that the marketing of the product in the EU would generate sufficient return to justify the necessary investment in its development and (3) there exists no satisfactory method of diagnosis, prevention, or treatment of the condition in question that has been authorized in the EU or, if such method exists, the medicinal product will be of a significant benefit to those affected by that condition.

An orphan designation provides a number of benefits, including fee reductions and, regulatory assistance. If a marketing authorization is granted for an orphan medicinal product, this results in a ten-year period of market exclusivity (extended to twelve years if pediatric studies are completed under a compliant PIP). During this market exclusivity period, neither the European Commission nor the EU Member States can grant a marketing authorization for a "similar medicinal product" in the same indication as the authorized orphan product. A "similar medicinal product" is defined as a medicinal product containing a similar active substance or substances as contained in a currently authorized orphan medicinal product, and which is intended for the same therapeutic indication. The market exclusivity period for the authorized therapeutic indication may, however, be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan designation because, for example, the product is sufficiently profitable not to justify maintenance of market exclusivity. A marketing authorization may be granted to a similar medicinal product in very select cases, such as if (i) it is established that the similar medicinal product is safer, more effective or otherwise clinically superior to the authorized orphan product; (ii) the marketing authorization holder for the original orphan product consents to the second medicinal product application; or (iii) the marketing authorization holder for the original orphan product cannot supply sufficient quantities of the orphan medicinal product. Orphan designation must be requested before submitting an application for marketing authorization.

Since January 1, 2021, a separate process for orphan designation has applied in the UK. There is now no pre-marketing authorization orphan designation (as there is in the EU) and the application for orphan designation will be reviewed by the MHRA, at the time of an application for a UK marketing authorization. The criteria are the same as in the EU, save that they apply to the UK only (e.g., there must be no satisfactory method of diagnosis, prevention or treatment of the condition concerned in the UK, as opposed to the EU, and the prevalence of the condition must be no more than five in 10,000 persons in the UK).

Regulatory requirements after marketing authorization

Following approval, the holder of the marketing authorization is required to comply with a range of requirements applicable to the manufacturing, marketing, promotion and sale of the medicinal product. The marketing authorization holder is also subject to the EU's stringent pharmacovigilance obligations, including periodic and ad hoc safety reporting, and may be required to conduct post-authorization studies, implement additional monitoring, or apply risk mitigation measures. In addition, the manufacturing of authorized products, for which a separate manufacturer's license is mandatory, must also be conducted in strict compliance with EU GMP requirements, which mandate the methods, facilities and controls used in manufacturing, processing and packing of products to assure their safety and identity. Finally, the marketing and promotion of authorized products, including industry-sponsored continuing medical education and advertising directed toward the prescribers of products and/or the general public, are strictly regulated in the EU under Directive 2001/83/EC, as amended, which is transposed into national legislation by the Member States.

Periods of authorization and renewals

A marketing authorization is valid for five years, in principle, and it may be renewed after five years on the basis of a re-evaluation of the risk benefit balance by the EMA for a centrally authorized product, or by the competent authority of the authorizing Member State for a nationally authorized product. Once renewed, the marketing authorization is valid for an unlimited period, unless the European Commission or the competent authority decides, on justified grounds relating to pharmacovigilance, to proceed with one additional five-year renewal period. Any marketing authorization that is not followed by the placement of the product on the EU market (in the case of the centralized procedure) or on the market of the authorizing Member State (for a nationally authorized product) within three years after authorization, or if the product is removed from the market for three consecutive years, ceases to be valid. The aforementioned EU rules are generally applicable in the EEA.

Reform of the regulatory framework in the European Union

The European Commission introduced legislative proposals in April 2023 that, if implemented, will replace the current regulatory framework in the EU for all medicines (including those for rare diseases and for children). The European Commission has provided the legislative proposals to the European Parliament and the European Council for their review and approval and, in April 2024, the European Parliament proposed amendments to the legislative proposals. In June 2025, the Council of the European Union adopted its position with regard to the proposals. On December 11, 2025, the EU legislative bodies reached a political agreement to overhaul, modernize, and streamline the existing general pharmaceutical legislation, including e.g., Directive 2001/83/EC and Regulation (EC) No. 726/2004, No. 141/2000, or No. 1901/2006. This agreement is still subject to formal approval by the European Parliament and the Council of the EU, before being formally adopted. It is expected that the new EU pharmaceutical legislation will become applicable in 2028. Key changes under the reform package include recalibrated data and market exclusivity periods, new obligations to ensure supply across Member States, streamlined regulatory procedures, and targeted incentives to support innovation and improve access to medicines across the EU.

Coverage, pricing and reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we may obtain regulatory approval. Even if our product candidates are approved for marketing, sales of such product candidates will depend, in part, on the extent to which third-party payors, including government health programs in the United States (such as Medicare and Medicaid), commercial health insurers, and managed care organizations, provide coverage and establish adequate reimbursement levels for such product candidates. Moreover, increasing efforts by governmental and third-party payors in the EU, the U.S. and other markets to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our product candidates. We expect to experience pricing pressures in connection with the sale of any of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become intense. As a result, increasingly high barriers are being erected to the entry of new products.

In the United States and markets in other countries, patients generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Patients are unlikely to use any product candidates we may develop unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of such product candidates.

Factors payors consider in determining reimbursement are based on whether the product is (i) a covered benefit under its health plan; (ii) safe, effective and medically necessary; (iii) appropriate for the specific patient; (iv) cost-effective; and (v) neither experimental nor investigational.

The Medicare and Medicaid programs increasingly are used as models for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs and biologics. Some third-party payors may require pre-approval of coverage for new or innovative devices or drug therapies before they will reimburse healthcare providers who use such therapies. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our product candidates. No uniform policy for coverage and reimbursement for drug products exists among third-party payors in the United States Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Each plan determines whether or not it will provide coverage for a product, what amount it will pay the manufacturer for the product, on what tier of its formulary the product will be placed and whether to require step therapy. The position of a product on a formulary generally determines the co-payment that a patient will need to make to obtain the product and can strongly influence the adoption of a product by patients and physicians. Third-party payors may limit coverage to specific products on a formulary, which might not include all of the approved products for a particular indication. Additionally, a payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. For example, the payor may require co-payments that patients find unacceptably high. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage and reimbursement for the product, and the level of coverage and reimbursement can differ significantly from payor to payor.

Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services and imposing controls to manage costs, especially drugs when an equivalent generic drug or a less expensive therapy is available. It is possible that a third-party payor may consider our product candidate and other therapies as substitutable and only offer to reimburse patients for the less expensive product. Even if we show improved efficacy or improved convenience of administration with our product candidate, pricing of existing drugs may limit the amount we will be able to charge for our product candidate. These payors may deny or revoke the reimbursement status of a given drug product or establish prices for new or existing marketed products at levels that are too low to enable us to realize an appropriate return on our investment in product development. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our product candidates and may not be able to obtain a satisfactory financial return on products that we may develop. Third-party payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the approved products for a particular indication.

Furthermore, rules and regulations regarding reimbursement change frequently, in some cases at short notice, and we believe that changes in these rules and regulations are likely. In order to secure coverage and reimbursement for any product that might be approved for sale, we have needed and may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product, and the cost of these studies would be in addition to the costs required to obtain FDA or other comparable marketing approvals. Conducting such studies could be expensive, involve additional risk and result in delays in our commercialization efforts. Even after pharmacogenomic studies are conducted, product candidates may not be considered medically necessary or cost-effective. A decision by a third-party payor not to cover any product candidates we may develop could reduce physician utilization of such product candidates once approved and have a material adverse effect on our sales, results of operations and financial condition. Third-party reimbursement and coverage may not be adequate to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development. The insurance coverage and reimbursement status of newly approved products for orphan diseases is particularly uncertain, and failure to obtain or maintain adequate coverage and reimbursement for any such product candidates could limit our ability to generate revenue.

The containment of healthcare costs also has become a priority of U.S. federal, state and international governments and the prices of pharmaceuticals have been a focus in this effort. Governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any future product candidate that we commercialize and, if reimbursement is available, the level of reimbursement. In addition, many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average sales price and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely. Further, these prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our potential revenue from the sale of any products for which we may obtain approval. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more of our products for which we or our collaborators receive marketing approval, less favorable coverage policies and reimbursement rates may be implemented in the future. Obtaining and maintaining reimbursement status is time-consuming and costly.

The delivery of healthcare in the EU, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than EU, law and policy. As a result, in the EU, despite recent legislative developments aiming at a certain level of harmonization in certain respects, pricing and reimbursement schemes vary widely from country to country. Some countries provide that products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular product candidate to currently available therapies (so called health technology assessments) in order to obtain reimbursement or pricing approval. For example, the EU provides options for its Member States to restrict the range of products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. EU Member States may approve a specific price for a product or may instead adopt a system of direct or indirect controls on the profitability of the company placing the product on the market. Other Member States allow companies to fix their own prices for products but monitor and control prescription volumes and issue guidance to physicians to limit prescriptions. Recently, many countries in the EU have increased the amount of discounts required on pharmaceuticals and these efforts could continue as countries attempt to manage healthcare expenditures, especially in light of the severe fiscal and debt crises experienced by many countries in the EU. The downward pressure on healthcare costs in general, particularly prescription products, has become intense. As a result, increasingly high barriers are being erected to the entry of new products. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various EU Member States and parallel trade (arbitrage between low-priced and high-priced Member States) can further reduce prices. Acceptance of any medicinal product for reimbursement may come with cost, use and often volume restrictions, which again can vary by country. In addition, results-based rules of reimbursement may apply. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products, if approved in those countries. Historically, products launched in the EU do not follow price structures of the U.S. and generally prices tend to be significantly lower.

In January 2022, Regulation (EU) 2021/2282 concerning a European health technology assessment entered into force, providing for its application as of January 2025. A transitional phase-in applies, whereby oncology products containing a new active substance and advanced therapy medicinal products (ATMPs) will fall under the scope as of January 2025; orphan medicines as of January 2028; and all centrally authorized products containing a new active substance as of January 2030. Despite the fact that the evaluation of clinical studies is mainly transferred to the European level, the socioeconomic impact assessments and the final assessment of the added benefit and the pricing remains a national responsibility. The joint clinical assessments within the framework of the Regulation are not binding for Member States; rather, Member States have broad discretion as to how to evaluate the results of the European health technology assessment procedure for the purposes of their national decision-making processes. The EU HTA Regulation may increase the burden of evidence required to demonstrate clinical benefit across diverse healthcare systems, potentially adding complexity, cost, and uncertainty to market access strategies.

Outside the U.S., many countries impose price controls or other regulatory mechanisms that limit the pricing and profitability of medicinal products. In Europe, Canada, and other markets, cost-containment pressures continue to intensify, and pricing is often subject to national health system rules, including direct price regulation, profit control schemes, mandatory rebates and clawback mechanisms. For example, in the UK, the Voluntary Scheme for Branded Medicines Pricing, Access and Growth (VPAG) requires companies to pay back a portion of NHS sales revenue when spending exceeds predefined growth thresholds, with clawback rates reaching around 23% in 2025. These measures, along with evolving reimbursement policies, may limit the revenue potential of our product candidates and result in lower reimbursement levels compared to the U.S., potentially undermining commercial viability.

Government pricing and reimbursement programs for marketed drugs in the United States

Federal law requires that a pharmaceutical manufacturer, as a condition of having its drug and biological products receive federal reimbursement under Medicaid and Medicare Part B, must pay rebates to state Medicaid programs for all units of its covered outpatient drugs dispensed to Medicaid beneficiaries and paid for by a state Medicaid program under either a fee-for-service arrangement or through a managed care organization. This federal requirement is effectuated through a Medicaid drug rebate agreement between the manufacturer and the Secretary of the U.S. Department of Health and Human Services, or HHS. Centers for Medicare & Medicaid Services, or CMS, administers the Medicaid drug rebate agreements, which provide, among other things, that the drug manufacturer will pay rebates to each state Medicaid agency on a quarterly basis and report certain price information on a monthly and quarterly basis. The rebates are based on prices reported to CMS by manufacturers for their covered outpatient drugs. For non-innovator products, generally generic drugs marketed under abbreviated NDAs, the rebate amount is 13% of the average manufacturer price, or AMP, for the quarter. The AMP is the weighted average of prices paid to the manufacturer (1) directly by retail community pharmacies and (2) by wholesalers for drugs distributed to retail community pharmacies. For innovator products (i.e., drugs that are marketed under NDAs or BLAs), the rebate amount is the greater of 23.1% of the AMP for the quarter or the difference between such AMP and the best price for that same quarter. The best price is essentially the lowest price available to non-governmental entities after accounting for discounts and rebates. Innovator products may also be subject to an additional rebate that is based on the amount, if any, by which the product's AMP for a given quarter exceeds the inflation-adjusted baseline AMP, which for most drugs is the AMP for the first full quarter after launch. Since 2017, non-innovator products are also subject to an additional rebate. Prior to January 1, 2024, the rebate amount for a drug was capped at 100% of the AMP; however, effective January 1, 2024, this cap was eliminated, which means that a manufacturer could pay a total rebate amount on a unit of the drug that is greater than the average price the manufacturer receives for the drug.

The terms of participation in the Medicaid drug rebate program impose an obligation to correct the prices reported in previous quarters, as may be necessary. Any such corrections could result in additional or lesser rebate liability, depending on the direction of the correction. In addition to retroactive rebates, if a manufacturer were found to have knowingly submitted false information to the government, federal law provides for civil monetary penalties for failing to provide required information, late submission of required information, and false information.

A manufacturer must also participate in a federal program known as the 340B drug pricing program in order for federal funds to be available to pay for the manufacturer's drug and biological products under Medicaid and Medicare Part B. Under this program, the participating manufacturer agrees to charge certain safety net healthcare providers no more than an established discounted price for its covered outpatient drugs. The formula for determining the discounted price is defined by statute and is based on the AMP and the unit rebate amount as calculated under the Medicaid drug rebate program, discussed above. Manufacturers are required to report pricing information to the Health Resources and Services Administration, or HRSA, on a quarterly basis. HRSA has also issued regulations relating to the calculation of the ceiling price as well as imposition of civil monetary penalties for each instance of knowingly and intentionally overcharging a 340B covered entity.

Federal law also requires that manufacturers report data on a quarterly basis to CMS regarding the pricing of drugs that are separately reimbursable under Medicare Part B. These are generally drugs and biologics, such as injectable products, that are administered incident to a physician service and are not generally self-administered. The pricing information submitted by manufacturers is the basis for reimbursement to physicians and suppliers for drugs covered under Medicare Part B. Under the Inflation Reduction Act of 2022, or IRA, manufacturers are also required to provide quarterly rebates for certain single-source drugs and biologics (including biosimilars) covered under Medicare Part B with prices that increase faster than the rate of inflation. This requirement started on January 1, 2023 for drugs approved on or before December 1, 2020 and begins six quarters after a drug is first marketed for all other drugs. As with the Medicaid drug rebate program, federal law provides for civil monetary penalties for failing to provide required information, late submission of required information, and false information.

Medicare Part D provides prescription drug benefits for seniors and people with disabilities. Medicare Part D enrollees previously had a gap in their annual coverage (between the point of hitting the annual initial coverage limit and the point at which catastrophic coverage began) where Medicare did not cover their prescription drug costs, known as the coverage gap or "donut hole." However, beginning in 2019, Medicare Part D enrollees paid 25% of brand drug costs after they reached the initial coverage limit-the same percentage they were responsible for before they reached that limit-thereby closing the coverage gap from the enrollee's point of view. Most of the cost of closing the coverage gap has been borne by innovator companies and the government through subsidies. Each manufacturer of drugs approved under NDAs or BLAs was required to enter into a Medicare Part D coverage gap discount agreement and provide a 70% discount on those drugs dispensed to Medicare Part D enrollees in the coverage gap, in order for its drugs to be reimbursed by Medicare Part D. Beginning in 2025, the IRA eliminated the coverage gap completely under Medicare Part D by significantly lowering the enrollee maximum out-of-pocket cost to $2,000 per year and requiring manufacturers to subsidize, through a newly established manufacturer discount program, 10% of Part D enrollees' prescription costs for brand drugs above a deductible and below the out-of-pocket maximum, and 20% once the out-of-pocket maximum has been reached. Although these discounts represent a lower percentage of enrollees' costs than the current discounts required below the out-of-pocket maximum (that is, in the coverage gap phase of Part D coverage), the new manufacturer contribution required above the out-of-pocket maximum could be considerable for very high-cost patients and the total contributions by manufacturers to a Part D enrollee's drug expenses may exceed those currently provided.

The IRA also requires manufacturers to provide annual Medicare Part D rebates for single-source drugs and biological products with prices that increase faster than the rate of inflation.

The IRA also allows HHS to directly negotiate the price of a statutorily specified number of drugs and biologics each year that CMS reimburses under Medicare Part B and Part D. Only high-expenditure single-source biologics that have been approved for at least 11 years (7 years for single-source drugs) can qualify for negotiation, with the negotiated price taking effect two years after the selection year. The first round of negotiations for Medicare Part D products began in 2024, with the negotiated price cap (also known the "maximum fair price") taking effect in 2026. The second round of Part D negotiations began in 2025, with maximum fair prices taking effect in 2027. Negotiations for Medicare Part B products begin in 2026 with the negotiated price taking effect in 2028.

U.S. federal contracting and pricing requirements

Manufacturers are also required to make their covered drugs, which are generally drugs approved under NDAs or BLAs, available to authorized users of the Federal Supply Schedule, or FSS, of the General Services Administration. The law also requires manufacturers to offer deeply discounted FSS contract pricing for purchases of their covered drugs by the Department of Veterans Affairs, the Department of Defense, the Coast Guard, and the Public Health Service (including the Indian Health Service) in order for federal funding to be available for reimbursement or purchase of the manufacturer's drugs under certain federal programs. FSS pricing to those four federal agencies for covered drugs must be no more than the Federal Ceiling Price, or FCP, which is at least 24% below the Non-Federal Average Manufacturer Price, or Non-FAMP, for the prior year. The Non-FAMP is the average price for covered drugs sold to wholesalers or other middlemen, net of any price reductions.

The accuracy of a manufacturer's reported Non-FAMPs, FCPs, or FSS contract prices may be audited by the government. Among the remedies available to the government for inaccuracies is recoupment of any overcharges to the four specified federal agencies based on those inaccuracies. If a manufacturer were found to have knowingly reported false prices, in addition to other penalties available to the government, the law provides for significant civil monetary penalties per incorrect item. Finally, manufacturers are required to disclose in FSS contract proposals all commercial pricing that is equal to or less than the proposed FSS pricing, and subsequent to award of an FSS contract, manufacturers are required to monitor certain commercial price reductions and extend commensurate price reductions to the government, under the terms of the FSS contract Price Reductions Clause. Among the remedies available to the government for any failure to properly disclose commercial pricing and/or to extend FSS contract price reductions is recoupment of any FSS overcharges that may result from such omissions.

Healthcare law and regulation

Healthcare providers and third-party payors play a primary role in the recommendation and prescription of pharmaceutical products that are granted marketing approval. Our current and future arrangements with providers, researchers, consultants, third-party payors and customers are subject to broadly applicable federal and state fraud and abuse, anti-kickback, false claims, transparency and patient privacy laws and regulations and other healthcare laws and regulations that may constrain our business and/or financial arrangements. Restrictions under applicable federal and state healthcare laws and regulations are listed below.

- The federal Anti-Kickback Statute, or AKS, prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering, or paying remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. A person or entity can be found guilty of violating the AKS without actual knowledge of the statute or specific intent to violate it. In addition, the government may assert that a claim including items or services resulting from a violation of the AKS constitutes a false or fraudulent claim for purposes of the federal False Claims Act or federal civil money penalties statute. Violations of the AKS carry potentially significant civil and criminal penalties, including imprisonment, fines, administrative civil monetary penalties, and exclusion from participation in federal healthcare programs.

- The U.S. federal false claims and civil monetary penalties laws, including the civil False Claims Act and federal civil monetary penalty laws, which, among other things, impose criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the U.S. federal government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim or obligation to pay or transmit money to the federal government, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the AKS constitutes a false or fraudulent claim for purposes of the False Claims Act. Manufacturers can be held liable under the False Claims Act even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. The False Claims Act also permits a private individual acting as a "whistleblower" to bring qui tam actions on behalf of the federal government alleging violations of the False Claims Act and to share in any monetary recovery. When an entity is determined to have violated the federal civil False Claims Act, the government may impose civil fines and penalties for each false claim, plus treble damages, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs.

- The U.S. federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or obtaining by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the pay (e.g., public or private) or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters; similar to the AKS, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and its implementing regulations, and as amended again by the Omnibus Rule in 2013, which imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without appropriate authorization by covered entities subject to the Final HIPAA Omnibus Rule, i.e., certain covered health plans, healthcare clearinghouses and healthcare providers, as well as their business associates, those independent contractors or agents of covered entities that perform certain services for or on their behalf involving the use or disclosure of individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions.

- The federal transparency requirements known as the federal Physician Payments Sunshine Act, under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the ACA, which requires certain manufacturers of approved drugs, devices, biologics and medical supplies to report annually to CMS information related to payments and other transfers of value made by that entity to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician providers such as physician assistants and nurse practitioners and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Failure to submit required information may result in civil monetary penalties for all payments, transfers of value or ownership or investment interests that are not timely, accurately, and completely reported in an annual submission.

- Federal government price reporting laws, which will require us to calculate and report complex pricing metrics in an accurate and timely manner to government programs for any approved products in the future.

- Federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.

- Analogous state laws and regulations, including: state anti-kickback and false claims laws, which may apply to our business practices, including, but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state and local laws that require the licensure of sales representatives; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and pricing information; state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect; and state laws related to insurance fraud in the case of claims involving private insurers.

- EU, UK and other foreign law equivalents, including reporting requirements detailing interactions with and payments to healthcare providers and data privacy and security laws and regulations that may be more stringent than those in the United States.

Violations of these laws or any future enacted laws can subject us to criminal, civil and administrative sanctions including monetary penalties, damages, fines, disgorgement, individual imprisonment and exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, reputational harm, and we may be required to curtail or restructure our operations. Moreover, we expect that there will continue to be federal and state laws and regulations, proposed and implemented, that could impact our future operations and business.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including administrative, civil and criminal penalties, damages, fines, disgorgement, the exclusion from participation in federal and state healthcare programs, individual imprisonment, reputational harm, and the curtailment or restructuring of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws. Further, defending against any such actions can be costly and time-consuming, and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. If any of the physicians or other providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment. If any of the above occur, our ability to operate our business and our results of operations could be adversely affected.

Healthcare reform

In the United States, the EU and other foreign jurisdictions, there have been a number of legislative and regulatory changes to the healthcare systems that could affect our future results of operations. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare. For example, the ACA, effective since March 2010, is a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms.

Healthcare reforms that have been adopted, and that may be adopted in the future, could result in further reductions in coverage and levels of reimbursement for pharmaceutical products, increases in rebates payable under U.S. government rebate programs and additional downward pressure on pharmaceutical product prices. As discussed above, these initiatives culminated in the enactment of the IRA in August 2022, which allows, among other things, HHS to directly negotiate the selling price of statutorily specified number of drugs and biologics each year that CMS reimburses under Medicare Part B and Part D. Also as discussed above the IRA also penalizes drug manufacturers that increase prices of Medicare Part B and Part D drugs at a rate greater than the rate of inflation. The IRA permits the Secretary of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. Manufacturers that fail to comply with the IRA may be subject to various penalties, including civil monetary penalties. The IRA also extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. These provisions began taking effect progressively starting in 2023, although they may be subject to legal challenges. For example, permissibility under the U.S. Constitution of the provisions related to the negotiation of selling prices of high-expenditure single-source drugs and biologics has been challenged in multiple lawsuits, including a recent suit that has been accepted for review by the U.S. Supreme Court. Thus, while it is unclear how the IRA will be implemented, it will likely have a significant impact on the pharmaceutical industry.

We expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

Further, legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals, if any, of our product candidates, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing conditions and other requirements.

Individual states in the United States have also become increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our products or put pressure on our product pricing, which could negatively affect our business, results of operations, financial condition and prospects.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we or our collaborators are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or our collaborators are not able to maintain regulatory compliance, our product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability, which would adversely affect our business.

C. Organizational structure

At December 31, 2025, AgomAb Therapeutics NV is the ultimate parent company of the following entities:

- Agomab US, Inc. (United States, 100%); and
- Agomab Spain, S.L.U. (Spain, 100%).

D. Property, Plants and Equipment

We lease approximately 1,100 square meters of office space in Antwerp, Belgium. This facility serves as our corporate headquarters. Our lease will expire on December 11, 2032. We also lease approximately 40 square meters of office and laboratory space in Galicia, Spain. This facility serves as a secondary office and central laboratory space. Our lease will expire on January 2, 2027. The lease automatically extends by successive one-year periods, unless earlier terminated. We believe that our current facilities are adequate to meet our ongoing needs, and that if we require additional space, we will be able to obtain additional facilities on commercially reasonable terms.

Item 4A: Unresolved Staff Comments

Not applicable.

Item 5: Operating and Financial Review and Prospects

You should read the following discussion and analysis of our financial condition and results of operations together with our audited financial statements, including the notes thereto, included elsewhere in this Annual Report. The following discussion is based on our financial statements prepared in accordance with IFRS Accounting Standards as issued by the International Accounting Standards Board (IASB) which might differ in material respects from GAAP in the United States. In addition to historical financial information, the following discussion and analysis includes forward-looking statements that involve risks, uncertainties and assumptions. See “Cautionary Note Regarding Forward-Looking Statements.” Our actual results and timing may differ materially from those anticipated in these forward-looking statements as a result of many factors, including but not limited to those described under Item 3.D: “Risk Factors” and elsewhere in this Annual Report.

A. Operating Results

Overview

We are a clinical-stage biopharmaceutical company focused on developing novel disease-modifying therapies for fibro-inflammatory diseases with high unmet medical need. Our product candidates are designed to target established pathways and utilize validated modalities with the aim of increasing efficacy while avoiding systemic toxicities in order to overcome the limitations of prior therapeutic approaches. Our initial focus for the treatment of fibrosis is through inhibition of one of the key signaling pathways involved in fibrosis, the transforming growth factor β, or TGFβ, pathway. Our mission is to develop disease-modifying therapeutics that aim to resolve fibrosis and restore organ function to enable patients with these disorders to live fuller and healthier lives.

Since our inception in 2017, we have devoted substantially all of our efforts to organizing and staffing our company, business planning, raising capital, establishing our intellectual property portfolio, acquiring or discovering product candidates, research and development activities and providing general and administrative support for these operations. On December 14, 2021, we acquired 100% of the share capital of Agomab Spain, S.L.U. (formerly known as Origo Biopharma, S.L.), a Spanish-based biotechnology company, strengthening our research and development portfolio.

In February 2026, we completed our initial public offering, or IPO, pursuant to which we issued and sold 12,500,000 ADSs. On March 4, 2026, the underwriters exercised a portion of their overallotment option, pursuant to which we issued and sold an additional 482,967 ADSs. The aggregate net proceeds received from the IPO, including the underwriters' overallotment exercise, were approximately $188 million, after deducting underwriting discounts and commissions and other offering costs. We have historically financed our operations from the issuance of preferred shares along with anti-dilution warrants, which generated gross proceeds of €299.7 million. We do not have any products approved for sale and have not generated any revenue from product sales or otherwise. We do not expect to generate significant revenue from product sales or royalties unless and until our product candidates are approved for marketing and successfully commercialized.

At December 31, 2025, we had cash, cash equivalents and cash investments of € 116.5 million. We believe that our existing cash, cash equivalents and cash investments, including the net proceeds from our IPO, will enable us to fund our operating expenses and capital expenditure requirements into the first half of 2029.

We have incurred significant operating losses since inception, and we expect to continue to incur significant expenses and operating losses for the foreseeable future. Our ability to generate product revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of any product candidates, if approved. For the years ended December 31, 2025, 2024 and 2023, we incurred net losses of € 62.5 million, €, 46.3 million and € 11.4 million, respectively. At December 31, 2025, we had an accumulated deficit of € 118.7 million. We expect to continue incurring losses for at least the next several years, and we do not anticipate achieving profitability in the future unless we successfully complete clinical development and obtain regulatory approvals necessary to commercialize any of our future product candidates.

Recent Accounting Pronouncements

New and amended Standards and interpretations applicable for annual period beginning on January 1, 2025, did not have any material impact on our consolidated financial statements. The Group has not early adopted any of the new and amended standards which have been issued but are not yet effective. For further information, see 'Item 18. Financial statements'

Foreign Private Issuer Exemptions

As a foreign private issuer, we are not subject to the same requirements that are imposed upon U.S. domestic issuers by the SEC. Under the Exchange Act, we will be subject to reporting obligations that, in certain respects, are less detailed and less frequent than those of U.S. domestic reporting companies. For example, we will not be required to issue quarterly reports, proxy statements that comply with the requirements applicable to U.S. domestic reporting companies, or individual executive compensation information that is as detailed as that required of U.S. domestic reporting companies. We will also have four months after the end of each fiscal year to file our annual reports with the SEC and will not be required to file current reports as frequently or promptly as U.S. domestic reporting companies. We may also present financial statements pursuant to IFRS instead of pursuant to U.S. GAAP. Furthermore, our senior management, directors and principal shareholders will be exempt from the short-swing profit liability provisions contained in Section 16 of the Exchange Act. These exemptions and leniencies will reduce the frequency and scope of information and protections available to you in comparison to those applicable to a U.S. domestic reporting companies.

Financial Operations Overview

Operating Expenses

Research and Development Expenses

Research and development, or R&D, expenses consist of internal and external costs incurred in the development of our product candidates. R&D expenses comprise costs incurred in performing research and development activities, including:

- personnel-related costs, including salaries, bonuses, benefits, and stock-based compensation for employees engaged in research and development functions;
- external expenses, including expenses incurred under arrangements with third parties, such as clinical research organizations, or CROs, who conduct our non-clinical studies and clinical trials, research organizations, consultants and our scientific advisors;
- the cost of developing and validating our manufacturing process for use in our preclinical studies and future clinical trials;
- costs for laboratory supplies, research materials and reagents; and
- facility costs, depreciation, and other expenses, which include direct and allocated expenses.

We expect our R&D expenses to further increase as our clinical programs, ontunisertib and AGMB-447, continue to progress further into clinical development. Furthermore, study and research expenses will increase due to progress made with other research programs.

Although R&D activities are central to our business model, the successful development of any future product candidates is highly uncertain. There are numerous factors associated with the successful development of any product, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at this time based on our stage of development. In addition, future regulatory factors beyond our control may impact our clinical development programs. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and longer duration of later-stage clinical trials. As a result, we expect our R&D expenses will increase substantially in connection with our ongoing and planned clinical and preclinical development activities in the near term and in the future. At this time, we cannot accurately estimate or know the nature, timing and costs of the efforts that will be necessary to complete the preclinical and clinical development of our current product candidates and any future product candidates. Our future R&D expenses may vary significantly based on a wide variety of factors such as:

- the number and scope, rate of progress, expense and results of our clinical trials and preclinical studies and any future product candidates we may choose to pursue, including any modifications to clinical development plans based on feedback that we may receive from regulatory authorities;

- per patient trial costs;
- the number of trials required for approval;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible patients;
- the number of patients that participate in the trials;
- the number of doses that patients receive;
- the drop-out or discontinuation rates of patients;
- the potential additional safety monitoring requested by regulatory agencies;
- the duration of patient participation in the trials and follow-up;
- the cost and timing of manufacturing clinical supply;
- the extent of changes in government regulation and regulatory guidance;
- the timing, receipt, and terms of any approvals from applicable regulatory authorities; and
- the extent to which we establish additional collaboration, license, or other arrangement.

A change in the outcome of any of these variables with respect to the development of our product candidates or any potential future product candidate could mean a significant change in the costs and timing associated with the development of that potential future product candidate. For example, if the FDA or another regulatory authority were to require us to conduct clinical trials beyond those that we anticipate would be required for the completion of clinical development of a potential future product candidate, or if we experience significant delays in our clinical trials due to slower than expected patient enrolment or other reasons, we would be required to expend significant additional financial resources and time on the completion of clinical development.

General and Administrative Expenses

General and administrative, or G&A, expenses include all costs incurred for overall day-to-day operations of the company. G&A expenses include professional service fees for consultants, lawyers, and other external experts, board fees, office supplies and sundries, travel and meeting costs incurred for investor and business conferences, facility rent and related expenses, depreciation and amortization costs for office and car leases, personnel costs and share-based compensation for employees not directly attributable to R&D.

As our R&D activities further increase, we expect a further increase in supportive functions and related G&A expenses. These increases will likely include increased costs related to the hiring of additional personnel and fees paid to outside consultants and for additional and larger facilities among other expenses. We also anticipate increased expenses related to audit, accounting, legal, regulatory, and tax-related services associated with maintaining compliance with the Nasdaq Global Select Market, or Nasdaq, and the Securities and Exchange Commission, or the SEC, requirements, director and officer insurance premiums, and investor relations costs associated with operating as a U.S. public company.

Other operating income

We currently have no marketable product, therefore we are not revenue generating. Income received consists of government grants, R&D tax credit income and R&D personnel credits relating to a government incentive to support innovation via a reduction in withholding income taxes for qualified personnel employed in R&D.

We receive R&D innovation grants issued by the Flanders Innovation and Entrepreneurship agency, or VLAIO. These grants are recognized as government grant income over the term of the related project subject to compliance with the applicable conditions. Grant income is recognized based on the timing of R&D expenses incurred.

R&D tax credits are a tax incentive measure allowed by the Belgian federal government for European Small and Medium-sized Enterprises, or SMEs. The tax credits are received in relation to eligible incurred R&D expenses. The R&D tax credits will be paid to us in cash four years from the time of the claim, to the extent it is not offset against the taxable income over the respective periods.

Lastly, we also receive a tax incentive issued by the Belgian federal government to support innovation via a reduction in withholding taxes paid for qualified personnel employed within R&D, which we refer to as social charges.

Changes in fair value of financial liabilities

Financial liabilities measured at fair value, valued based on level three input, comprise of the anti-dilution warrants, or ADWs, and the contingent consideration linked with the acquisition of Agomab Spain in 2021. These ADWs and earn-out consideration are measured at fair value as of the balance sheet dates and the changes recognized through profit and loss.

ADWs are financial instruments to protect existing shareholders from the potential dilutive effect of future capital increases. An ADW grants the holder the right to obtain an additional variable number of preferred A, B, C or D shares, as applicable, in the event of a dilutive capital increase. The protection these ADWs provide expires 10 years after issuance and in case of changes or termination of the shareholders agreement or in case of an initial public offering, or IPO, or liquidity event. These ADWs have however been cancelled as a result of our initial public offering in February 2026.

The contingent consideration issued as a result of the acquisition of Agomab Spain consists of a maximum future contingent milestone payment to Agomab Spain's former equity holders of €20.0 million if all the targets agreed to in connection with the acquisition are achieved, of which €3.0 million was paid in the second quarter of 2025. At each reporting date, the fair value of the contingent consideration is remeasured based on the present value of expected future cash flows, adjusted for risk, and discounted using the Weighted Average Cost of Capital, or WACC.

Financial income and expenses

Financial income and expenses consist of interest income and expenses and foreign exchange gains or losses. The financial expenses also include bank charges paid.

Income taxes

We incurred tax losses in current and prior years. It is not assessed as probable that future taxable profits will be available against which the tax losses can be utilized. Therefore, no deferred tax assets have been recognized in excess of the deferred tax liabilities, relating to the same taxation authority and the same taxable entity. We are subjected to corporate income taxation in Belgium, Spain and the U.S., of which we have a statutory tax rate of 25% for both the Company in Belgium and its subsidiary in Spain. For the US subsidiary, a domestic tax rate is applied of 21% Federal tax rate and 5% State Corporation tax.

Results of Operations

Comparison of the periods ended December 31, 2025 and 2024

The following table sets forth our results of operations for the periods indicated.

	For the year ended December 31,			
	2025	2024	Change	% Change
	(in thousands EUR)			
Research and development expenses	(48,877)	(39,310)	9,567	(24)%
General and administrative expenses	(12,791)	(10,133)	2,658	(26)%
Total operating expenses	**(61,668)**	**(49,443)**	**12,225**	**(25)%**
Other operating income	2,393	1,422	971	(68)%
Operating loss	**(59,275)**	**(48,021)**	**11,254**	**(23)%**
Changes in fair value of financial liabilities	(4,857)	848	5,705	673 %
Financial expenses	(133)	(357)	(224)	63 %
Financial income	1,718	1,267	451	36 %
Loss before taxes	**(62,547)**	**(46,263)**	**16,284**	**(35)%**
Tax income	0	(4)	(4)	(100)%
Loss for the year	**(62,547)**	**(46,267)**	**16,280**	**(35)%**

Total operating expenses

Research and development expenses

The following table provides an allocation of the R&D expenses by R&D project for the year ended December 31, 2025 and 2024:

	For the year ended December 31,			
	2025	2024	Change	% Change
	(in thousands EUR)			
ontunisertib	(25,938)	(19,383)	6,555	(34)%
AGMB-447	(15,468)	(12,497)	2,971	(24)%
Unallocated expenses on other research programs[(1)]	(7,471)	(7,430)	41	(1)%
Total R&D expenses	**(48,877)**	**(39,310)**	**9,567**	**(24)%**

(1) The costs primarily consist of directly attributable R&D expenses and related payroll costs.

The increase in R&D expenses of €6.6 million relating to ontunisertib for the year ended December 31, 2025, is related to progress made within the clinical testing phase, which resulted in increased R&D expenses. For program AGMB-447 the R&D expenses increased to €15.5 million during 2025, from €12.5 million for the year ended, 2024, for a similar reason as progression has been made on a clinical phase.

Our other programs are still in a preclinical phase, which means that most of the expenses are related to study research. The expenses relating to these other programs, slightly increased due to the increase of our studies that are in a preclinical phase.

General and administrative expenses

The increase of €2.7 million in general and administrative expenses for the year ended December 31, 2025, related to an increase in employee benefits expenses by €1.3 million, reflecting the organizational scaling to support growth. Furthermore, share-based payments increased by €2.9 million due to increases in the value of underlying common share and the timing and amount of ESOPs and due to accelerated vesting of ESOPs issued under the 2024 ESOP plans. Those increases were mainly offset by a decrease in professional service fees of €1.3 million, linked to lawyer, notary and consulting fees, and audit and accounting fees as such fees for the year ended December 31, 2024 included significant one-off costs related to the IPO process. Professional service fees for the IPO that was completed on in 2026 are mainly incurred in 2026.

Other operating income

Other operating income increased by €1.0 million for the year ended December 31, 2025, from €1.4 million for the year ended December 31, 2024. This relates mainly to an increase of €0.7 million in government grants. Furthermore R&D personnel and tax credits increased by a net €0.3 million in line with increasing number of R&D employees and progress of R&D programs.

Changes in fair value of financial liabilities

The loss resulting from changes in fair value was €4.9 million for the year ended December 31, 2025, compared to €1.6 million loss for the year ended December 31, 2024. This net loss is the result of changes in the fair value of our ADWs and the contingent earn-out consideration. Both are financial liabilities measured at fair value, based on level three inputs.

For the year ended December 31, 2025, the probability of an exit, being a qualified IPO or liquidity event, remained 100%, in line with December 31, 2024, resulting in the ADWs having no remaining value.

During the year ended December 31, 2025, a first payment of €3.0 million was made to the former shareholders of Agomab Spain due to the achievements of the first tranche of the first milestone. The earn-out consideration for both tranches of the first milestone amounts to €10.0 million in aggregate. The first €3.0 million payment thus resulted in a decrease of the earn-out liability for the same amount, an increase in probability to 100% for payment of remaining €7.0 million of the first milestone, and an increase in the probabilities of meeting subsequent milestones. As a result, an additional cost of €4.9 million was recognized within the statement of comprehensive income for the year ended December 31, 2025. For the year ended December 31, 2024, an additional cost of €0.4 million was recognized within the statement of comprehensive income resulting from a small decrease within the WACC applied within the remeasurement of the fair value of the earn-out consideration at the year ended December 31, 2024.

Financial income and expenses

Financial income and expenses for both years ended December 31, 2025 and 2024, consists of interest expenses or income and gains or losses from exchange rate differences. For the year ended December 31, 2025, the financial income exceeded the financial expenses resulting in a net income of €1.6 million which can be explained due to the increased interest income received over short term deposits offset against minor interest expenses. For the year ended December 31, 2024, financial income exceeded the financial expenses resulting in a net income of €0.9 million which can be explained due to the increased interest rates received over short term deposits offset against minor interest expenses.

Tax income

Current income tax expenses for both financial year 2025 and 2024, are negligible. For the years ended December 2025 and 2024, no deferred tax assets have been recognized in excess of the deferred tax liabilities, relating to the same taxation authority and the same taxable entity, as it is uncertain the Company will have taxable profits available against which these deferred tax assets could be offset.

Comparison of the periods ended December 31, 2024 and 2023

For discussion related to the results of operations and changes in financial condition for the year ended December 31, 2024 compared to the year ended December 31, 2023, refer to the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" for the year ended December 31, 2024 included in our registration statement on Form F-1 (333-292790).

B. Liquidity and Capital Resources

We are a clinical-stage biopharmaceutical company focused on developing novel disease-modifying therapies for fibro-inflammatory diseases that has not generated any revenues to date. Since inception, we have incurred substantial losses and negative cash flows from operations and expect to further incur significant operating losses for the foreseeable future and may never become profitable. We had an accumulated loss of € 181.6 million as of December 31, 2025.

Sources of liquidity

Since our inception, we have financed our operations through our IPO and the private placement of equity securities.

In the year ended December 31, 2025 we have received government grants in Belgium of € 0.6 million.

Our present and future funding requirements will depend on several factors, including, but not limited to:

- progression, timing and completion of our preclinical and clinical-stage activities;
- the number of product candidates we identify and decide to further develop;
- the costs incurred for filing for, applying for, maintaining, enforcing or defending our patents against claims or infringements by third parties;
- the time and costs incurred in obtaining regulatory approval for our product candidates and any delays we may encounter as a result of evolving regulatory requirements or adverse results with respect to our product candidates;
- the costs incurred for the creation of effective selling and marketing activities to commercialize, if any, our future product candidates; and
- the amount of revenue, if any, generated from product sales or royalties from any of our future product candidates, if any, after obtaining regulatory approval for commercialization.

Cash Flows

The table below summarizes our statement of cash flows for the years ended December 31, 2025 and 2024.

	For the year ended December 31,			
	2025	2024	Change	% Change
	(in thousands EUR)			
Net cash used in operating activities	(51,744)	(46,828)	4,916	(10)%
Net cash provided by (used in) investing activities	(33,004)	(675)	32,329	(4,789)%
Net cash provided by (used in) financing activities	(338)	96,762	97,100	100 %
Net increase (decrease) in cash and cash equivalents	**(85,086)**	**49,260**	**134,346**	**212 %**

Operating activities

Net cash used in operating activities for the year ended December, 2025 was €51.7 million compared to €46.8 million for year ended December 31, 2024. Net cash used in operating activities in each year were primarily driven by net losses incurred during the year ended December 31, 2025 and 2024. The increase of €4.9 million in net cash used in operating activities for the year ended December 31, 2025, when compared to the year ended December 31, 2024, was as a result of an increase in total operating expenses of €12.2 million during the year ended December 2025. This was offset by the effect of timing of payments and collections of working capital payables and receivables, respectively, when compared with the prior year.

Investing activities

Net cash used in investing activities for the year ended December 31, 2025 increasing with €32.3 million was mainly the result of a €3.0 million milestone payment payable to the former shareholders and ESOP holders of Agomab Spain S.L.U. and €30.0 million has been invested in a money market fund that is readily available to cash and is subject to insignificant changes in value.

Financing activities

Net cash used in financing activities was € 0.4 million for the year ended December 31, 2025, a change from a net cash provided by financing activities of €96.8 million for the year ended December 31, 2024. The financing activities relate to the repayment of lease liabilities during the year ended December 31, 2025. The financing activities during the year ended December 31, 2024 relate to a capital funding round, for a total subscription amount of €82.1 million. An additional €15.0 million of proceeds was received on April 15, 2024, relating to a capital funding round in 2023.

Comparison for the years ended December 31, 2024 and 2023

See “Item18. Financial statements,” which contains our audited financial statements prepared in accordance with IFRS Accounting Standards as issued by the International Accounting Standards Board (IASB).

Contractual obligations and commitments

In the ordinary course of our business, we regularly use the services of subcontractors and enter into research and partnership arrangements with various Contract Research Organizations, or CROs, Contract Development and Manufacturing Organizations, or CDMOs, and other subcontractors, who conduct clinical trials, preclinical activities and manufacturing activities in relation to the product candidates. Any obligations we have are commitments related to these contractual agreements. They are classified as less than one year maturity in the absence of a fixed schedule in contracts. In case of multiple-year contracts, such as CRO contracts, they will typically include payments that are conditional to the completion of future development milestones.

Off-balance sheet arrangements

We did not have for the periods reported, and we do not currently have, any material off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

C. Research and Development

See Item 4.B: “Business Overview” and Item 5: “Operating and Financial Review and Prospects”.

D. Trend Information

Other than as disclosed elsewhere in this Annual Report, we are not aware of any trends, uncertainties, demands, commitments or events for the period from January 1, 2025 to December 31, 2025 that are reasonably likely to have a material adverse effect on the Company’s net income, profitability, liquidity or capital resources, or that caused the reported financial information to be not necessarily indicative of future operating results or financial conditions. For a discussion of trends, see Item 5.A: “Operating results”.

E. Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which we have prepared in accordance with IFRS Accounting Standards as issued by the International Accounting Standards Board (IASB). The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenues and expenses during the reporting periods. Actual results may differ from these estimates under different assumptions or conditions. There have been no material adjustments to prior period estimates for any of the periods included in this Annual Report. Significant estimates and judgements are disclosed in disclosure Note 2 *Basis of preparation* to the financial statements, under (e) Use of estimates and judgements.

Our significant accounting policies are fully described in note 2 of our financial statements appearing elsewhere in this Annual Report.

Item 6: Directors, Senior Management and Employees

A. Directors and Senior Management

We have a one-tier governance structure with the board of directors as the ultimate decision-making body. Our board is supported by our senior management. Our management team is comprised of our executive director together with our senior management, or Management Team. Below is a summary of relevant information concerning our board members and senior management.

Board structure

We have a one-tier board structure consisting of a board of directors comprising one executive and five non-executive directors.

Board of directors

Our board of directors consists of six members, comprised of one executive director, whom we consider to be one of our executive officers, and five non-executive directors. Each of our directors will hold office for the term set by our general meeting, except in the case of his or her earlier death, resignation or dismissal. Our directors do not have a retirement age requirement under our articles of association. The following table sets forth the name, age, position and term of our directors as of the date hereof. Unless otherwise stated, the business address of our members of our directors is c/o AgomAb Therapeutics NV at Posthoflei 1/6, 2600 Antwerpen, Belgium.

Name	Age	Position(s)	Term
Executive Director:			
Tim Knotnerus	43	Chief Executive Officer and Executive Director	Until March 2027
Non-Executive Directors:			
David Epstein	64	Chairman of the Board of Directors	Until May 2030
Angelika Jahreis(2)	60	Non-Executive Director	Until October 2029
Colin Bond(1)(2)	66	Non-Executive Director	Until May 2030
Felice Verduyn-van Weegen(1)(2)	39	Non-Executive Director	Until October 2029
Ohad Hammer(1)	45	Non-Executive Director	Until May 2026

(1) Member of our audit committee
(2) Member of our remuneration, nomination and corporate governance committee

Executive director

Tim Knotnerus has been our Chief Executive Officer since February 2019 and member of our Board of Directors since March 2021. Prior to AgomAb, Mr. Knotnerus held positions of increasing responsibility at AM-Pharma B.V., most recently as Vice President of Corporate Development from June 2012 to April 2020. Prior to that, Mr. Knotnerus was a Senior Associate at Aescap Venture, a venture capital fund investing in European medical companies, from August 2008 to May 2012. Mr. Knotnerus holds an executive MBA from IMD, where he was named Valedictorian, and earned two Master degree programs from Utrecht University. We believe Mr. Knotnerus is qualified to serve on our board of directors because of his breadth of experience with biotechnology companies and his service as our Chief Executive Officer.

Non-executive directors

David R. Epstein has been a member of our board of directors since July, 2024. Mr. Epstein currently serves as Chief Executive Officer and Chairman of the Board of Directors of Ottimo Pharma Limited and is the former Chief Executive Officer and Director of Seagen, Inc. (formerly Nasdaq: SGEN), from November 2022 until Seagen's acquisition by Pfizer Inc. in December 2023. Previously, Mr. Epstein was a consultant and executive partner at Flagship Pioneering from January 2017 until October 2022. Prior to that, Mr. Epstein was Chief Executive Officer for Novartis Pharmaceuticals, a division of Novartis AG (NYSE: NVS). Early in his career, he was an associate in the strategy practice of consulting firm Booz, Allen and Hamilton. He also serves on the board of directors of Tempus AI Inc. (Nasdaq: TEM) since January 2024, Valo Health, LLC, since September 2019 and Frontier Medicines Corporation since April 2026. He has served as a director of a number of biotechnology companies, including OPY Acquisition Corp. I (formerly Nsadaq: OHAA), from October 2021 to December 2023, Senti Biosciences, Inc. (Nasdaq: SNTI), from June 2022 to June 2023, Dynamics Special Purpose Corp, Senti's predecessor, from March 2021 to June 2022, Evelo Biosciences, Inc. from March 2017 to February 2023, Axcella Heath Inc. (formerly Nasdaq: AXLA) (formerly Axcella Therapeutics) from May 2019 to October 2022, Rubius Therapeutics Inc. (formerly Nasdaq: RUBY) from January 2017 to October 2022 and Shape Therapeutics, from May 2024 to April 2025. Mr. Epstein also serves and has served as a director at the non-profit Three Opinions Foundation Inc. and at South Florida's Pelican Harbor Seabird Station. Mr. Epstein holds a B.S. in Pharmacy from Rutgers University College of Pharmacy and an M.B.A. in Finance and Marketing from Columbia University Graduate School of Business. We believe that Mr. Epstein is qualified to serve on our board of directors because of his extensive experience serving in executive roles in the life sciences industry and leading the development and commercialization of numerous therapeutics.

Angelika Jahreis has been a member of our board of directors since October 2023. Ms. Jahreis has been the Senior Vice President, Global Head Immunology and Clinical Development Excellence at Novartis AG (NYSE: NVS), or Novartis, since January 2022 and the Global Head Development Unit Immunology, Hepatology & Dermatology at Novartis since September 2020. Prior to Novartis, she was the Vice President Rheumatology and Autoimmunity at Gilead Sciences (Nasdaq: GILD), or Gilead, from June 2019 to September 2020. From June 2008 to June 2019, Ms. Jahreis worked at Genentech, Inc. which was acquired by Roche Holdings, most recently as Group Medical Director. Ms. Jahreis earned her M.D. and Ph.D. from the University of Freiburg, Germany and conduced her postdoctoral research at The Scripps Research Institute in La Jolla. We believe Ms. Jahreis is qualified to serve on our board of directors because of her extensive experience with biotechnology companies.

Felice Verduyn-van Weegen has been a member of our board of directors since October 2023. Ms. Verduyn-van Weegen has been a Partner at EQT Life Sciences, or EQT, a healthcare investment company, since July 2022. Ms. Verduyn-van Weegen worked for EQT's predecessor, LSP Advisory B.V., or LSP, from March 2015 until July 2022. Prior to joining LSP, Ms. Verduyn-van Weegen worked as a consultant at McKinsey & Company in Amsterdam, Netherlands. Prior to McKinsey, Ms. Verduyn-van Weegen was a neuroscientist and statistical geneticist, working with the prestigious complex traits genetics group at the Broad Institute and Harvard Medical School in Cambridge, Massachusetts. Ms. Verduyn-van Weegen serves and has served on several company boards, including Amolyt Pharma, a clinical-stage endocrine company which was sold to AstraZeneca in 2024, from July 2019 to July 2024, and Evommune, Inc. (NYSE: EVMN), a clinical-stage immunology company, since September 2021. Ms. Verduyn-van Weegen holds a MSc degree (cum laude) in Neuroscience from VU University Amsterdam and an MBA degree (with distinction) from Columbia Business School in New York. We believe Ms. Verduyn is qualified to serve on our board of directors because of her extensive experience in healthcare investments and her board service.

Ohad Hammer has been a member of our board of directors since April 2019. Mr. Hammer has been a Partner at Pontifax Venture Capital, or Pontifax, since January 2013. He also serves on the board of several of Pontifax's portfolio companies including Step Pharma SAS since March 2021 and ADCendo ApS since April 2023. Mr. Hammer obtained his MSc in Biology from Tel-Aviv University. We believe Mr. Hammer is qualified to serve on our board of directors because of his experience in venture investments and service on numerous boards of directors of biotechnology companies.

Colin Bond has been a member of our board of directors since November 2024. Mr. Bond served as Chief Financial Officer at Sandoz, where he successfully led the spin-out of the company from Novartis. Previously, he was Chief Financial Officer at Vifor Pharma where he was instrumental in the separation of Galenica from Vifor Pharma onto the Swiss Exchange in 2017. During his career, he also served as Chief Financial Officer of Evotec and worked as a pharmacist, auditor and management consultant. Mr. Bond also has extensive Board experience and serves and has served as Audit Committee Chair at Siegfried Holding AG (SWX: SFZN), from April 2013 to April 2023, BioPharma Credit PLC (BOPCF), since November 2016, Faron Pharmaceuticals Ltd. (LON: FARN), since March 2025, Oxford Biomedica PLC (OXBDF), since January 2025 and Formycon AG (ETR: FYB). In addition, he is currently on the Boards of Faron Pharmaceuticals Ltd., since March 2025, Medichem S.A., since February 2025, Formycon AG, since October 2024 and OneSource Specialty Pharma Ltd. (NSE: ONESOURCE), since June 2025. He is a Fellow of the Institute of Chartered Accountants in England and Wales and a member of the Royal Pharmaceutical Society of Great Britain. Mr. Bond holds an MBA from London Business School. We believe that Mr. Bond is qualified to serve on our board of directors because of his extensive experience serving in executive and board roles in the life sciences industry.

Executive Committee

The following table sets forth the name, age and position of our senior management as of the date hereof. Unless otherwise stated, the business address of our senior management is c/o AgomAb Therapeutics NV at Posthoflei 1/6, 2600 Antwerpen, Belgium.

Name	Age	Position(s)
Philippe Wiesel	59	Chief Medical Officer
Pierre Kemula	52	Chief Financial Officer
Andrea Sáez	45	Chief Development Officer
Paul van der Horst	39	Chief Business Officer
Ellen Lefever	41	General Counsel

Philippe Wiesel has been our Chief Medical Officer since January 2021. Previously, from August 2010 to December 2020, Dr. Wiesel was the Chief Medical Officer at Genkyotex SA, a clinical development company developing treatment for fibrotic disorders in the liver, lung, and kidney, which was acquired by Calliditas Therapeutics AB in 2021. Prior to this role, Dr. Wiesel co-founded Genexion SA, which was focused on developing early-stage clinical assets in partnership with emerging biotechnology companies. Before this, Dr. Wiesel was Medical Director at EMD Serono, Inc., where he was involved with the global development of several biologics. In particular, he led the late-stage clinical development of Raptiva, achieving the first marketing authorization in Europe for a biological therapy targeting psoriasis. Dr. Wiesel received an M.D. in Medicine from Lausanne University Medical School and was a postdoctoral researcher at Harvard University Medical School and the Division of Hypertension at Lausanne University.

Pierre Kemula, B.Sc. has been our Chief Financial Officer since November 2024. He previously served as the Chief Financial Officer of Nasdaq listed biotech Company, CureVac N.V. from October 2016 to November 2024. Prior to this, Mr. Kemula was Chief Financial Officer of Euronext listed Pixium Vision from May 2014 to September 2016, and Vice President of Corporate Finance, Treasury and Financial Markets, as well as Director of Investor Relations, Vice President of Investor Relations at lpsen from September 2008 to May 2014 and December 2008 to July 2012, respectively. He holds a Bachelor of Science in Management Sciences from the London School of Economics, or LSE, in the United Kingdom.

Andrea Sáez has been our Chief Development Officer since November 2023 and was previously our Head of Portfolio Development from January 2022 to November 2023. Prior to joining AgomAb she was Chief Operating Officer from July 2021 to January 2022 and Chief Scientific Officer from September 2020 to January 2022 at Origo Biopharma S.L., or Origo, which we acquired in 2021. Prior to joining Origo, Dr. Sáez was a Senior Associate and Associate, respectively, from June 2020 to September 2020 and October 2018 to June 2020 at Asabys Partners, a venture capital firm in Barcelona. From January 2015 to September 2018, Dr. Sáez was the Director of Research and Development at Pangaea Oncology and from May 2012 to January 2015, she was a Scientific and Regulatory Affairs Manager at Asphalion, a leading consultancy firm. Dr. Sáez was a Board Observer at ONA Therapeutics, a Barcelona-based biotechnology company, from May 2019 to June 2020. Dr. Sáez obtained a Ph.D. in Immunology at the Pompeu Fabra University followed by a postdoctoral stay at Vall d'Hebron Hospital where she studied and published on the therapeutic benefit of TGF-β inhibitors in preclinical cancer models.

Paul van der Horst has been our Chief Business Officer since May 2021 and was our Chief Financial Officer between May 2024 and November 2024. Prior to joining AgomAb, he was Head of Corporate Development at Galapagos NV (Nasdaq: GLPG), or Galapagos, from April 2019 to April 2021. From March 2016 to March 2019, he was the Director of Business Development at Galapagos and from March 2016 to September 2018 he was the Investor Relations Officer Europe at Galapagos. Earlier in his career, he worked at boutique investment bank, Kempen & Co., in Amsterdam. From January 2020 to April 2021 he was a nonexecutive Board Member of Fibrocor Therapeutics (Toronto, Canada). In addition, from April 2021 to January 2023, Dr. van der Horst was an advisor at ImmuneTune in the Netherlands and, since January 2022, was a member, and as of June 2023 became president, of the Supervisory Board of Molecure S.A. in Poland. Dr. van der Horst studied medicine and holds a Ph.D. in Gynaecology from the Erasmus University Medical Centre in Rotterdam, The Netherlands.

Ellen Lefever has been our General Counsel since July 2021. She previously served as Deputy General Counsel at Galapagos from April 2019 to June 2021 and as Legal Counsel at Galapagos from May 2014 to April 2019. Prior to this, from September 2007 to April 2014, she worked at corporate law firms Linklaters, Simpson, Thacher & Bartlett and Eubelius, where she focused on M&A and capital markets transactions. Ms. Lefever holds an L.L.M. in Corporate Governance & Practice from Stanford Law School and a master's degree in law from the University of Leuven. She is qualified to practice in Belgium and New York.

Other than directorships or employment relationships with our shareholders as disclosed above, there are no arrangements or understandings with major shareholders, customers, suppliers or others pursuant to which any director or member of senior management was selected for their position.

Family relationships

There are no family relationships among any of the members of our senior management or directors.

B. Compensation

Compensation of members of our senior management and directors

Each of the members of our executive committee has entered into an employment agreement with us. The aggregate compensation, including benefits in kind, accrued or paid to the current members of our executive committee with respect to the year ended December 31, 2025, was €3.1 million. Equity-based compensation of the members of our executive committee at December 31, 2025 included warrants to purchase an aggregate of 2,540,650 common shares (on a post-stock split basis) with an exercise price of €0.00046, 296,126 common shares (on a post-stock split basis) with an exercise price of €0.98, 486,213 common shares (on a post-stock split basis) with an exercise price of €2.41, 6,927 common shares (on a post-stock split basis) with an exercise price of €2.45, 234,178 common shares (on a post-stock split basis) with an exercise price of €2.77 and 140,758 common shares (on a post-stock split basis) with an exercise price of €2.98, in each case expiring ten years after the date of issuance. As of December 31, 2025, we have made pension contributions of €26,266 to defined contribution pension plans for the benefit of the current members of our executive committee.

Our Remuneration Committee recommends the level of remuneration for directors. These recommendations are subject to approval by our board of directors and, subsequently, by our shareholders at a general meeting of shareholders. The aggregate compensation, including benefits in kind, accrued or paid to our independent directors with respect to the year ended December 31, 2025 for services in all capacities was €62,681. Equity-based compensation of our independent directors at December 31, 2025 included warrants to purchase an aggregate of 772,555 common shares (on a post-stock split basis) with an exercise price of €2.45, 94,438 common shares (on a post-stock split basis) with an exercise price of €2.70 and 96,321 common shares (on a post-stock split basis) with an exercise price of €2.77, in each case expiring ten years after the date of issuance. In addition, on November 19, 2025 warrants to purchase 271,624 common shares (on a post-stock split basis) with an exercise price of €4.58 were offered to independent directors.

As a foreign private issuer, in accordance with Nasdaq listing requirements, we will comply with home country compensation requirements and certain exemptions thereunder rather than complying with Nasdaq compensation requirements. Belgian law does not provide for limitations with respect to the aggregate annual compensation paid to our directors or members of our executive committee. These compensation packages may consist of a mix of fixed and variable compensation components, including base salary, short-term incentives, long-term incentives, fringe benefits, severance pay and pension arrangements, as determined by our board of directors. Our executive director may not participate in the discussions or decision-making regarding his remuneration. A proposal with respect to remuneration schemes in the form of shares or rights to shares in which directors may participate is subject to approval by our general meeting by simple majority of votes cast.

C. Board Practices

Our board of directors is currently composed of one executive director (who is our Chief Executive Officer) and five non-executive directors. Our board of directors has determined that no director other than Mr. Knotnerus has a relationship that would interfere with the exercise of independent judgment in carrying out his or her responsibilities as a director and that each of these directors is "independent" as that term is defined under Nasdaq rules.

Each director shall serve until his or her successor is duly elected and qualified or until his or her earlier death, resignation or removal. See Item 6: "Directors, Senior Management and Employees."

The business and affairs of the Company are managed by or under the direction of the board of directors. Our board of directors has delegated to the executive director the authority and responsibility for managing the Company's everyday affairs and has delegated certain powers to the executive committee of the Company.

Our board of directors reserves the right at any time to propose to increase or decrease its size, subject to any provisions in the Company's articles of association, depending on the board's assessment of its needs and other factors. The size of the Board may vary based upon the size of the business and the availability of qualified candidates. Board size should facilitate active interaction and participation by all Board members. The board will review from time to time the appropriateness of its size.

Service Agreements

We have entered into service agreements, or employment agreements, with certain of our directors and members of our senior management. These employment agreements contain customary provisions and representations, including confidentiality, non-competition and non-solicitation undertakings by the directors and members of our senior management. The enforceability of the non-competition provisions may be limited under applicable law.

Committees of the Board

During 2025, our board of directors had two standing committees: an audit committee and a remuneration, nomination and corporate governance committee, each of which operates pursuant to a charter adopted by our board of directors. Each committee is governed by a charter that is posted on our website. We believe that the composition and functioning of all of our committees will comply with the applicable requirements of Nasdaq, the SOX act and SEC rules and regulations that will be applicable to us. We intend to comply with future requirements to the extent they become applicable to us.

Audit committee

The audit committee consists of Colin Bond, Ohad Hammer and Felice Verduyn-van Weegen. Colin Bond serves as chairperson of the audit committee. Our board of directors has determined that each member of the audit committee satisfies the "independence" requirements set forth in Rule 10A-3 under the Exchange Act and Colin Bond qualifies as an "audit committee financial expert," as such term is defined in the rules of the SEC.

The audit committee is responsible for, among other things:

- monitoring the preparation of accounting and financial information and, where appropriate, formulating recommendations in this respect to ensure its accuracy;
- reviewing the effectiveness of the internal control and risk management systems;
- assisting the board of directors in ensuring proper oversight of the preparation of the annual financial statements and audit of financial statements by the statutory auditors; and
- appointment, compensation, retention and oversight of the work of, and ensuring the independence of, the statutory auditors; and
- monitoring compliance with the adopted related person transaction policy referred to below in the section "*Related party transaction policy*", and, as the case may be, approve certain related person transactions in accordance with the aforementioned policy.
- The audit committee will be responsible for approving:
    - non-audit services provided by the statutory auditors (including the permitted level of fees); and
    - all budgets for statutory audits and other engagements provided by the statutory auditors.
- The audit committee will further control the services provided by the auditors in relation to what is permitted by law or regulation.
- The audit committee will be responsible for formulating recommendations regarding the proposal for the appointment of the statutory auditor to be submitted for shareholder approval and the renewal of their term.
- Within this context, the audit committee will be able to examine our annual financial statements in the form that they are presented to the Board, hear the opinions of the statutory auditors and the finance director and receive communications in relation to their analysis work and their conclusions.

Remuneration, nomination and corporate governance committee

The remuneration, nomination and corporate governance committee consists of Angelika Jahreis, Colin Bond and Felice Verduyn-van Weegen. Felice Verduyn-van Weegen serves as chairperson of the remuneration, nomination and corporate governance committee. Under SEC and Nasdaq rules, there are heightened independence standards for members of a remuneration committee, including a prohibition against the receipt of any compensation from us other than standard director fees.

The remuneration, nomination and corporate governance committee is responsible for, among other things:

- assisting our board of directors in determining remuneration for our directors and members of our executive committee;
- identifying individuals qualified to become our directors or members of our executive committee consistent with criteria established by us;

- reviewing the composition of the board of directors and the executive management to ensure that it is composed of members containing the appropriate skills and expertise to advise us;
- reviewing and establishing our overall remuneration philosophy and policy;
- overseeing and administering our remuneration and similar plans;
- overseeing the evaluation of our board of directors and the executive management; and
- developing and recommending to the board of directors a code of business conduct and ethics and a set of corporate governance guidelines.

Insurance and Indemnification of Board Members

We maintain customary director and officer insurance that covers potential liability of the directors, officers and certain agents of the Company and its subsidiaries.

D. Employees

As of December 31, 2025, we had 62 employees and 18 consultants providing us directly with services. 38 of our employees and consultants hold M.D. or Ph.D. degrees. 55 of our employees and consultants work in research and development or intellectual property and 25 work in management and administrative areas. We do not employ a significant number of temporary employees. 53 of our employees have an employment contract with AgomAb Therapeutics NV, six have a Spanish employment contract with Agomab Spain and three have an employment contract with Agomab US. 33 of our employees are females and 29 are males. As far as we know, our employees are not represented by a labor union. We have never experienced any employment related work stoppages, and we consider our relations with our employees to be good in general.

E. Share Ownership

Refer to Item 7.A: “Major Shareholders” in this Annual Report.

F. Disclosure of a Registrant’s Action to Recover Erroneously Awarded Compensation

Not applicable.

Item 7: Major Shareholders and Related Party Transactions

A. Major Shareholders

The following table sets forth information with respect to the beneficial ownership of our ordinary shares as of March 31, 2026 by:

- each person, or group of affiliated persons, known by us to beneficially own more than 5% of our common shares;
- each of our directors and members of our executive committee; and
- all of our directors and members of our executive committee as a group.

The percentage of shares beneficially owned is based on a total of 49,247,975 common shares outstanding as at March 31, 2026. The numbers and percentages of ordinary shares beneficially owned are reported on the basis of regulations of the SEC governing the determination of beneficial ownership of securities. Under the applicable SEC rules, a person is deemed to be a "beneficial owner" of a security if that person has or shares voting power, which includes the power to vote or direct the voting of such security, or investment power, which includes the power to dispose of or to direct the disposition of such security, or to receive the economic benefit of ownership of the securities. A person is also deemed to be a beneficial owner of any securities of which that person has a right to acquire beneficial ownership within 60 days of March 31, 2026, and such securities are considered outstanding for the purpose of calculating the percentage ownership of that person but not for the purpose of calculating the percentage ownership of any other person. Under these rules, more than one person may be deemed beneficial owner of the same securities and a person may be deemed to be a beneficial owner of securities as to which such person has no economic interest. Except as otherwise indicated, each of the beneficial owners has, to our knowledge, sole voting and investment power with respect to the indicated common shares, subject to community property laws, where applicable.

Except as otherwise indicated, all of the shares reflected in the table are ordinary shares or ADSs, and all persons listed below have sole voting and investment power with respect to the shares beneficially owned by them, subject to applicable community property laws.

The information is not necessarily indicative of beneficial ownership for any other purpose. Except as otherwise set forth below, the address of the beneficial owner is c/o AgomAb Therapeutics NV, Posthoflei 1/6 2600 Antwerpen, Belgium.

	Shares beneficially owned	
Name of beneficial owner	**Number**	**Percentage**
5% or Greater Shareholders:		
LSP 7 Coöperatief U.A.(1)	5,141,992	10.44 %
Entities affiliated with Fidelity Management & Research Company(2)	4,873,680	9.90 %
Entities affiliated with Pontifax(3)	3,305,846	6.71 %
Sanofi Foreign Participations B.V.(4)	2,783,096	5.65 %
Redmile Biopharma Investments III, L.P.(5)	2,735,926	5.56 %
Entities affiliated with Cormorant Asset Management(6)	2,652,847	5.39 %
Members of Senior Management and Directors:		
Tim Knotnerus(7)	1,340,736	2.65 %
David Epstein	*	*
Angelika Jahreis	*	*
Colin Bond	*	*
Felice Verduyn-van Weegen(8)	5,141,992	10.44 %
Ohad Hammer(9)	3,305,846	6.71 %
Members of our executive committee (excluding our chief executive officer)(10)	1,582,253	3.11 %
All members of our executive committee and directors as a group (11 persons)(11)	12,035,460	23.09 %

1 Consists of (i) 4,016,992 common shares held directly by LSP 7 Coöperatief U.A ("LSP 7") and (ii) 1,125,000 American Depositary Shares (each representing one common share) held directly by LSP 7. LSP 7 Management B.V. is the sole director of LSP 7 and may be deemed to have voting and investment power over the shares held by LSP 7. Martijn Kleijwegt, Renee Kuijten and Joachim Rothe are the managing directors of LSP 7 Management B.V. and make voting and investment decisions with respect to the shares held by LSP 7. LSP 7 Management B.V. is an (indirect) subsidiary of EQT AB and is part of EQT Life Sciences (the early stage life sciences investment franchise of EQT). Felice Verduyn-van Weegen is a partner in the EQT Life Sciences team and is a member of our board of directors, but does not hold voting or dispositive power over the shares held by LSP 7. The business address of each of the entities and individuals identified in this footnote is Johannes Vermeerplein 9 1071 DV Amsterdam, the Netherlands.

2 All of the shares listed in the table above are owned by funds or accounts managed by direct or indirect subsidiaries of Fidelity Management & Research Company LLC ("FMR LLC"), all of which shares are beneficially owned, or may be deemed to be beneficially owned, by FMR LLC, certain of its subsidiaries and affiliates, and other companies. Abigail P. Johnson is a Director, the Chairman and the Chief Executive Officer of FMR LLC. Members of the Johnson family, including Abigail P. Johnson, are the predominant owners, directly or through trusts, of Series B voting common shares of FMR LLC, representing 49% of the voting power of FMR LLC. The Johnson family group and all other Series B shareholders have entered into a shareholders' voting agreement under which all Series B voting common shares will be voted in accordance with the majority vote of Series B voting common shares. Accordingly, through their ownership of voting common shares and the execution of the shareholders' voting agreement, members of the Johnson family may be deemed, under the Investment Company Act of 1940, to form a controlling group with respect to FMR LLC. The address of FMR LLC is 245 Summer Street, Boston, MA 02210.

3 Consists of (i) 1,628,204 common shares and 131,370 American Depositary Shares (each representing one common share) held directly by Pontifax Israel V L.P. ("Pontifax Israel"), (ii) 632,576 common shares and 51,040 American Depositary Shares (each representing one common share) held directly by Pontifax China V L.P. ("Pontifax China"), (iii) 434,892 common shares and 35,090 American Depositary Shares (each representing one common share) held directly by Pontifax Cayman V L.P. ("Pontifax Cayman" and together with Pontifax Israel and Pontifax China, the "Pontifax V Entities") and (iv) 360,174 common shares and 32,500 American Depositary Shares (each representing one common share) held directly by Pontifax Late Stage Fund L.P. ("Pontifax Late Stage Fund"). Pontifax Management 4 G.P. (2015) Ltd. ("Pontifax Management") is the ultimate general partner of each of the Pontifax V Entities. Ran Nussbaum and Tomer Kariv are the sole shareholders of Pontifax Management and, as a result, may be deemed to share voting and investment power with respect to the shares held by each of the Pontifax V Entities. Pontifax Late Stage GP Ltd. is the general partner of Pontifax Late Stage Fund, and Mr. Shlomo Karako is the sole shareholder of Pontifax Late Stage GP Ltd. Pursuant to a Strategic Alliance Agreement between Pontifax Late Stage Fund and the Pontifax V GP LP, Pontifax Late Stage Fund invests side-by-side with the Pontifax V Entities. By virtue of the strategic relationship, each of Pontifax Management Managing Partners, Mr. Kariv and Mr. Nussbaum may be deemed to share voting and investment power with respect to the shares held by Pontifax Late Stage Fund in a manner similar to the voting and investment power with respect to the shares held by each of the Pontifax V Entities. Ohad Hammer is the CFO at Pontifax Management and is a member of our board of directors but does not have voting or investment power with respect to the shares held by the Pontifax V Entities or Pontifax Late Stage Fund. The address of each of entities identified in this footnote is c/o The Pontifax Group, 14 Shenkar Street, Herzelia, Israel.

4 Consists of 2,708,096 common shares and 75,000 American Depositary Shares (each representing one common share) held directly by Sanofi Foreign Participations B.V. Sanofi Foreign Participations B.V. is a wholly owned subsidiary of Sanofi, and as such, Sanofi has the ability to exercise voting and dispositive power over the shares held by Sanofi Foreign Participations B.V. The address for Sanofi Foreign Participations B.V. is Paasheuvelweg 25, 1105BP Amsterdam, the Netherlands.

5 Consists of 2,579,676 common shares and 156,250 American Depositary Shares (each representing one common share) held directly by Redmile Biopharma Investments III, L.P. (the "Redmile Fund"). Redmile Group, LLC ("Redmile") is the investment manager of the Redmile Fund and, in such capacity, exercises voting and investment power over all of the shares held by the Redmile Fund and may be deemed to be the beneficial owner of these shares. Jeremy C. Green serves as the managing member of Redmile and also may be deemed to be the beneficial owner of these shares. Redmile and Mr. Green each disclaim beneficial ownership of these shares except to the extent of its or his pecuniary interest in such shares, if any. The address of the foregoing entities and individuals is c/o Redmile Group, LLC, One Letterman Drive, Building D, Suite D3-300, San Francisco, California 94129.

6 Consists of (i) 396,148 common shares held directly by Cormorant Global Healthcare Master Fund, LP ("Master Fund"), (ii) 1,683,680 common shares held directly by Cormorant Private Healthcare Fund III, LP ("Fund III"), (iii) 129,762 common shares held directly by Cormorant Private Healthcare Fund IV, LP ("Fund IV"), (iv) 225,758 common shares held directly by Cormorant Private Healthcare Fund V, LP ("Fund V") and (v) 30,000 common shares held directly by CRMA SPV, L.P. ("CRMA"), and 187,500 American Depositary Shares (each representing one common share) held by one or more entities affiliated with Cormorant. Cormorant Global Healthcare GP, LLC serves as the general partner of Master Fund, Cormorant Private Healthcare GP III, LLC serves as the general partner of Fund III, Cormorant Private Healthcare GP IV, LLC serves as the general partner of Fund IV, Cormorant Private Healthcare GP V, LLC serves as the general partner of Fund V, and Cormorant Asset Management, LP ("Cormorant") serves as the investment manager to Master Fund, Fund III, Fund IV, Fund V and CRMA. Bihua Chen serves as the managing member of Cormorant Global Healthcare GP, LLC, Cormorant Private Healthcare GP III, LLC, Cormorant Private Healthcare GP IV, LLC and Cormorant Private Healthcare GP V, LLC, and the general partner of Cormorant and therefore may be deemed to have voting and investment power over such shares. The business address of each of the entities and individuals identified in this footnote is 200 Clarendon Street 52nd Floor, Boston, Massachusetts 02116.

7 Consists of (i) 34,394 common shares held by TJK Life Sciences B.V., a limited liability company organized and existing under the laws of the Netherlands ("TJK Life Sciences"), (ii) 10,823 common shares held directly by Mr. Knotnerus and (iii) 1,295,519 common shares underlying outstanding share options that are immediately exercisable within 60 days of March 31, 2026. Mr. Knotnerus exercises voting and dispositive power over the shares beneficially owned by TJK Life Sciences.

8 Consists of the shares described in footnote (1) above. Ms. Verduyn-van Weegen disclaims beneficial ownership of such shares except to the extent of her pecuniary interest therein, if any.

9 Consists of the shares described in footnote (3) above. Mr. Hammer disclaims beneficial ownership of such shares except to the extent of his pecuniary interest therein, if any.

10 Consists of 1,582,253 common shares underlying outstanding share options that are immediately exercisable within 60 days of March 31, 2026 beneficially owned by members of our executive committee, excluding our chief executive officer.

11 Consists of (i) 8,493,054 common shares and (ii) 3,542,406 common shares underlying outstanding share options that are immediately exercisable within 60 days of March 31, 2026.

In November 2024, we issued and sold 342,206 Series D preferred shares to certain investors pursuant to a share subscription agreement among us and the investors party thereto. Each of the following parties was also issued ten anti-dilution warrants in connection with its purchase, which expired upon the closing of our initial public offering.

The following table summarizes purchases of our Series D preferred shares and anti-dilution warrants and corresponding change in the percentage ownership held by major shareholders upon the purchase:

Name	Shares purchased	Change in percentage of shares held on a fully diluted basis
Entities affiliated with Cormorant Asset Management(1)	12,511	(14.06)%
Entities affiliated with Fidelity Management & Research Company(2)	34,273	(2.29)%
LSP 7 Coöperatief U.A.(3)	41,704	(1.33)%
Entities affiliated with Pontifax(4)	8,340	(18.69)%
Sanofi Foreign Participations B.V.(5)	125,114	100 %

(1) Entities affiliated with Cormorant Asset Management collectively hold more than 5% of our voting securities.
(2) Entities affiliated with Fidelity Management & Research Company collectively hold more than 5% of our voting securities.
(3) LSP 7 Coöperatief U.A holds more than 5% of our voting securities. LSP 7 Coöperatief U.A is affiliated with EQT Life Sciences and Felice Verduyn-van Weegen is a partner in the EQT Life Science team and is a member of our board of directors.
(4) Entities affiliated with Pontifax collectively hold more than 5% of our voting securities. Ohad Hammer is a partner at Pontifax and is a member of our board of directors.
(5) Sanofi Foreign Participations B.V., or Sanofi, holds more than 5% of our voting securities. Prior to the Series D financing round, Sanofi did not hold any of our shares.

For more information regarding changes in percent ownership held by major shareholders since January 1, 2025, please see "Item 7.B—Related Party Transactions" below.

Each of our shareholders is entitled to one vote per ordinary share. All shareholders have identical voting rights per share. We are not aware of any arrangement that may result in a change of control of our company.

Holdings by U.S. Shareholders

As at March 31, 2026, 54.94% of our ordinary shares were held by record holders in the United States, which excludes shareholders whose shares were held in nominee or street name by brokers.

B. Related Party Transactions

Within this section, we have calculated the euro amounts using the historical exchange rate as of the date of each transaction. Other than compensation arrangements described in "Item 6.B—Compensation" in this Annual Report, since January 1, 2025, we have engaged in the following transactions with our members of our executive committee, directors or holders of more than 5% of our share capital, including their affiliates, which we refer to as our related parties.

Initial Public Offering

In February 2026, in connection with our initial public offering, or the IPO, we issued an aggregate of 12,500,000 ADSs at a price of $16.00 per ADS. In addition, upon the closing of the IPO, all outstanding shares of our convertible preferred shares converted into an aggregate of 33,626,042 common shares and we issued 2,069,611 common shares to argenx BV upon the conversion of the profit sharing certificate. On March 4, 2026, the underwriters exercised a portion of their overallotment option, pursuant to which we issued and sold an additional 482,967 ADSs at a price of $16.00 per ADS. Proceeds from the IPO, including proceeds from the underwriters' overallotment option, net of underwriting discounts and commissions and offering expenses, were approximately $188 million. The following table summarizes purchase of our ADSs by related person in connection with our IPO:

Name	ADSs	Aggregate purchase price paid
LSP 7 Coöperatief U.A. (1)	1,125,000	$ 18,000,000
Entities affiliated with Fidelity Management & Research Company (2)	1,458,677	$ 23,338,832
Entities affiliated with Pontifax (3)	250,000	$ 4,000,000
Sanofi Foreign Investments B.V. (4)	75,000	$ 1,200,000
Redmile Biopharma Investments III L.P. (5)	156,250	$ 2,500,000
Entities affiliated with Cormorant (6)	187,500	$ 3,000,000
Pfizer, Inc. (7)	75,000	$ 1,200,000

(1) LSP 7 Coöperatief U.A holds more than 5% of our voting securities. LSP 7 Coöperatief U.A is affiliated with EQT Life Sciences and Felice Verduyn -van Weegen is a partner in the EQT Life Science team and is a member of our board of directors.
(2) Entities affiliated with Fidelity Management & Research Company collectively hold more than 5% of our voting securities.
(3) Entities affiliated with Pontifax collectively hold more than 5% of our voting securities. Ohad Hammer is a partner at Pontifax and is a member of our board of directors.
(4) Sanofi Foreign Participations B.V., or Sanofi, holds more than 5% of our voting securities
(5) Redmile Biopharma Investments III L.P. holds more than 5% of our voting securities.
(6) Entities affiliated with Cormorant Asset Management collectively hold more than 5% of our voting securities.
(7) Pfizer, Inc. held more than 5% of our voting securities.

There are no outstanding loans granted by our Company to any of the members of the board of directors and members of the executive management, nor are there any guarantees provided by our Company for the benefit of any of the members of the board of directors and members of the executive management.

C. Interests of Experts and Counsel

Not applicable.

Item 8: Financial Information

A. Consolidated Statements and Other Financial Information

Consolidated financial statements

See "Item18. Financial statements," which contains our audited financial statements prepared in accordance with IFRS Accounting Standards as issued by the International Accounting Standards Board (IASB).

Legal proceedings

From time to time we could be involved in legal proceedings that arise in the ordinary course of business. As at December 31, 2025, we believe no proceedings exists of which the outcome, if determined adversely, would have a material adverse effect on our financial position. During the period covered by the audited and approved financial statements contained herein, we have not been a party to or paid any damages in connection with litigation that has had a material adverse effect on our financial position. Any future litigation may result in substantial costs and be a distraction to management and employees. No assurance can be given that future litigation will not have a material adverse effect on our financial position. Refer to "Item 3.D: Risk Factors."

Dividends and other Distributions

Under Belgian law, companies can make distributions to shareholders either as dividends of profits or as a return of capital from a reduction of share capital or issue premium.

Dividends of profits

All shares participate equally in our company's profits (if any). Pursuant to the Belgian Companies and Associations Code, the shareholders can in principle decide on the distribution of profits with a simple majority vote at the occasion of the annual general shareholders' meeting, based on the most recent non-consolidated statutory audited financial statements, prepared in accordance with Belgian GAAP and based on a (non-binding) proposal of the Company's board of directors. The Belgian Companies and Associations Code and the Company's articles of association also authorize the board of directors to declare interim dividends without shareholder approval. The right to pay such interim dividends is, however, subject to certain legal restrictions.

Our ability to distribute dividends is subject to availability of sufficient distributable profits as defined under Belgian law on the basis of our stand-alone statutory accounts prepared in accordance with accounting principles generally accepted in Belgium, or Belgian GAAP (and hence not on the basis of the IFRS consolidated accounts). In particular, dividends can only be distributed if, following the declaration and issuance of the dividends, the amount of our net assets on the date of the closing of the last financial year as shown on the stand-alone statutory financial statements (i.e., summarized, the amount of the assets as shown on the balance sheet, decreased by provisions and liabilities, and, save in exceptional cases, to be mentioned and justified in the notes to the annual accounts, decreased by the non-amortized costs of incorporation and extension and the non-amortized costs for research and development, all in accordance with Belgian GAAP), does not fall below the amount of the paid-up capital (or, if higher, the issued capital), increased by the amount of non-distributable reserves (which include, as the case may be, the unamortized part of any revaluation surpluses).

Furthermore, pursuant to Belgian law and our articles of association, we must allocate each year an amount of at least 5% of our annual net profit under our stand-alone statutory accounts (prepared in accordance with Belgian GAAP) to a legal reserve on our stand-alone statutory accounts, until the legal reserve amounts to 10% of our share capital. Our legal reserve currently does not meet this requirement. Accordingly, 5% of our annual net profit under our stand-alone statutory accounts (prepared in accordance with Belgian GAAP) during future years will need to be allocated to the legal reserve, further limiting our ability to pay out dividends to our shareholders.

In addition, further financial restrictions and other limitations may be contained in future credit agreements.

The right to payment of dividends expires five years after the board of directors declared the dividend payable.

Under the DGCL, a Delaware corporation may pay dividends out of its surplus (the excess of net assets over capital), or in case there is no surplus, out of its net profits for either or both of the fiscal year in which the dividend is declared and the preceding fiscal year (provided that the amount of the capital of the corporation is not less than the aggregate amount of the capital represented by the issued and outstanding stock of all classes having a preference upon the distribution of assets). Dividends may be paid in the form of shares, property or cash.

Return of capital via reduction of share capital or issue premium

All shares will be entitled to participate in the same manner if we return our capital to our shareholders via reducing our share capital or issue premium. Pursuant to the Belgian Companies and Associations Code, reducing our share capital would require an amendment to our articles of association. As described above, such an amendment would be subject to approval of 75% of the votes of our shareholders cast at a shareholders' meeting at which at least 50% of the share capital is represented, or, where quorum was not reached at the first meeting, a subsequent meeting to which quorum requirements will not apply. Subject to the foregoing requirements, we can return our share capital to shareholders as long as it is not reduced to less than a certain de minimis amount. A reduction of our issue premium would not constitute an amendment to our articles of association, but would be subject to the same approval and quorum requirements as such an amendment. Furthermore, if we return capital to shareholders, creditors who have a receivable that has not yet been paid by us, or have an outstanding claim that is subject to arbitration or litigation, can, within two months following the publication of the shareholder approval of the capital return, demand collateral to secure their receivable or claim.

B. Significant Changes

We refer to note 26 of our financial statements.

Item 9: The Offer and Listing

A. Offering and Listing Details

See "Item 9.C The Offer and Listing - Markets."

B. Plan of Distribution

Not applicable.

C. Markets

Since February 6, 2026, our ADSs have been listed on Nasdaq. Our ADSs are currently trading on Nasdaq Global Select Market under ticker symbol "AGMB".

D. Selling Shareholders

Not applicable.

E. Dilution

Not applicable.

F. Expenses of the Issue

Not applicable.

Item 10: Additional Information

A. Share Capital

Not applicable.

B. Memorandum and Articles of Association

Our shareholders adopted the form of Amended and Restated Articles of Association filed as Exhibit 3.2 to our registration statement on Form F-1 (File no. 333-292790) with the SEC on January 16, 2026. In connection with our initial public offering, the Amended and Restated Articles of Association became effective on February 9, 2026. In connection with the underwriters' partial exercise of their overallotment option, the further Amended and Restated Articles of Association became effective on March 4, 2026. On March 12, 2026, in connection with employee exercise of warrants under our equity plan, a further updated version of our Amended and Restated Articles of Association became effective. A copy of our Amended and Restated Articles of Association is attached as Exhibit 1.1 to this Annual Report.

We incorporate by reference into this Annual Report the description of our amended articles of association contained in our F-1 registration statement (File No. 333-292790) originally filed with the SEC on January 16, 2026, as amended. For additional information on our memorandum and articles of association, please see Exhibit 2.3 "Description of Securities" to this Annual Report.

C. Material Contracts

Except as otherwise disclosed in this Annual Report (including the Exhibits), we are currently not, and have not been in the two years preceding publication of this Annual Report, party to any material contract, other than contracts entered into in the ordinary course of business.

D. Exchange Controls

There are no Belgian exchange control regulations that impose limitations on our ability to make, or the amount of, cash payments to residents of the United States. We are in principle under an obligation to report to the National Bank of Belgium certain cross-border payments, transfers of funds, investments and other transactions in accordance with applicable balance-of-payments statistical reporting obligations. Where a cross-border transaction is carried out by a Belgian credit institution on our behalf, the credit institution will in certain circumstances be responsible for the reporting obligations.

E. Taxation

Material Belgian tax considerations

General

The following paragraphs are a summary of material Belgian tax consequences of the ownership of ADSs by an investor. The summary is based on laws, treaties and regulatory interpretations in effect in Belgium on the date of this document, all of which are subject to change, including changes that could have retroactive effect.

The summary only discusses Belgian tax aspects which are relevant to U.S. holders of ADSs, or Holders. This summary does not address Belgian tax aspects which are relevant to persons who are residents in Belgium or engaged in a trade or business in Belgium through a permanent establishment or a fixed base in Belgium. This summary does not purport to be a description of all of the tax consequences of the ownership of ADSs and does not take into account the specific circumstances of any particular investor, some of which may be subject to special rules, or the tax laws of any country other than Belgium. This summary does not describe the tax treatment of investors that are subject to special rules, such as banks, insurance companies, collective investment undertakings, dealers in securities or currencies, persons that hold, or will hold, ADSs in a position in a straddle, share-repurchase transaction, conversion transactions, synthetic security or other integrated financial transactions. Investors should consult their own advisers regarding the tax consequences of an investment in ADSs in the light of their particular circumstances, including the effect of any state, local or other national laws, treaties and regulatory interpretation thereof.

In addition to the assumptions mentioned above, it is also assumed in this discussion that for purposes of the domestic Belgian tax legislation, the owners of ADSs will be treated as the owners of the common shares represented by such ADSs. However, the assumption has not been confirmed by or verified with the Belgian Tax Administration.

For the purposes of this summary, ADSs or common shares means common shares represented by ADSs. Both terms are used interchangeably.

Dividend withholding tax

As a general rule under applicable Belgian tax law as of the date of this Annual Report, a withholding tax of 30% is levied on the gross amount of dividends paid on or attributed to the common shares represented by the ADSs, subject to such relief as may be available under applicable domestic or tax treaty provisions. Dividends subject to the dividend withholding tax include all benefits attributed to the common shares represented by the ADSs, irrespective of their form. A reimbursement of fiscal capital made in accordance with the Belgian Companies and Associations Code is partly considered to be a distribution of the existing taxed reserves (irrespective whether incorporated into the capital or not) and/or the tax-free reserves incorporated into the capital. The proportion is determined on the basis of the ratio between certain taxed reserves and tax-free reserves incorporated into the capital on the one hand and, on the other hand, the aggregate of such reserves and the fiscal capital. In principle, fiscal capital includes paid-up statutory share capital, and subject to certain conditions, the paid-up issue premiums and the cash amounts subscribed to at the time of the issue of profit sharing certificates.

In case of a redemption by us of own shares represented by ADSs, the redemption distribution (after deduction of the portion of fiscal capital represented by the redeemed shares) will be treated as a dividend which in certain circumstances may be subject to a withholding tax of 30%, subject to such relief as may be available under applicable domestic or tax treaty provisions. In case of a liquidation of our Company, any amounts distributed in excess of the fiscal capital will be subject to a 30% withholding tax, subject to such relief as may be available under applicable domestic or tax treaty provisions.

For non-residents, the dividend withholding tax will be the only tax on dividends in Belgium, unless the non-resident holds ADSs in connection with a business conducted in Belgium, through a fixed base in Belgium or a Belgian permanent establishment.

The Belgian Program Act of July 18, 2025 introduced a so-called “exit tax” that entered into force on July 29, 2025. This exit tax introduces a deemed liquidation dividend at the shareholder level in case of emigration, cross-border mergers, demergers, and similar reorganisations of a Belgian company provided that they result in assets no longer being used or retained in Belgium. This deemed dividend will be taxed as an ordinary dividend (subject to domestic or treaty reductions or exemptions as may be available).

Relief of Belgian dividend withholding tax

Under the Treaty there is a reduced Belgian withholding tax rate of 15% on dividends paid by us to a U.S. resident which beneficially owns the dividends and is entitled to claim the benefits of the Treaty under the limitation of benefits article included in the Treaty, or a Qualifying Holder. If such Qualifying Holder is a company that owns directly at least 10% of our voting stock, the Belgian withholding tax rate is further reduced to 5%. No withholding tax is however applicable if the Qualifying Holder, is: (i) a company that is a resident of the United States that has owned directly ADSs representing at least 10% of our capital for a 12-month period ending on the date the dividend is declared, or (ii) a pension fund that is a resident of the United States, provided that such dividends are not derived from the carrying on of a business by the pension fund or through an associated enterprise.

Under the normal procedure, we or our paying agent must withhold the full Belgian withholding tax (without taking into account the Treaty rate). Qualifying Holders may make a claim for reimbursement for amounts withheld in excess of the rate defined by the Treaty. The reimbursement form (Form 276 Div-Aut.) may be obtained online on the website of the Belgian tax authorities. Qualifying Holders may also, subject to certain conditions, obtain the reduced Treaty rate at source. Qualifying Holders should deliver a duly completed Form 276 Div-Aut., accompanied with an appropriate U.S. tax residence certificate, no later than ten days after the date on which the dividend is paid or attributed. U.S. Holders should consult their own tax advisors as to whether they qualify for reduction in withholding tax upon payment or attribution of dividends, and as to the procedural requirements for obtaining a reduced withholding tax upon the payment of dividends or for making claims for reimbursement.

Withholding tax is also not applicable, pursuant to Belgian domestic tax law, on dividends paid to certain U.S. pension funds provided that the U.S. pension fund (i) qualifies as a non-resident saver for Belgian withholding tax purposes (i.e., it has a separate legal personality and fiscal residence outside of Belgium and without a permanent establishment or fixed base in Belgium), (ii) has a corporate purpose that consists solely in managing and investing funds collected in order to pay legal or complementary pensions, (iii) has activity that is limited to the investment of funds collected in the exercise of its statutory purpose, without any profit making activity and (iv) is exempt from income taxes in the United States. Furthermore, such pension fund may not contractually be obligated to redistribute the dividends to any beneficial owner of such dividends for whom it would manage the ADSs nor obligated to pay a manufactured dividend with respect to the ADSs under a securities borrowing transaction (save in certain particular cases as described in Belgian law) and subject to certain procedural formalities. A pension fund not holding the shares-which give rise to dividends-for an uninterrupted period of 60 days in full ownership amounts to a rebuttable presumption that the arrangement or series of arrangements which are connected to the dividend distributions, are not genuine. The withholding tax exemption will in such case be rejected, unless counterproof is provided by the OFP that the arrangement or series of arrangements are genuine.

Additionally, pursuant to Belgian domestic tax law, dividends paid or attributed to non-resident individuals who do not use our shares in the exercise of a professional activity may be exempt from non-resident individual income tax up to the taxable amount of EUR 833 (for income year 2026-hence EUR 249.90 of non-resident individual income tax if the 30% withholding tax rate is applicable).

Consequently, if Belgian withholding tax has been levied on dividends paid or attributed to our shares, such Belgian non-resident may request in his or her non-resident income tax return that any Belgian withholding tax levied on dividends up to the amount of EUR 833 (for income year 2026) be credited and, as the case may be, reimbursed. However, if no Belgian non-resident income tax return has to be filed by the non-resident individual, any Belgian withholding tax levied on dividends up to such an amount could in principle be reclaimed by filing a request thereto addressed to the designated tax official. Such a request has to be made at the latest on December 31 of the calendar year following the calendar year in which the relevant dividend(s) have been received, together with an affidavit confirming the non-resident individual status and certain other formalities which are determined by Royal Decree. For the avoidance of doubt, all dividends paid or attributed to the non-resident individual are taken into account to assess whether the maximum amount of EUR 833 (for income year 2026) is reached (and hence not only the amount of dividends paid or attributed on our shares).

Under Belgian domestic tax law, a withholding tax exemption is available to dividends paid to a non-resident corporate shareholder (located in a Member State of the European Union or in a country with which Belgium has entered in a double tax treaty including sufficient information exchange provisions) provided that (i) at the date of payment or attribution of the dividend it holds a participation in our company representing at least 10% of our share capital, (ii) this holding is held or will be held in full ownership for an uninterrupted period of at least one year, (iii) this non-resident corporate shareholder is tax resident of the country where it is established according to the tax laws of and the bilateral tax treaties established by such country, (iv) this non-resident corporate shareholder is subject to a corporate income tax regime similar to Belgian corporate income tax regime without benefitting from a tax regime that derogates from the ordinary tax regime and (v) its legal form is (similar to one of the legal forms) listed in the annex of the E.U. directive dated 2011/96/EU as amended by the directive of 8 July 2014(2014/86/EU). This withholding tax exemption will apply provided that certain procedural formalities are complied with.

Finally, a withholding tax exemption is available, pursuant to Belgian domestic tax law, to dividends paid to a non-resident corporate shareholder (located in the European Economic Area or in a country with which Belgium has entered in a double tax treaty including sufficient information exchange provisions) to the extent that at the date of payment or attribution of the dividend it holds a participation in our company representing less than 10% of our share capital but the acquisition value of which is at least €2.5 million and provided that certain other conditions are met, i.e., that (i) this holding is held or will be held in full ownership for an uninterrupted period of at least one year (ii) this non-resident corporate shareholder is subject to a corporate income tax regime similar to Belgian corporate income tax regime without benefitting from a tax regime that derogates from the ordinary tax regime, (iii) its legal form is (similar to one of the legal forms) listed in the annex I, part A, of the E.U. directive dated 30 November 2011 (2011/96/EU) as amended by the directive of 8 July 2014 (2014/86/EU) and (iv) this participation, if the company receiving the income is not a small company, is classified as a financial fixed asset. This withholding tax exemption will apply only if and to the extent that the ordinary Belgian withholding tax cannot be credited or reimbursed to the non-resident corporate shareholder referred to above and subject to certain procedural formalities.

Please note that the above withholding tax exemptions will not be applicable to dividends which are connected to an arrangement or a series of arrangements (acte juridique ou un ensemble d'actes juridiques/rechtshandeling of geheel van rechtshandelingen) for which the Belgian tax administration, taking into account all relevant facts and circumstances, has proven, unless evidence to the contrary, that this arrangement or this series of arrangements is not genuine (non authentique/kunstmatig) and has been put in place for the main purpose or one of the main purposes of obtaining a tax benefit. An arrangement or a series of arrangements is regarded as not genuine to the extent that they are not put into place for valid commercial reasons which reflect economic reality.

Capital gains and losses

Pursuant to the Treaty, capital gains and/or losses realized by a Qualifying Holder from the sale, exchange or other disposition of ADSs do not generally fall within the scope of application of Belgian domestic tax law.

Capital gains realized on ADSs by a corporate Holder which is not entitled to claim the benefits of the Treaty under the limitation of benefits article included in the Treaty are generally not subject to taxation in Belgium unless the corporate Holder is acting through a Belgian permanent establishment or a fixed place in Belgium to which the ADSs are effectively connected. Capital losses are not deductible.

Private individual Holders who are not entitled to claim the benefits of the Treaty under the limitation of benefits article included in the Treaty and which are holding ADSs as a private investment will, as a rule, not be subject to tax on any capital gains arising out of a disposal of ADSs. Losses will, as a rule, not be deductible in Belgium.

However, if the gain realized by such individual Holders on ADSs is deemed to be realized outside the scope of the normal management of such individual's private estate and the capital gain is obtained or received in Belgium, the gain will in principle be taxable at 33%. The Official Commentary to the ITC 1992 stipulates that occasional transactions on a stock exchange regarding ADSs should not be considered as transactions realized outside the scope of normal management of one's own private estate.

Capital gains realized by such individual Holders on the disposal of ADSs for consideration, outside the exercise of a professional activity, to a non-resident company (or a body constituted in a similar legal form), to a foreign state (or one of its political subdivisions or local authorities) or to a non-resident legal entity who is established outside the European Economic Area, are in principle taxable at a rate of 16.5% if, at any time during the five years preceding the sale, such individual Holder has owned directly or indirectly, alone or with his/her spouse or with certain relatives, a substantial shareholding in us (that is, a shareholding of more than 25% of our shares).

Capital gains realized by a Holder upon the redemption of ADSs or upon our liquidation will generally be taxable as a dividend. See section titled "-Dividend withholding tax."

On April 2, 2026, the Belgian Parliament approved a new law introducing a capital gains tax on financial assets realized by individuals and entities subject to the legal entities tax (not companies). This tax comes in addition of the abovementioned taxes and in case the capital gain is considered realized in the context of a normal management of one's own private estate. The capital gains tax amounts in principle to 10% and applies on capital gains realized after the entry into force of the law (retroactively, January 1, 2026) and only on capital gains accrued as of this date (historical capital gains remain out of scope). Capital losses on financial assets are deductible from capital gains realized in the same taxable year (without possibility of loss carry forward). The regime includes an exemption of the first EUR 10,000 (indexed) of capital gains on an annual basis. A special regime (a higher exemption and lower progressive rates) applies to capital gains on substantial participations of at least 20%.

Moreover, on so-called "internal capital gains", a rate of 33% applies. It is to be noted that the law introducing the above capital gains tax also abolishes taxation of capital gains on shares realized by Belgian non-residents. Any such taxation should in any event not apply to U.S. Holders who can claim the benefits of the Treaty.

Estate and gift tax

There is no Belgian estate tax on the transfer of ADSs upon the death of a Belgian non-resident.

Donations of ADSs made in Belgium may or may not be subject to gift tax in Belgium depending on the modalities under which the donation is carried out.

Belgian tax on stock exchange transactions

A tax on stock exchange transactions (*taxe sur les opérations de bourse/taks op de beursverrichtingen*) is generally levied on the purchase and the sale and on any other acquisition and transfer for consideration of existing ADSs on the secondary market carried out by a Belgian resident investor through a professional intermediary if (i) executed in Belgium through a professional intermediary, or (ii) deemed to be executed in Belgium, which is the case if the order is directly or indirectly made to a professional intermediary established outside of Belgium, either by private individuals having their usual residence in Belgium, or legal entities for the account of their seat or establishment in Belgium.

The applicable rate amounts to 0.35% of the consideration paid but with a cap of €1,600 per transaction and per party. The tax is due separately from each party to any such transaction, i.e., the seller (transferor) and the purchaser (transferee), both collected by the professional intermediary.

However, if the intermediary is established outside of Belgium, the tax will in principle be due by the ordering private individual or legal entity, unless that individual or entity can demonstrate that the tax has already been paid. Professional intermediaries established outside of Belgium can, subject to certain conditions and formalities, appoint a Belgian representative for tax purposes, which will be liable for the tax on stock exchange transactions in respect of the transactions executed through the professional intermediary.

Belgian non-residents who purchase or otherwise acquire or transfer, for consideration, ADSs in Belgium for their own account through a professional intermediary may be exempt from the tax on stock exchange transactions if they deliver a sworn affidavit to the intermediary in Belgium confirming their non-resident status.

No stock exchange tax is payable by: (i) professional intermediaries described in Article 2, 9° and 10° of the Belgian Act of August 2, 2002 acting for their own account, (ii) insurance companies described in Article 6 of the Belgian Act of 13 March 2016 on the status and control of insurance and reinsurance companies, (iii) professional retirement institutions referred to in Article 2, 1° of the Belgian Act of October 27, 2006 relating to the control of professional retirement institutions acting for their own account, (iv) collective investment institutions acting for their own account, or (v) regulated real estate companies (for the stock exchange tax only).

No stock exchange tax will thus be due by Holders on the subscription, purchase or sale of ADSs, if the Holders are acting for their own account. In order to benefit from this exemption, the Holders must file with the professional intermediary in Belgium a sworn affidavit evidencing that they are non-residents for Belgian tax purposes.

Belgian annual tax on securities accounts

Pursuant to the Belgian Act of February 17, 2021 introducing a new annual tax on securities accounts due on securities accounts held through an intermediary if the average value of the taxable financial instruments held on this securities account exceeds €1 million during a reference period of 12 consecutive months, starting on October 1st and ending on September 30th of the subsequent year.

The annual tax on securities accounts is due irrespective of whether the holder of a securities account is a physical person or a legal entity. If the holder of a securities account is a Belgian resident, the annual tax on securities accounts will be applicable both to securities accounts held in Belgium as well as securities accounts held abroad. For non-residents, only securities accounts held in Belgium fall in scope of the annual tax on securities accounts. A double tax treaty could prevent Belgium to levy the annual tax on securities accounts. Each securities account is assessed separately. The Treaty does not apply to this tax. When multiple holders hold a securities account, each holder shall be jointly and severally liable for the payment of the tax and each holder may fulfil the declaration requirements for all holders.

Certain exemptions exist to mitigate the impact of the annual tax on securities accounts on the financial sector. As such, securities accounts held by certain financial undertakings are exempt.

All securities held on a securities account are targeted, such as shares, bonds, participations in investment funds and investment companies, but also derived products, such as index trackers, turbos, real estate certificates and cash. The rate of the annual tax on securities accounts amounts to 0.15% on securities accounts of which the average value exceeds €1 million during a reference period of 12 consecutive months. On February 23, 2026, a proposal has also been introduced in Belgian parliament to increase the annual tax on securities accounts from 0.15% to 0.30%.

In order to avoid that the payment of the tax would result in a decrease of the average value below the €1 million threshold, the rate is limited to 10% of the difference between the taxable base and €1 million in those cases. The reference period is a subsequent period of 12 months starting on October 1 and ending September 30 of the subsequent year or (i) any earlier date when the account is closed; or (ii) the moment when the account holder becomes a resident of a state with which Belgium has concluded a tax treaty and the tax treaty allocates the taxing rights to the other state. The average value is calculated by taking the average of the securities accounts values on December 31, March 31, June 30 and September 30.

The tax must be declared and paid by the Belgian resident intermediary with whom the securities account is held. If a securities account is held with a non-resident intermediary, the holder of the securities account itself is responsible for the declaration and the payment of the annual tax on securities accounts. Alternatively, the foreign intermediary could also voluntarily appoint a recognized responsible representative in Belgium to declare and pay the tax.

In case of non-declaration, late, inaccurate or incomplete declaration, as well as non-payment or late payment, a penalty varying from 10% to 200% of the tax due can be imposed. Every holder of the securities account is jointly and severally liable to pay these penalties. The Act includes a general anti-abuse provision and specific anti-abuse provisions. Under the latter, there is a rebuttable presumption that abuse exists in case of (i) splitting of a securities account into multiple securities accounts; and (ii) the conversion of taxable financial instruments held in a securities account to nominative financial instruments (the latter out of scope of the tax).

Prospective Holders should consult their own tax advisors as to whether they are subject to the new annual tax on securities accounts.

Proposed financial transactions tax

On February 14, 2013, the European Commission published a proposal for a Directive for a common financial transactions tax, or FTT, in Belgium, Germany, Greece, Spain, France, Italy, Austria, Portugal, Slovenia, Estonia and Slovakia, collectively, the Participating Member States. On December 8, 2015, Estonia declared that it will no longer support the FTT.

The proposed FTT has a very broad scope and could, if introduced in its current form, apply to certain dealings in ADSs in certain circumstances. The FTT could apply in certain circumstances to persons both within and outside of the Participating Member States. Generally, it would apply to certain dealings in ADSs where at least one party is a financial institution, and at least one party is established in a Participating Member State.

A financial institution may be, or be deemed to be, "established" in a Participating Member State in a broad range of circumstances, including by transacting with a person established in a Participating Member State.

In June 2023, the European Commission stated that 'the prospects of reaching an agreement' on the FTT in the future were 'limited' adding there was 'little expectation that any proposal would be agreed in the short term.'

In its 2026 Work Programme of October 21, 2025, the European Commission announced its intention to formally withdraw the Draft Directive within 6 months, on the grounds that its adoption would no longer be in the general interest in view of its adoption date, lack of progress in the legislative process, potential burden and non-alignment with the EU's priorities. As the sole legislator in EU tax matters, the EU Council may oppose the withdrawal of said Draft Directive within 6 months. If the EU Council does not oppose it, this withdrawal would become final. Please note that this does not mean that the FTT could not be reintroduced in another form in the future.

Material U.S. federal income tax considerations for U.S. Holders

The following is a description of certain material U.S. federal income tax considerations for U.S. Holders (defined below) with respect to their ownership and disposition of the ADSs. It is not a comprehensive description of all tax considerations. This discussion applies only to a U.S. Holder that holds the ADSs as a capital asset for tax purposes (generally, property held for investment). In addition, it does not describe all of the tax consequences that may be relevant in light of a U.S. Holder's particular circumstances, including state and local tax consequences, estate tax consequences, alternative minimum tax consequences, the potential application of the Medicare contribution tax, tax consequences of Section 451(b) of the Code (as defined below), and tax consequences applicable to U.S. Holders subject to special rules, such as:

- banks, insurance companies, and certain other financial institutions;
- U.S. expatriates and former citizens or long-term residents of the United States;
- dealers or traders in securities who use a mark-to-market method of tax accounting;
- persons holding ADSs as part of a hedging transaction, "straddle," wash sale, conversion transaction or integrated transaction or persons entering into a constructive sale with respect to ADSs;
- persons whose "functional currency" for U.S. federal income tax purposes is not the U.S. dollar;
- brokers, dealers or traders in securities, commodities or currencies;
- tax-exempt entities or government organizations;
- S corporations, partnerships, or other entities or arrangements classified as partnerships for U.S. federal income tax purposes, or persons that will hold the ADSs through such an entity;
- regulated investment companies or real estate investment trusts;
- persons who acquired the ADSs pursuant to the exercise of any employee share option or otherwise as compensation;
- persons holding the ADSs in connection with a trade or business, permanent establishment, or fixed base outside the United States;
- persons holding ADSs through a Belgian (or other non-U.S.) financial institution; and
- persons who own (directly, constructively or through attribution) 10% or more (by vote or value) of our outstanding ADSs.

If an entity that is classified as a partnership for U.S. federal income tax purposes holds ADSs, the U.S. federal income tax treatment of a partner will generally depend on the status of the partner and the activities of the partnership. Partnerships holding ADSs and partners in such partnerships are encouraged to consult their tax advisors as to the particular U.S. federal income tax consequences of holding and disposing of ADSs.

The discussion is based on the Code, administrative pronouncements, judicial decisions, final, temporary and proposed Treasury Regulations, and the Treaty, all as of the date hereof, changes to any of which may affect the tax consequences described herein-possibly with retroactive effect.

A "U.S. Holder" is a holder who, for U.S. federal income tax purposes, is a beneficial owner of ADSs and is:

- an individual who is a citizen or individual resident of the United States;
- a corporation, or other entity taxable as a corporation, created or organized in or under the laws of the United States, any state thereof or the District of Columbia;
- an estate the income of which is subject to U.S. federal income taxation regardless of its source; or
- a trust if (1) a U.S. court is able to exercise primary supervision over the administration of the trust and one or more U.S. persons have authority to control all substantial decisions of the trust or (2) the trust has a valid election to be treated as a U.S. person under applicable U.S. Treasury Regulations.

PERSONS CONSIDERING AN INVESTMENT IN ADSS SHOULD CONSULT THEIR TAX ADVISORS AS TO THE PARTICULAR TAX CONSEQUENCES APPLICABLE TO THEM RELATING TO OWNERSHIP AND DISPOSITION OF THE ADSs, INCLUDING THE APPLICABILITY OF U.S. FEDERAL, STATE AND LOCAL TAX LAWS.

PFIC rules

A non-U.S. corporation will be classified as a PFIC for any taxable year in which, after applying certain look-through rules with respect to the income and assets of its subsidiaries, either:

- at least 75% of its gross income is passive income (such as interest income); or
- at least 50% of its gross assets (determined on the basis of a quarterly average) is attributable to assets that produce passive income or are held for the production of passive income.
- We will be treated as owning our proportionate share of the assets and earning our proportionate share of the income of any other entity treated as a corporation for U.S. federal income tax purposes, the equity of which we own, directly or indirectly, 25% or more (by value).

There is a significant risk that we may be a PFIC for any taxable year prior to the commercialization of our drug candidates. It is currently uncertain whether we will be treated as a PFIC for the 2026 taxable year. A separate determination must be made after the close of each taxable year as to whether we are a PFIC for that year. As a result, our PFIC status may change from year to year. In addition, any U.S. Holder who held our ADSs during any time when we were a PFIC will continue to be subject to adverse tax consequences unless certain elections (as described below) are made. Following our initial public offering, the total value of our assets (including intangibles) for purposes of the asset test may be calculated by reference to our market capitalization, which may fluctuate considerably, particularly prior to the commercialization of any of our drug candidates. Fluctuations in the market price of the ADSs may result in our being or becoming a PFIC for the current or any other taxable year. In addition, the composition of our assets will also be affected by how, and how quickly, we spend the cash we raised in the offering. Our income and PFIC status for a taxable year will also be affected by the amount of positive interest earned on our bank deposits and the characterization of other sources of gross income that we may receive. To date our only active income has been from government grants, but there can be no assurance that we will continue to receive governmental grants. Therefore, prior to the commercialization of any of our drug candidates we may be a PFIC if our interest and other investment income is substantial in comparison to our total gross income.

Our status as a PFIC is a fact-intensive determination made on an annual basis applying principles and methodologies that in some circumstances are unclear and subject to varying interpretation.

Because of the uncertainties involved in determining our PFIC status, the possible volatility of our ADS price and the lack of certainty regarding our income streams, we cannot provide any assurances regarding our PFIC status in the current taxable year or any future taxable year.

If we are classified as a PFIC in any year with respect to which a U.S. Holder owns ADSs, we will continue to be treated as a PFIC with respect to such U.S. Holder in all succeeding years during which the U.S. Holder owns ADSs, regardless of whether we continue to meet the tests described above unless we cease to be a PFIC and the U.S. Holder has made a "deemed sale" election under the PFIC rules. If the "deemed sale" election is made, a U.S. Holder will be deemed to have sold the ADSs the U.S. Holder holds at their fair market value and any gain from such deemed sale would be subject to the rules described in the subsequent paragraph. After the deemed sale election, so long as we do not become a PFIC in a subsequent taxable year, the U.S. Holder's ADSs with respect to which such election was made will not be treated as shares in a PFIC and the U.S. Holder will not be subject to the rules described below with respect to any "excess distribution" the U.S. Holder receives from us or any gain from an actual sale or other disposition of ADSs.

For each taxable year that we are treated as a PFIC with respect to a U.S. Holder, such U.S. Holder will generally be subject to special tax rules with respect to any "excess distribution" such U.S. Holder receives and any gain such U.S. Holder recognizes from a sale or other disposition of the ADSs. Distributions a U.S. Holder receives in a taxable year to the extent greater than 125% of the average annual distributions a U.S. Holder received during the shorter of the three preceding taxable years or the U.S. Holder's holding period for ADSs will be treated as an excess distribution. Under these special tax rules:

- the excess distribution or gain will be allocated ratably over a U.S. Holder's holding period for the ADSs;
- the amount allocated to the current taxable year, and any taxable year prior to the first taxable year in which we became a PFIC, will be treated as ordinary income; and
- the amount allocated to each other year will be subject to the highest tax rate in effect for that year and the interest charge generally applicable to underpayments of tax will be imposed on the resulting tax attributable to each such year.

The tax liability for amounts allocated to years prior to the year of disposition or "excess distribution" cannot be offset by any net operating losses for such years, and gains (but not losses) realized on the sale of the ADSs cannot be treated as capital, even if a U.S. Holder holds the ADSs as capital assets.

Certain elections may alleviate some of the adverse consequences of PFIC status and would result in an alternative treatment of the ADSs. If a U.S. Holder makes an effective "qualified electing fund" election, or QEF Election, for our first taxable year as a PFIC in which the U.S. Holder owns our ADSs, the U.S. Holder will be required to include in gross income each year, whether or not we make distributions, as long-term capital gains, such U.S. Holder's pro rata share of our net capital gains and, as ordinary income, such U.S. Holder's pro rata share of our earnings in excess of our net capital gains, on a current basis. However, a U.S. Holder can only make a QEF Election with respect to interests in a PFIC if such company agrees to furnish such U.S. Holder with certain tax information annually. If we determine that we are a PFIC in any taxable year, we intend to make available to U.S. Holders a "PFIC Annual Information Statement" (as described in U.S. Treasury Regulations Section 1.1295-1(g)) with respect to the company for such taxable year, although no assurance is given in this regard.

If a U.S. Holder makes a QEF election for a taxable year after our first taxable year as a PFIC in which the U.S. Holder owned our ADSs, the excess distribution regime described above, adjusted to take into account the current income inclusions resulting from the QEF election, will continue to apply, unless the U.S. Holder makes a deemed sale election, as described above. A QEF election is made on an individual basis and, once made, can be revoked only with the consent of the U.S. Internal Revenue Service, or IRS. A retroactive QEF election generally may be made only if a protective statement was timely filed and certain other conditions are met, or with the consent of the IRS.

Alternatively, U.S. Holders can avoid the interest charge on excess distributions or gain relating to ADSs by making a mark-to-market election with respect to the ADSs, provided that the ADSs are "marketable."

ADSs will be marketable if they are "regularly traded" on certain U.S. stock exchanges or on a foreign stock exchange that meets certain conditions. For these purposes, the ADSs will be considered regularly traded during any calendar year during which they are traded, other than in de minimis quantities, on at least 15 days during each calendar quarter. Any trades that have meeting this trading requirement as one of their principal purposes will be disregarded and/or may be disregarded under of their anti-abuse rules. We intend to list the ADSs on the Nasdaq Global Market, which is a qualified exchange for these purposes. Each U.S. Holder should consult its tax advisor as to the whether a mark-to-market election is available or advisable with respect to ADSs.

A U.S. Holder that makes a mark-to-market election with respect to the ADSs must include in ordinary income for each year an amount equal to the excess, if any, of the fair market value of the ADSs at the close of the taxable year over the U.S. Holder's adjusted tax basis in the ADSs. An electing holder may also claim an ordinary loss deduction for the excess, if any, of the U.S. Holder's adjusted basis in the ADSs over the fair market value of the ADSs at the close of the taxable year, but this deduction is allowable only to the extent of any net mark-to-market gains for prior years. Gains from an actual sale or other disposition of ADSs will be treated as ordinary income, and any losses incurred on a sale or other disposition of the shares will be treated as an ordinary loss to the extent of any net mark-to-market gains for prior years. Once made, the election cannot be revoked without the consent of the IRS unless the ADSs cease to be marketable.

Unless otherwise provided by the U.S. Treasury, each U.S. shareholder of a PFIC is required to make an annual filing containing such information as the U.S. Treasury may require. U.S. Holders should consult their tax advisors regarding the requirements of filing such information returns under these rules.

WE STRONGLY URGE YOU TO CONSULT YOUR TAX ADVISOR REGARDING THE IMPACT OF OUR PFIC STATUS ON ANY INVESTMENT IN OUR ADSs AS WELL AS THE APPLICATION OF THE PFIC RULES TO ANY INVESTMENT IN OUR ADSs.

Taxation of distributions

Subject to the discussion above under "PFIC rules," distributions paid on ADSs, other than certain pro rata distributions of ADSs, will generally be treated as dividends to the extent paid out of our current or accumulated earnings and profits (as determined under U.S. federal income tax principles). Because we do not intend to calculate our earnings and profits under U.S. federal income tax principles, we expect that distributions generally will be reported to U.S. Holders as dividends. Non-corporate U.S. Holders may qualify for the current preferential rates of taxation applicable to long-term capital gains (i.e., gains from the sale of capital assets held for more than one year) applicable to "qualified dividend income" with respect to dividends on the ADSs. However, the qualified dividend income treatment will only apply if (1) we are not treated as (and are not treated with respect to a U.S. Holder as) a PFIC in the taxable year in which the dividend is paid or in the preceding taxable year and (2) either (i) the ADSs are readily tradable on an established securities market in the United States or (ii) we are eligible for the benefits of a comprehensive tax treaty with the U.S. that the U.S. Treasury determines is satisfactory for purposes of this provision and that includes an exchange of information program. The ADSs are listed on NASDAQ, which is an established securities market in the United States, and the ADSs are readily tradable on NASDAQ. However, there can be no assurance that the ADSs will be considered readily tradable on an established securities market in the United States in future years. We are incorporated under the laws of Belgium, and we believe that we qualify as a resident of Belgium for purposes of, and are eligible for the benefits of the Treaty, although there can be no assurance in this regard. The preferential tax rate on dividends paid to a non-corporate U.S. Holder is subject to limitations based on the U.S. Holder's circumstances. Any Belgian tax on stock exchange transactions (as discussed above under "*Material Belgian Tax Considerations-Belgian tax on stock exchange transactions*") generally will not be creditable.

The amount of any dividend will be treated as foreign-source dividend income to U.S. Holders and will not be eligible for the dividends-received deduction generally available to U.S. corporations under the Code. Dividends will generally be included in a U.S. Holder's income on the date of the U.S. Holder's receipt of the dividend. The amount of any dividend income paid in foreign currency will be the U.S. dollar amount calculated by reference to the exchange rate in effect on the date of actual or constructive receipt, regardless of whether the payment is in fact converted into U.S. dollars. If the dividend is converted into U.S. dollars on the date of receipt, a U.S. Holder should not be required to recognize foreign currency gain or loss in respect of the dividend income. A U.S. Holder may have foreign currency gain or loss if the dividend is converted into U.S. dollars after the date of receipt. Such gain or loss would generally be treated as U.S.-source ordinary income or loss.

Subject to applicable limitations, some of which may vary depending upon your circumstances, Belgian income taxes withheld from dividend payments on shares at a rate not exceeding an applicable rate under the Treaty will be creditable against your U.S. federal income tax liability. Belgian income taxes withheld in excess of the applicable rate under the Treaty will not be eligible for credit against your U.S. federal income tax liability. The rules governing foreign tax credits are complex and U.S. Holders should therefore consult their tax advisors regarding the effect of the receipt of dividends for foreign tax credit limitation purposes. For example, Treasury regulations provide that, in the absence of an election to apply the benefits of an applicable income tax treaty, in order for non-U.S. income taxes to be creditable, the relevant non-U.S. income tax rules must be consistent with certain U.S. federal income tax principles, and we have not determined whether the Belgian income tax system meets these requirements. However, the IRS released notices that indicate that the Treasury Department and the IRS are considering amendments to these Treasury regulations and provide relief from certain of their provisions for taxable years ending before the date that a notice or other guidance withdrawing or modifying the temporary relief is issued (or any later date specified in such notice or other guidance). You should consult your tax advisor regarding the creditability of Belgian taxes in your particular circumstances. In lieu of claiming a credit, you may be able to elect to deduct Belgian taxes in computing your taxable income, subject to applicable limitations. An election to deduct non-U.S. taxes instead of claiming foreign tax credits applies to all otherwise creditable non-U.S. taxes paid or accrued in the taxable year.

Sale or other taxable disposition of ADSs

Subject to the discussion above under "PFIC rules," gain or loss realized on the sale or other taxable disposition of ADSs will be capital gain or loss, and will be long-term capital gain or loss if the U.S. Holder held the ADSs for more than one year. The amount of the gain or loss will equal the difference between the U.S. Holder's tax basis in the ADSs disposed of and the amount realized on the disposition, in each case as determined in U.S. dollars. This gain or loss will generally be U.S.-source gain or loss for foreign tax credit purposes. The deductibility of capital losses is subject to limitations.

If the consideration received by a U.S. Holder is not paid in U.S. dollars, the amount realized will be the U.S. dollar value of the payment received determined by reference to the spot rate of exchange on the date of the sale or other disposition. However, if the ADSs are treated as traded on an "established securities market" and you are either a cash basis taxpayer or an accrual basis taxpayer that has made a special election (which must be applied consistently from year to year and cannot be changed without the consent of the IRS), you will determine the U.S. dollar value of the amount realized in a non-U.S. dollar currency by translating the amount received at the spot rate of exchange on the settlement date of the sale. If you are an accrual basis taxpayer that is not eligible to or does not elect to determine the amount realized using the spot rate on the settlement date, you will recognize foreign currency gain or loss to the extent of any difference between the U.S. dollar amount realized on the date of sale or disposition and the U.S. dollar value of the currency received at the spot rate on the settlement date.

Information reporting and backup withholding

Payments of dividends and sales proceeds that are made within the United States or through certain U.S.-related financial intermediaries generally are subject to information reporting, and may be subject to backup withholding, unless (i) the U.S. Holder is a corporation or other exempt recipient or (ii) in the case of backup withholding, the U.S. Holder provides a correct taxpayer identification number and certifies that it is not subject to backup withholding on a duly executed IRS Form W-9 or otherwise establishes an exemption.

Backup withholding is not an additional tax. The amount of any backup withholding from a payment to a U.S. Holder will be allowed as a credit against the U.S. Holder's U.S. federal income tax liability and may entitle the U.S. Holder to a refund, provided that the required information is timely furnished to the IRS.

Information with respect to foreign financial assets

Certain U.S. Holders who are individuals (and, under regulations, certain entities) may be required to report information relating to the ADSs, subject to certain exceptions (including an exception for ADSs held in accounts maintained by certain U.S. financial institutions), by filing IRS Form 8938 (Statement of Specified Foreign Financial Assets) with their federal income tax return. Such U.S. Holders who fail to timely furnish the required information may be subject to a penalty. U.S. Holders should consult their tax advisors regarding their reporting obligations with respect to their ownership and disposition of the ADSs.

THE DISCUSSION SET OUT ABOVE IS INCLUDED FOR GENERAL INFORMATION ONLY AND MAY NOT BE APPLICABLE DEPENDING UPON A HOLDER'S PARTICULAR SITUATION. IT DOES NOT COVER ALL TAX MATTERS THAT MAY BE RELEVANT TO A HOLDER. EACH HOLDER IS URGED TO CONSULT THEIR TAX ADVISOR WITH RESPECT TO THE TAX CONSEQUENCES OF THE OWNERSHIP AND DISPOSITION OF THE SHARES INCLUDING TAX CONSEQUENCES UNDER STATE, LOCAL AND OTHER TAX LAWS AND THE POSSIBLE TAX EFFECTS OF CHANGES IN THE UNITED STATES FEDERAL AND OTHER TAX LAWS.

F. Dividends and Paying Agents

Not applicable.

G. Statement by Experts

Not applicable.

H. Documents on Display

We are subject to the information reporting requirements of the Exchange Act applicable to foreign private issuers and under those requirements will file reports with the SEC. Those reports may be inspected without charge on the websites described below. As a foreign private issuer, we are exempt from the rules under the Exchange Act related to the furnishing and content of proxy statements, and our senior management, directors and principal shareholders are exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act. In addition, we are not required under the Exchange Act to file periodic reports and financial statements with the SEC as frequently or as promptly as United States companies whose securities are registered under the Exchange Act. Nevertheless, we will file with the SEC an Annual Report on Form 20-F containing financial statements that have been examined and reported on, with an opinion expressed by an independent registered public accounting firm.

We maintain a corporate website at *www.agomab.com*. We intend to post our Annual Report on our website promptly following it being filed with the SEC. Information contained on, or that can be accessed through, our website does not constitute a part of this Annual Report. We have included our website address in this Annual Report solely as an inactive textual reference.

The SEC maintains a website (*www.sec.gov*) that contains reports, proxy and information statements and other information regarding registrants, such as AgomAb, that file electronically with the SEC.

With respect to references made in this Annual Report to any contract or other document relating to AgomAb, such references are not necessarily complete and you should refer to the exhibits attached or incorporated by reference to this Annual Report for copies of the actual contract or document.

I. Subsidiary information

Not applicable.

J. Annual Report to Security Holders

Not applicable.

Item 11: Quantitative and Qualitative Disclosures about Market Risk

Market risks

The Company is not significantly exposed to market risks such as interest rate risk, foreign currency risks and other market risks that may impact the fair value or future cash flows of its financial instruments. As such, sensitivity analysis is not provided.

24.2. Interest rate risk

The Company is only subject to changes in variable interest rates on cash and cash equivalents. The Company is not subject to immediate changes in interest rates from borrowings.

24.3. Foreign exchange risk

The Group does not currently have any customers and purchases the majority of its materials and services in Euros, which is the functional currency of the Group entities. The Group is however exposed to limited purchase contracts in USD, CHF, and GBP. On that basis, the Group is not subject to significant foreign exchange risks. Any purchases in foreign currencies are settled at the spot rate at the time of payment, which is within one month of the invoice date. As such, sensitivity analysis is not provided.

24.4. Liquidity risk

The Company manages liquidity risk by maintaining adequate reserves, by continuously monitoring forecast and actual cash flows, and by matching the maturity profiles of financial assets and liabilities. The Company's main sources of cash inflows are through capital increases and government grants. All cash is held in immediately accessible current accounts with reputable banks and, if deemed appropriate, term deposit accounts with maturity of one year or less in duration and money market funds that are readily convertible to cash and subject to a marginal risk of changes in value. The Company does not have any unused credit lines available.

24.5. Credit risk

Credit risk is the risk that third parties may not meet their contractual obligations resulting in a loss for the Group. The Group is exposed to credit risk from its operating activities, which are currently only cash held, short-term deposits and money market funds with high-creditworthy financial institutions. The Group limits this exposure by contracting with credit-worthy business partners or with financial institutions which meet high credit rating requirements. Grant receivables are from the government and are considered a very low credit risk.

Item 12: Description of Securities other than Equity Securities

A. Debt Securities

Not applicable.

B. Warrants and Rights

Not applicable.

C. Other Securities

Not applicable.

D. American Depositary Shares

The Bank of New York Mellon, as depositary, registers and delivers our ADSs. Each ADS will represent one common share (or a right to receive one common share) deposited with ING Securities Services, Inc., as custodian for the depositary. Each ADS will also represent any other securities, cash or other property that may be held by the depositary. The deposited shares together with any other securities, cash or other property held by the depositary are referred to as the deposited securities. The depositary's office at which the ADSs will be administered and its principal executive office are located at 240 Greenwich Street, New York, New York 10286.

Fees and Expenses

The following table shows the fees and charges that a holder of our ADSs may have to pay, either directly or indirectly. The majority of these costs are set by the depositary bank and are subject to change.

Holders or persons depositing or withdrawing shares, surrendering ADSs, or to whom or from whom ADSs are delivered or cancelled, must pay:	**For:**
$10.00 (or less) per 100 ADSs (or portion of 100 ADSs)	Issuance of ADSs, including issuances resulting from a distribution of shares or rights or other property or in relation to a change in the number of shares represented by ADSs Surrender of ADSs for the purpose of withdrawal or cancellation of ADSs, including if the deposit agreement terminates or in relation to a change in the number of shares represented by ADSs
$.10 (or less) per ADS	Any cash distribution to ADS holders
A fee equivalent to the fee that would be payable if securities distributed to you had been shares and the shares had been deposited for issuance of ADSs	Distribution of securities distributed to holders of deposited securities (including rights) that are distributed by the depositary to ADS holders
Fees assessed from time to time, but not exceeding $.10 per ADS during any calendar year	Depositary services
Registration or transfer fees	Transfer and registration of shares on our share register to or from the name of the depositary or its agent when you deposit or withdraw shares
Expenses of the depositary	Cable (including SWIFT) and facsimile transmissions (when expressly provided in the deposit agreement) Converting foreign currency to U.S. dollars
Taxes and other governmental charges the depositary or the custodian has to pay on any ADSs or shares underlying ADSs, such as stock transfer taxes, stamp duty or withholding taxes	As necessary
Any charges incurred by the depositary or its agents for servicing the deposited securities	As necessary

Part II

Item 13: Defaults, Dividend Arrearages and Delinquencies

No matters to report.

Item 14: Material Modifications to the Rights of Security Holders and Use of Proceeds

In February 2026, we sold 12,500,000 ADSs, each representing one ordinary share, no nominal value, in our initial public offering at a price of $16.00 per ADS, for aggregate gross proceeds to us of approximately $200.0 million. In March 2026, the underwriters exercised a portion of their overallotment option, pursuant to which we issued and sold an additional 482,967 ADSs at a price of $16.00 per ADS, for aggregate gross proceeds to us of approximately $7.7 million. The net offering proceeds to us, after deducting underwriting discounts and commissions and offering expenses, were approximately $188.0 million. The offering commenced on February 2, 2026 and did not terminate before all of the securities registered in the registration statement were sold. The effective date of the registration statement, File No. 333-292790, for our initial public offering was January 30, 2026. J.P. Morgan Securities LLC, Morgan Stanley & Co. LLC, Leerink Partners, LLC and Van Lanschot Kempen (USA) Inc. acted as joint book-running managers of the offering.

We expect to use the net proceeds from the offering, together with our cash and cash equivalents, to advance clinical development of ontunisertib, advance clinical development of AGMB-447, general and administrative expenses, working capital, one milestone payment pursuant to our acquisition agreement relating to Origo Biopharma, S.L. and other general corporate purposes.

None of the net proceeds of our initial public offering were paid directly or indirectly to any director, officer, general partner of ours or to their associates, persons owning 10% or more of any class of our equity securities, or to any of our affiliates.

Item 15: Controls and Procedures

A. Disclosure Controls and Procedures

Under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934) has been evaluated as of the end of the period covered by the Annual Report (December 31, 2025). The term “disclosure controls and procedures” means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms and that such information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosures.

Based on this evaluation, our principal executive officer and principal financial officer have concluded that our disclosure controls and procedures were not effective as of December 31, 2025 due to material weaknesses in our internal control over financial reporting described below.

Previously Reported Weaknesses

A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the Company’s annual or interim consolidated financial statements will not be prevented or detected on a timely basis.

In conjunction with preparing our financial statements as of and for the years ended December 31, 2024 and 2023, material weaknesses in our internal controls over financial reporting and IT general controls were identified. We have determined that we did not:

- design or maintain an effective control environment commensurate with our financial reporting requirements due to a lack of a formal, documented implemented processes, controls and review procedures, lack of resources for assessment of complex accounting topic and insufficient segregation of duties in our finance and accounting functions;

- design and maintain formal accounting policies, procedures and controls to achieve complete, accurate and timely financial accounting, year-end reporting and disclosures, including controls over the preparation and review of account reconciliations, journal entries and period end financial reporting; and

- design and maintain effective controls over certain information technology general controls for IT systems that are relevant to the preparation of our consolidated financial statements. Specifically, we did not design and maintain: (i) user access controls to ensure appropriate segregation of duties and that adequately restrict user and privileged access to financial applications, programs, and data to appropriate personnel, and (ii) program change management controls to ensure that IT program and data changes affecting financial IT applications and underlying accounting records are identified, tested, authorized and implemented appropriately.

These material weaknesses did not result in a material misstatement to our financial statements included herein.

Management's Remediation Plan

We are developing a remediation plan to address these material weaknesses and strengthen our controls in these areas. In this regard, we have started to expand our finance and accounting team by hiring additional experienced employees to provide more review and oversight over our financial processes. We have also begun the process of reviewing and documenting our accounting and financial processes and internal controls, improving and formalizing accounting and reporting policies, and building out the appropriate technical, financial management and reporting systems infrastructure to automate and standardize such policies. As part of these efforts, we have implemented an enterprise resource planning (ERP) system to further enhance the efficiency, consistency, and reliability of our financial reporting and controls. While we are working to remediate the material weaknesses as quickly and efficiently possible, we cannot at this time provide the expected timeline in connection with implementing our remediation plan. Please see the section entitled "Item 3.D. Risk Factors — We identified material weaknesses in our internal control over financial reporting. If we are unable to successfully remediate the existing material weaknesses in our internal control over financial reporting, the accuracy and timing of our financial reporting may be adversely affected."

B. Management's Annual Report on Internal Control over Financial Reporting

This Annual Report does not include a report of management's assessment regarding internal control over financial reporting due to a transition period established by the SEC's rules for newly public companies.

C. Attestation report of the registered public accounting firm

This Annual Report does not include an attestation report of our registered public accounting firm due to a transition period established by rules of the SEC for newly public companies. For so long as we qualify as an "emerging growth company" as defined under the JOBS Act, our registered public accounting firm is not required to issue an attestation report on our internal control over financial reporting.

D. Changes in Internal Control over Financial Reporting

During the year ended December 31, 2025, there have been no changes in our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 16: [Reserved]

Item 16A: Audit Committee Financial Expert

Currently, Colin Bond qualifies as an "audit committee financial expert," as defined by the SEC and as determined by our board. In addition, each of Colin Bond, Felice Verduyn-van Weegen and Ohad Hammer satisfies the independence requirements of the Nasdaq listing standards and Rule 10A-3(b)(1) under the Exchange Act and the criteria for independence set forth in best practice 2.1.8 of the DCGC.

Item 16B:Code of Ethics

We have adopted a Code of Business Conduct and Ethics applicable to all of our board members and our employees, including our Chief Executive Officer, Chief Financial Officer, controller or principal accounting officers, or other persons performing similar functions, which is a "code of ethics" as defined by the SEC. The full text of the Code of Business Conduct and Ethics is posted on our company website at www.agomab.com.

If we make any material amendment to the Code of Business Conduct and Ethics or grant any waivers, including any implicit waiver, from a provision of the Code of Business Conduct and Ethics for our Board members or other executive officers, we will disclose the nature of such amendment or waiver on our website within five working days to the extent required by the rules and regulations of the SEC.

Item 16C:Principal Accountant Fees and Services

For the years ended December 31, 2025 and 2024, our independent registered public accounting firm was PwC Bedrijfsrevisoren BV / Reviseurs d'Entreprises SRL is Culliganlaan 5, 1831 Diegem, Belgium and was engaged in connection with our SEC reporting obligations, as well as our statutory auditor for the Belgian company and tax law purposes.

Audit fees

Audit fees in 2025 and 2024 amounted to €1,027,613 and €680,844 respectively, and relate to audit services provided by our principal accountants in 2025 and 2024, respectively, PwC Bedrijfsrevisoren BV / Reviseurs d'Entreprises SRL, in connection with our annual audit, and review of registration statements and comfort letters for the Company.

Audit-related fees

Audit-related fees in 2025 and 2024 amounted to €21,840 and €21,250 respectively, and relate to assurance and related services by the principal accountant respectively, PwC Bedrijfsrevisoren BV / Reviseurs d'Entreprises SRL.

Over the last two years, audit-related services were mainly incurred in relation to various special reports.

Tax Fees

No tax fees were billed in 2025. Tax fees in 2024 amounted to €8,500. These tax fees related to advisory services.

All other fees

None.

Audit Committee pre-approval policies and procedures

The Audit Committee is responsible for recommending the appointment, replacement and compensation of the independent auditor to the Board. The Audit Committee is also responsible for the evaluation and oversight of the work of the independent auditor. As part of this responsibility, the Audit Committee pre-approves all audit and non-audit services performed by the independent auditor in order to assure that they do not impair the auditor's independence from the Company in accordance with the Audit Committee's pre-approval policy.

Audit Work Performed by Other Than Principal Accountant if Greater than 50%

Not Applicable.

Item 16D: Exemptions from the Listing Standards for Audit Committees

Not applicable.

Item 16E: Purchases of Equity Securities by the Issuer and Affiliated Purchasers

In 2025, no purchases of our registered equity securities were made by us or on our behalf or on the behalf of any affiliated purchaser.

Item 16F: Change in Registrant's Certifying Accountant

Not applicable.

Item 16G: Corporate Governance

We are a "foreign private issuer," as defined by the SEC. As a result, in accordance with Nasdaq listing requirements, we may rely on home country governance requirements and certain exemptions thereunder rather than relying on, and complying with, Nasdaq corporate governance standards. While we expect to voluntarily follow most Nasdaq corporate governance rules, we may choose to take advantage of the following limited exemptions:

- exemption from filing quarterly reports on Form 10-Q containing unaudited financial and other specified information or current reports on Form 8-K upon the occurrence of specified significant events;
- exemption from the Nasdaq requirement necessitating disclosure of any waivers of the Code of Business Conduct and Ethics for directors and executive officers;
- exemption from the requirement to obtain shareholder approval for certain issuances of securities, including shareholder approval of share option plans;
- exemption from the requirement that our audit committee have review and oversight responsibilities over all "related party transactions," as defined in Item 7.B of Form 20-F;
- exemption from the requirement that our board have a remuneration committee that is composed entirely of independent directors with a written charter addressing the committee's purpose and responsibilities; and
- exemption from the requirement to have independent director oversight of director nominations.

The Listing Rules of Nasdaq include certain accommodations in relation to the corporate governance requirements that allow foreign private issuers, such as us, to follow "home country" corporate governance practices in lieu of the otherwise applicable corporate governance standards of Nasdaq. The application of such exceptions requires that we disclose each instance of noncompliance with Nasdaq Listing Rules that we do not follow and describe the Belgian corporate governance practices we do follow in lieu of the relevant Nasdaq corporate governance standard. If and when the ADSs are listed on Nasdaq, we intend to continue to follow Belgian corporate governance practices in lieu of the corporate governance requirements of Nasdaq in respect of the following:

- *Quorum at shareholder meetings*. Nasdaq Listing Rule 5620(c) requires that for any meeting of shareholders, the quorum must be no less than 33 1/3% of the outstanding common shares. There is no general quorum requirement under Belgian law or our articles of association for our shareholders' meetings, except as provided for by law in relation to decisions regarding certain matters. See "Description of Share Capital and Articles of Association-Description of the rights and benefits attached to our shares-Quorum and majority requirements" in Exhibit 2.3 to this Annual Report.

- *Independent director majority on board/meetings*. Nasdaq Listing Rules 5605(b)(1) and (2) require that a majority of the board of directors must be comprised of independent directors and that independent directors must have regularly scheduled meetings at which only independent directors are present. We are not required under Belgian law to have any independent directors on our board of directors.

- *Director Nominations/Remuneration and Nomination Committee Composition*. Nasdaq Listing Rule 5605(d)(2) requires that compensation of officers must be determined by, or recommended to, the board of directors for determination, either by a majority of the independent directors, or a remuneration committee comprised solely of independent directors. Nasdaq Listing Rule 5605(e) requires that director nominees be selected, or recommended for selection, either by a majority of the independent directors or a nominations committee comprised solely of independent directors. Under Belgian law, we are not subject to any such requirements. In particular, we are not required by Belgian law to set up any compensation or nominations committees within our board of directors, and are therefore not subject to any Belgian legal requirements as to the composition of such committees either. However, our articles of association provide that our board of directors may set up one or more advisory committees from among its members. See Item 6: "Directors, Senior Management and Employees." Our board of directors has two standing committees: an audit committee and a remuneration, nomination and corporate governance committee.

- *Shareholder approval for certain issuances of securities*. Nasdaq Listing Rule 5635 requires that a company obtain shareholder approval prior to making certain issuances of securities (including the issuance of shares in connection with (i) the acquisition of the stock or assets of another company, or (ii) equity-based compensation of officers, directors, employees or consultants of the Company). Pursuant to the Belgian Companies and Associations Code and subject to the conditions set forth therein and in our articles of association, our board of directors will be allowed to increase the share capital of the Company in one or several times, and to issue new shares or ADSs through the use of authorized capital limited to the maximum amount of our share capital. The authorized capital mandate will be limited in time and can be renewed and conditioned by the shareholders' meeting. The authorized capital may however not be used for (i) capital increases by contribution in kind exclusively reserved for one of our shareholders holding shares to which more than 10% of the voting rights are attached, (ii) the issuance of shares with multiple voting rights, (iii) the issuance of a new class of securities, or (iv) the issuance of subscription rights intended mainly for one or more specified persons other than our or our subsidiaries' personnel.

Item 16H: Mine Safety Disclosure

Not applicable.

Item 16I: Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

Item 16J: Insider Trading Policies

We have adopted an Insider Trading Policy which, among other things, governs the purchase, sale and other dispositions of our securities by our directors, executive officers, employees and consultants. Our Insider Trading Policy aims to promote compliance with applicable insider trading laws, rules and regulations, and the Nasdaq listing standards. A copy of our Insider Trading Policy is filed as an exhibit to this Annual Report.

Item 16K: Cybersecurity

Governance Related to Cybersecurity Risks

Our Board of Directors is responsible for the oversight of our risk management activities, and has delegated to the Audit Committee the responsibility to assist our Board in this task. While our Board of Directors oversees our risk management, our Executive Committee is responsible for day-to-day risk management processes.

Specifically, the Audit Committee is responsible for evaluating our system of internal control and risk management, including the set-up of a cybersecurity risk management program and related controls. The Head of IT reviews risks from cybersecurity threats and incidents with the Audit Committee during an annual review, and report incidents that require escalation per set procedures. The Head of IT has extensive experience in the area of cybersecurity. The Audit Committee is responsible for the final approval of any disclosure of a material cybersecurity incident.

The Executive Committee is responsible for setting up and maintaining policies related to the risk profile of the Company and its systems to identify, assess, manage and monitor cybersecurity risks.

Cyber Risk Management and Strategy

Our cybersecurity risk management program is integrated within our business continuity planning and overall risk management. We are implementing an enterprise risk management program that includes processes designed to identify, assess, and mitigate cybersecurity risks. These processes include the deployment of third-party security solutions, tools and assessments designed to monitor, identify, and address cybersecurity risks. In addition, we have engaged an external security partner to support us on cybersecurity activities, day-to-day security operations and related services. We also review the data management and business continuity practices of certain third party vendors, and are setting up additional processes to assess and review the cybersecurity practices of certain third-party vendors and service providers prior to onboarding.

We, like other companies in our industry, face a number of risks from cybersecurity threats in connection with our business. Although such risks have not materially affected, and we do not believe they are reasonably likely to materially affect us, including our business strategy, results of operations or financial condition. For additional information, see "Item 3.D—Risk Factors—Our internal computer systems, or those of our third-party collaborators or other contractors or consultants, may fail or suffer cybersecurity incidents or breaches, which could result in a material disruption of our current or future product candidates' development programs, the disclosure of confidential or proprietary information, including personal data, damage our reputation, and subject us to significant financial and legal exposure."

Part III

Item 17: Financial Statements

For Financial Statements, see Item 18.

Item 18: Financial Statements

Financial Statements are filed as part of this Annual Report, starting on page F-1.

Item 19: Exhibits

The Exhibits listed in the Exhibit Index at the end of this Annual Report are filed as Exhibits to this Annual Report.

Index of Exhibits

Exhibit Number	Description of Exhibit
*1.1	Articles of Association of AgomAb Therapeutics NV
2.1	Form of Deposit Agreement (incorporated by reference to Exhibit 4.2 to the Registrant's Registration Statement on Form F-1/A (File No. 001-292790) filed on January 29, 2026).
2.2	Form of American Depositary Receipt (included in Exhibit 4.2) (incorporated by reference to Exhibit 4.3 to the Registrant's Registration Statement on Form F-1/A (File No. 001-292790) filed on January 29, 2026).
*2.3	Description of Securities
3.1†+	Amended and Restated Shareholders' Agreement, dated as of November 4, 2024, by and between AgomAb Therapeutics NV and the shareholders party thereto (incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form F-1/A (File No. 001-292790) filed on January 29, 2026).
4.1#	March 2019 Employee Stock Option Plan and forms of notice of grant thereunder (incorporated by reference to Exhibit 10.1 to the Registrant's Registration Statement on Form F-1/A (File No. 001-292790) filed on January 29, 2026).
4.2#	September 2019 Employee Stock Option Plan and forms of notice of grant thereunder (incorporated by reference to Exhibit 10.2 to the Registrant's Registration Statement on Form F-1/A (File No. 001-292790) filed on January 29, 2026).
4.3#	March 2020 Employee Stock Option Plan and forms of notice of grant thereunder (incorporated by reference to Exhibit 10.3 to the Registrant's Registration Statement on Form F-1/A (File No. 001-292790) filed on January 29, 2026).
4.4#	October 2020 Employee Stock Option Plan and forms of notice of grant thereunder (incorporated by reference to Exhibit 10.4 to the Registrant's Registration Statement on Form F-1/A (File No. 001-292790) filed on January 29, 2026).
4.5#	March 2021 Employee Stock Option Plan and forms of notice of grant thereunder (incorporated by reference to Exhibit 10.5 to the Registrant's Registration Statement on Form F-1/A (File No. 001-292790) filed on January 29, 2026).
4.6#	June 2022 Employee Stock Option Plan and forms of notice of grant thereunder (incorporated by reference to Exhibit 10.6 to the Registrant's Registration Statement on Form F-1/A (File No. 001-292790) filed on January 29, 2026).
4.7#	October 2023 Employee Stock Option Plan and forms of notice of grant thereunder (incorporated by reference to Exhibit 10.7 to the Registrant's Registration Statement on Form F-1/A (File No. 001-292790) filed on January 29, 2026).
4.8#	2024 Stock Option and Incentive Plan and forms of award agreements thereunder (incorporated by reference to Exhibit 10.8 to the Registrant's Registration Statement on Form F-1/A (File No. 001-292790) filed on January 29, 2026).
4.9#	2024 (B) Stock Option and Incentive Plan and forms of award agreements thereunder (incorporated by reference to Exhibit 10.9 to the Registrant's Registration Statement on Form F-1/A (File No. 001-292790) filed on January 29, 2026).
4.10	Lease Agreement by and between Ring Building NV and AgomAb Therapeutics NV, dated December 28, 2023 (incorporated by reference to Exhibit 10.10 to the Registrant's Registration Statement on Form F-1/A (File No. 001-292790) filed on January 29, 2026).
4.11	Lease Agreement by and between Galchimia, S.A. and AgomAb Spain S.L.U., dated as of October 26, 2021, as amended by the First Amendment to the Lease Agreement, dated as of July 15, 2022, Second Amendment to the Lease Agreement, dated as of March 27, 2023, the Third Amendment to the Lease Agreement, dated as of April 18, 2024 and the Fourth Amendment to the Lease Agreement, dated as of February 6, 2025 (incorporated by reference to Exhibit 10.11 to the Registrant's Registration Statement on Form F-1/A (File No. 001-292790) filed on January 29, 2026).
4.12#	2026 Global Stock Option Plan (incorporated by reference to Exhibit 10.12 to the Registrant's Registration Statement on Form F-1/A (File No. 001-292790) filed on January 29, 2026).
*4.13	Fifth Amendment to the Lease Agreement by and between Galchimia S.A. and Agomab Spain, S.L.U. dated as of February 26, 2026.
8.1	Subsidiaries of the Registrant (incorporated by reference to Exhibit 21.1 to the Registrant's Registration Statement on Form F-1/A (File No. 001-292790) filed on January 29, 2026).
*11.1	AgomAb Therapeutics NV Insider Trading Policy
*12.1	Certification by Principal Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
*12.2	Certification by Principal Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

*13.1	Certification by Principal Executive Officer and Principal Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
*15.1	Consent of PwC Bedrijfsrevisoren BV / Reviseurs d'Entreprises SRL, independent registered public accounting firm.
*97.1	AgomAb Therapeutics NV Compensation Recovery Policy.
101.INS	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

* Filed herewith.
# Indicates a management contract or any compensatory plan, contract or arrangement.
† Portions of this exhibit (indicated by asterisks) have been omitted pursuant to Item 601 of Regulation S-K because it is both not material and is the type that the registrant treats as private or confidential.
+ Certain exhibits and schedules to these agreements have been omitted pursuant to Item 601(a)(5) and (6) of Regulation S-K. The registrant will furnish copies of any of the exhibits and schedules to the SEC upon request.

Signatures

The registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this annual report on its behalf.

Antwerpen, April 23, 2026

AGOMAB THERAPEUTICS NV

By: /s/ Tim Knotnerus

Name: Tim Knotnerus

Title: Chief Executive Officer (Principal Executive Officer)

INDEX TO FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Shareholders of AgomAb Therapeutics NV

Opinion on the Financial Statements

We have audited the accompanying consolidated statements of financial position of AgomAb Therapeutics NV (the "Company") as of December 31, 2025 and 2024, and the related consolidated statements of profit or loss, of comprehensive income or loss, of changes in equity and of cash flows for each of the three years in the period ended December 31, 2025, including the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as December 31, 2025 and 2024, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2025 in conformity with IFRS Accounting Standards as issued by the International Accounting Standards Board.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits of these consolidated financial statements in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

PwC Bedrijfsrevisoren BV / Reviseurs d'Entreprises SRL
Represented by

/s/ Didier Delanoye
Statutory Auditor

Diegem, Belgium
April 23, 2026

We have served as the Company's auditor since 2021.

Consolidated statement of profit or loss

(in thousands of €)	Notes	For the year ended December 31 2025	2024	2023
Research and development expenses	7.1	(48,877)	(39,310)	(26,311)
General and administrative expenses	7.1	(12,791)	(10,133)	(6,097)
Total operating expenses		**(61,668)**	**(49,443)**	**(32,408)**
Other operating income	7.4	2,393	1,422	1,218
Operating loss		**(59,275)**	**(48,021)**	**(31,190)**
Changes in fair value of financial liabilities	23	(4,857)	848	18,964
Financial expenses	7.3	(133)	(357)	(86)
Financial income	7.3	1,718	1,267	303
Loss before taxes		**(62,547)**	**(46,263)**	**(12,009)**
Income tax (expense)/income	8	—	(4)	619
Loss for the year		**(62,547)**	**(46,267)**	**(11,390)**
				—
Weighted average number of common shares outstanding	9	541,126	541,126	541,126
Basic and diluted loss per share (in €)	9	(143.22)	(107.09)	(35.63)

The accompanying notes form an integral part of these Consolidated Financial Statements.

Consolidated statement of comprehensive income or loss

(in thousands of €)	Notes	For the year ended December 31 2025	2024	2023
Loss for the year		**(62,547)**	**(46,267)**	**(11,390)**
Items that may be reclassified to profit or loss				
Foreign currency translation differences	7.3	21	(10)	—
Items that will not be reclassified to profit or loss				
Remeasurement of post-employment benefit obligations	21	(8)	(73)	—
Other comprehensive income or loss for the year, net of tax		13	(83)	—
Total comprehensive income or loss for the year*		**(62,534)**	**(46,350)**	**(11,390)**

** The loss and total comprehensive loss for the year are fully attributable to the owners of the parent*

The accompanying notes form an integral part of these Consolidated Financial Statements.

Consolidated statement of financial position

(In thousands of €)	Notes	For the year ended per December 31 2025	2024
Assets			
Non-current assets			
Intangible assets	11	20,110	20,110
Goodwill	10	8,612	8,612
Property, plant and equipment	13	503	619
Right-of-use assets	12	1,083	1,373
Other financial assets		11	12
Other non-current assets	14	2,150	1,787
Total non-current assets		**32,469**	**32,513**
Current assets			
Other current assets	15	4,723	2,386
Current financial investments	16	30,096	—
Cash and cash equivalents	16	86,418	171,459
Total current assets		121,237	173,845
Total assets		**153,706**	**206,358**
Equity			
Share capital	17	223,072	223,072
Share premium reserve	17	76,634	76,634
Retained earnings	17	(181,714)	(119,181)
Share-based payment reserves	19	13,877	8,522
Other reserves	17	(967)	(966)
Equity attributable to the owners of the parent		130,902	188,081
Total equity		**130,902**	**188,081**
Liabilities			
Non-current liabilities			
Non-current lease liabilities	12	1,005	1,272
Non-current contingent consideration	22	3,210	7,879
Total non-current liabilities		**4,215**	**9,151**
Current liabilities			
Current lease liabilities	12	249	273
Anti-dilutive warrants	18	—	—
Current contingent consideration	22	6,526	—
Trade and other payables	20	10,266	8,052
Deferred income and accrued charges	20	1,548	801
Total current liabilities		18,589	9,126
Total liabilities		**22,804**	**18,277**
Total equity and liabilities		**153,706**	**206,358**

The accompanying notes form an integral part of these Consolidated Financial Statements.

Consolidated statement of changes in equity

(In thousands of €)	Share capital	Share premium reserve	Retained earnings	Translation reserve	Actuarial losses	Share-based payment reserve	Other reserves	Equity attributable to owners of the Company	Total equity
Balance at January 1, 2023	**110,412**	**12,368**	**(61,440)**	**—**	**—**	**5,293**	**(385)**	**66,248**	**66,248**
Loss for the year	—	—	(11,390)	—	—	—	—	(11,390)	(11,390)
Total comprehensive income or loss for the year	**—**	**—**	**(11,390)**	**—**	**—**	**—**	**—**	**(11,390)**	**(11,390)**
Increase of capital	64,300	30,571	—	—	—	—	—	94,871	94,871
Share-based payments	—	—	—	—	—	2,159	—	2,159	2,159
Transaction costs to be deducted from equity (IAS 32)	—	—	—	—	—	—	(453)	(453)	(453)
Balance at December 31, 2023	**174,712**	**42,939**	**(72,831)**	**—**	**—**	**7,452**	**(837)**	**151,435**	**151,435**
Balance at January 1, 2024	**174,712**	**42,939**	**(72,831)**	**—**	**—**	**7,452**	**(837)**	**151,435**	**151,435**
Loss for the year	—	—	(46,267)	—	—	—	—	(46,267)	(46,267)
Other comprehensive income or loss	—	—	—	(10)	(73)	—	—	(83)	(83)
Total comprehensive income or loss for the year	**—**	**—**	**(46,267)**	**(10)**	**(73)**	**—**	**—**	**(46,350)**	**(46,350)**
Increase of capital	48,360	33,695	—	—	—	—	—	82,055	82,055
Share-based payments	—	—	—	—	—	1,070	—	1,070	1,070
Transaction costs to be deducted from equity (IAS 32)	—	—	—	—	—	—	(129)	(129)	(129)
Balance at December 31, 2024	**223,072**	**76,634**	**(119,098)**	**(10)**	**(73)**	**8,522**	**(966)**	**188,081**	**188,081**
Balance at January 1, 2025	**223,072**	**76,634**	**(119,098)**	**(10)**	**(73)**	**8,522**	**(966)**	**188,081**	**188,081**
Loss for the year	—	—	(62,547)	—	—	—	—	(62,547)	(62,547)
Other comprehensive income or loss	—	—	—	21	(8)	—	—	13	13
Total comprehensive income or loss for the year	**—**	**—**	**(62,547)**	**21**	**(8)**	**—**	**—**	**(62,534)**	**(62,534)**
Share-based payments	—	—	—	—	—	5,355	—	5,355	5,355
Balance at December 31, 2025	**223,072**	**76,634**	**(181,645)**	**11**	**(81)**	**13,877**	**(966)**	**130,902**	**130,902**

The accompanying notes form an integral part of these Consolidated Financial Statements.

Consolidated statement of cash flows

(In thousands of €)	For the years ended per December 31 2025	2024	2023
Net loss for the year	**(62,547)**	**(46,267)**	**(11,390)**
Adjustments for non-cash items:			
Current income tax expense (income)	—	4	3
Deferred income tax expense (income)	—	—	(622)
Fair value (gain) loss on financial assets	(96)	—	—
Fair value (gain) loss on financial liabilities	4,857	(848)	(18,964)
Depreciation & amortization	219	311	99
Share-based payment expenses	5,355	1,071	2,159
Net foreign exchange losses (gains)	57	231	—
Interest expense	69	77	86
Interest income	(1,614)	(1,218)	(303)
Operating cash flows before movements in working capital	**(53,700)**	**(46,640)**	**(28,932)**
movements in working capital:			
Decrease/(increase) in other current assets	(2,337)	(315)	1,343
Decrease/(increase) in other non-current assets	(363)	(342)	(331)
Increase/(decrease) in trade and other payables	2,359	(230)	3,686
Increase/(decrease) in deferred income	747	(395)	(580)
Income taxes paid	—	(4)	(3)
Interest paid	(69)	(10)	(20)
Interest received	1,622	1,106	245
Net cash flow from /(used in) operating activities	**(51,741)**	**(46,828)**	**(24,592)**
Purchases of property, plant and equipment	(4)	(675)	—
Purchase of financial investments	(30,000)	—	40,000
Payment of contingent consideration from previous acquisition	(3,000)	—	—
Net cash flow from /(used in) investing activities	**(33,004)**	**(675)**	**40,000**
Repayment of lease liabilities	(338)	(163)	(100)
Proceeds from capital increase	—	97,055	79,871
Share issue costs	—	(129)	(453)
Other financial expense, net	—	—	6
Net cash flow from /(used in) financing activities	**(338)**	**96,762**	**79,324**
Net increase/(decrease) in cash and cash equivalents	**(85,083)**	**49,260**	**94,732**
Cash and cash equivalents at beginning of year	**171,459**	**122,402**	**27,670**
Effect of foreign exchange rate changes	45	(204)	—
Cash and cash equivalents at end of year	**86,418**	**171,459**	**122,402**

The accompanying notes form an integral part of these Consolidated Financial Statements.

Notes to the Consolidated Financial Statements

1. Corporate information

AgomAb Therapeutics NV (further referred to as "the Company") is a limited liability company incorporated and domiciled in Belgium. The registered office is located at 1/6 Posthoflei, 2600 Antwerp, Belgium.

The Company has two fully owned subsidiaries, Agomab Spain S.L.U. (further referred as 'Agomab Spain' and formerly known as Origo Biopharma, S.L.) and a subsidiary within the United States of America (the "US"), Agomab US, Inc. (further referred to as "Agomab US"), established on May 31, 2024. The Company, its Spanish and US subsidiaries (together referred to as the "Group") are clinical-stage biopharmaceutical companies focused on developing novel disease-modifying therapies for fibro-inflammatory diseases. The Group is active primarily in Europe.

AgomAb Therapeutics NV is a publicly traded company with American Depositary Shares listed on NASDAQ Global Select Market under the symbol "AGMB" since February 6, 2026 (see note 26).

Information on other related party transactions is provided in note 25.

The Consolidated Financial Statements under IFRS Accounting Standards (further referred to as "the consolidated financial statements") of the Group for the year ended December 31, 2025, were authorized for issue in accordance with a resolution of the directors on April 17, 2026.

2. Material accounting policies

2.1. Basis of preparation

The consolidated financial statements of the Group have been prepared in accordance with IFRS Accounting Standards as issued by the International Accounting Standards Board (IASB).

The consolidated financial statements have been prepared on a historical cost basis, except for Money Market Funds (current financial investments), derivative instruments, defined benefit pension plan assets and contingent consideration, that are measured on the basis of fair value (see note 23). Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date, regardless of whether that price is directly observable or estimated using another valuation technique. In estimating the fair value of an asset or a liability, the Group takes into account the characteristics of the asset or liability if market participants would take those characteristics into account when pricing the asset or liability at the measurement date. All financial assets and liabilities for which fair value is measured or disclosed in the consolidated financial statements are categorized within the fair value hierarchy, described as follows, based on the lowest level input that is significant to the fair value measurement as a whole:

- Level 1: quoted (unadjusted) market prices in active markets for identical assets or liabilities;
- Level 2: valuation techniques for which the lowest level input that is significant to the fair value measurement, is directly or indirectly observable; or
- Level 3: valuation techniques for which the lowest level input that is significant to the fair value measurement is, unobservable.

The financial statements are presented in thousands of euros and all currency amounts are rounded to the nearest thousands, except where otherwise indicated.

The material accounting policies applied in the preparation of these financial statements are set out below. These policies have been consistently applied to all the years presented and by all Group entities if applicable in the respective years.

The preparation of financial statements requires the use of certain critical accounting estimates. It also requires management to exercise judgment in applying the Company's accounting policies. The areas where significant judgment and estimates have been made in preparing the financial statements and their effect are disclosed in note 4.

On February 9, 2026, the Company effected a stock split, each common share was split into 21.645 common shares (rounded). Accordingly, all common shares and per common share amounts for all periods presented in these consolidated financial statements and notes thereto have been adjusted retroactively, where applicable (unless otherwise noted), to reflect this share split.

2.2. Summary of material accounting policies

2.2.1. Basis of consolidation

The consolidated financial statements incorporate the financial statements of the Company and entities controlled by the Company (its subsidiaries–see note 6). Control is achieved when the Company has the power over the investee, is exposed, or has rights, to variable returns from its involvement with the investee and has the ability to use its power to affect its returns.

Consolidation of a subsidiary begins when the Company obtains control over the subsidiary and ceases when the Company loses control of the subsidiary. Specifically, the results of subsidiaries incorporated, acquired or disposed of during the year are included in profit or loss from the date the Company gains control until the date when the Company ceases to control the subsidiary. Where necessary, adjustments are made to the financial statements of subsidiaries to bring the accounting policies used into line with the Group's accounting policies. All intragroup assets and liabilities, equity, income, expenses and cash flows relating to transactions between the members of the Group are eliminated on consolidation.

2.2.2. Foreign Currency Transactions

2.2.2.1. Functional and presentation currency

Items included in the consolidated financial statements of each of the entities are measured using the currency of the primary economic environment in which the entity operates ('the functional currency'). The consolidated financial statements are presented in EUR (€), which is the Company's functional and presentation currency.

2.2.2.2. Foreign currency transactions

Foreign currency transactions are accounted for at exchange rates prevailing at the date of the transactions. Monetary assets and liabilities denominated in foreign currencies are translated at the exchange rates prevailing on the reporting date. Gains and losses resulting from the settlement of foreign currency transactions and from the translation of monetary assets and liabilities denominated in foreign currencies are recognized in the income statement. Non-monetary assets and liabilities denominated in foreign currencies are translated at the foreign exchange rate prevailing at the date of the transaction or, for those stated at fair value, at the dates the fair value was determined. Translation of the results and financial position of foreign operations.

2.2.2.3. Translation of the results and financial position of foreign operations

The results and financial position of foreign operations (none of which has the currency of a hyper-inflationary economy) that have a functional currency different from the presentation currency are translated into the presentation currency as follows:

- assets and liabilities for each statement of financial position presented are translated at the closing rate at the date of that statement of financial position;
- income and expenses for each statement of profit or loss and statement of comprehensive income are translated at average exchange rates (unless this is not a reasonable approximation of the cumulative effect of the rates prevailing on the transaction dates, in which case income and expenses are translated at the dates of the transactions); and
- all resulting exchange differences are recognized in other comprehensive income; and
- goodwill and fair value adjustments arising on the acquisition of a foreign operation are treated as assets and liabilities of the foreign operation and translated at the closing rate.

2.2.3. Taxation

The current tax payable is based on the taxable profit for the year. Taxable profit differs from the net result as reported in the statement of profit or loss for the period as there are some items which may never be taxable or deductible for tax and other items which may be deductible or taxable in other periods. The Company's liability for current tax is calculated based on the tax laws enacted or substantively enacted by the end of the reporting period.

Deferred tax is the tax expected to be payable or recoverable on differences between the carrying amounts of assets and liabilities in the financial statements and the corresponding tax bases used in the computation of taxable profit. Deferred tax liabilities are generally recognized for all taxable temporary differences and deferred tax assets are recognized on deductible temporary differences and on the carry-forward of unused tax losses and tax credits only to the extent that it is probable that taxable profits will be available in the foreseeable future. Deferred tax liabilities are not recognized if they arise from the initial recognition of goodwill. The carrying amount of the deferred tax assets are reviewed at each reporting date.

Deferred tax is calculated at the tax rates that are expected to apply in the period when the liability is settled or the asset is realized based on tax laws and rates that have been enacted or substantively enacted at the reporting date.

Deferred tax assets and liabilities are offset when there is a legally enforceable right to offset current tax assets against current tax liabilities and when they relate to income taxes levied by the same taxation authority and the Company intends to settle its current tax assets and liabilities on a net basis.

Current and deferred tax is recognized in profit or loss, except to the extent that it relates to items recognized in other comprehensive income or directly in equity. In this case, the tax is also recognized in other comprehensive income or directly in equity, respectively.

2.2.4. Goodwill

Goodwill represents the future economic benefits arising from intangible assets acquired in a business combination that are not individually identified and separately recognized. Such benefits include future synergies expected from the combination recognized as a result of the purchase price allocation. Agomab Spain brings a dedicated pipeline of organ-restricted small molecule drug candidates targeting the transforming growth factor beta (TGF-β) pathway. The synergies are stemming from the potential additional commercial revenue expected from these products upon regulatory and marketing approvals.

Goodwill is initially measured at cost (being the excess of the aggregate of the consideration transferred and the amount recognized for non-controlling interests and any previous interest held over the net amount of assets and liabilities).

After initial recognition, goodwill is measured at cost less any accumulated impairment losses. Goodwill is not amortized and annually (i.e., in the fourth quarter) tested for impairment at cash generating unit (CGU) level. The Group distinguishes two CGU's, being Agomab Spain and AgomAb Therapeutics NV. The goodwill has been allocated in full to the CGU "Agomab Spain" as it is the level at which the synergies from the combination are expected to materialize. The recoverable amount of the Agomab Spain CGU is based on its value in use, i.e. net present value of the expected future cash flows. No impairment was recorded as the recoverable amount is not lower than the carrying amount of the CGU. The pre-tax discount rates are derived from the Company's weighted average cost of capital, taking into account the cost of equity and debt, to which specific market-related premium adjustments are made. When the recoverable amount of the goodwill is less than its carrying amount, an impairment loss is recognized immediately in the income statement which cannot be subsequently reversed.

2.2.4. Intangible assets

2.2.4.1. Research and Commercialization license

The Company has entered into a research and commercialization license agreement for certain third-party patent rights and know-how. The license agreement is a non-exclusive, worldwide milestone-free and royalty-free research license grant under third-party intellectual property (IP) for the sole purpose of researching anti-MET SIMPLE Antibodies in the field. The third-party grants a worldwide, exclusive, sublicensable license under the third- party IP to research, develop, manufacture, use and sell, licensed products in the field. The license agreement expires on the last to expire third-party patent right and cannot be terminated by either party other than for cause or due to insolvency.

The license is received in exchange for a profit share certificate. The license is considered a right-to-use license and meets the definition of an intangible asset as the license rights obtained are identifiable, i.e., both separable and arising from contractual or legal rights.

The profit share certificate was immediately vested as at the effective date of the research and commercialization license agreement and correspondingly, an intangible asset is recognized equal to the fair value of the profit share certificate at grant date. The intangible asset will not be subsequently remeasured, although the number of equity instruments to be issued upon exercise may vary as a result of the continued development efforts by the Company on their product pipeline and other events, independent of the third-party license. We also refer to note 2.2.8.2 for further details.

The license will be amortized as from the moment one or more products that uses the license are available for use (i.e., when regulatory approval is obtained to launch the product on the market). Intangible assets not available for use and hence not subject to amortization, are tested annually for impairment or if there is an indication that an asset may be impaired. External indicators may be: market value declines, overall macro-economic climate, increase in market interest rates and a decrease of the Group's market capitalization below its net assets. Internal indicators could be negative outcome of R&D and issues identified with the corresponding intellectual property.

During 2025, the Company has decided to pause the start of any further development on one of its preclinical stage assets, relating to the research and commercialization license. This strategic decision has been made because the Company will focus its efforts on other therapeutic areas. The Company is assessing strategic options for the accumulated know-how and IP related to this asset.

2.2.4.2. In-process research and development

Internally generated research and development

Expenditure on research activities is recognized as an expense in the period in which it is incurred.

An internally generated intangible asset arising from development is recognized to the extent that all the following conditions for capitalization have been satisfied:

- the technical feasibility of completing the intangible asset so that it will be available for use or sale;
- its intention to complete the intangible asset and use or sell it;
- its ability to use or sell the intangible asset;
- how the intangible asset will generate probable future economic benefits;
- the availability of adequate technical, financial and other resources to complete the development and to use or sell the intangible asset; and
- its ability to measure reliably the expenditure attributable to the intangible asset during its development.

The above recognition criteria are only met when a regulatory filing has been made in a major market and the approval from the regulators is considered as highly probable. Where no internally generated intangible asset can be recognized, development expenditure is recognized in profit or loss in the period in which it is incurred. All costs incurred to legally protect the intellectual property of the Group on research and development activities not qualifying for recognition as an intangible asset, are also expensed as incurred.

The amount initially recognized for internally generated intangible assets is the sum of the expenditure incurred from the date when the intangible asset first meets the recognition criteria listed above. Subsequent to initial recognition, internally generated intangible assets are reported at cost less accumulated amortization and accumulated impairment losses, on the same basis as intangible assets that are acquired separately.

Acquired research and development

The fair value of the in-process research and development projects acquired via the acquisition of Agomab Spain are capitalized and accounted for as intangible assets not yet ready for use until:

- the underlying project receives regulatory approval, at which point the intangible asset will be accounted for as a definite-lived intangible asset, or
- discontinuation, at which point the intangible asset will be written off.

Research and development costs incurred subsequent to the acquisition are expensed as incurred. In-process R&D assets are tested annually for impairment or if there is an indication that an in-process R&D asset is impaired when the recoverable amount is lower than the carrying amount at CGU level. The Group distinguishes two CGU's, being Agomab Spain and AgomAb Therapeutics NV. As the related R&D projects are not expected to generate cash inflows independently from the CGU (i.e. Agomab Spain), the in-process R&D has been fully allocated to the Agomab Spain CGU. The recoverable amount of the Agomab Spain CGU is based on its value in use, i.e. net present value of the expected future cash flows. No impairment was recorded as the recoverable amount is not lower than the carrying amount of the CGU. The pre-tax discount rates are derived from the Company's weighted average cost of capital, taking into account the cost of equity and debt, to which specific market-related premium adjustments are made. When the recoverable amount of the in-process R&D is less than its carrying amount, an impairment loss is recognized immediately in the income statement which could be potentially subsequently reversed.

2.2.5. Financial assets

Financial assets are initially recognized either at fair value or at transaction price. All recognized financial assets are subsequently measured at either amortized cost or fair value under IFRS 9 on the basis of both the Company's model for managing the financial assets and the contractual cash flow characteristics of the financial asset.

- A financial asset that (i) is held within a business model whose objective is to collect the contractual cash flows and (ii) has contractual cash flows that are solely payments of principal and interest on the principal amount outstanding is measured at amortized cost (net of any write down for impairment), unless the asset is designated at fair value through profit or loss ("FVTPL") under the fair value option.
- A financial asset that (i) is held within a business model whose objective is achieved both by collecting contractual cash flows and selling financial assets and (ii) has contractual term that give rise on specified dates to cash flows that are solely payments of principal and interest on the principal outstanding, is measured at fair value through other comprehensive income ("FVTOCI"), unless the asset is designated at FVTPL under the fair value option.
- All other financial assets are measured at FVTPL.

A financial asset is classified as current when the cash flows expected to flow from the instrument mature within one year.

The Company derecognizes a financial asset when the contractual rights to the cash flows from the asset expire, or the Company transfers the right to receive the contractual cash flows on the financial asset in a transaction in which substantially all the risks and rewards of ownership of the financial asset are transferred.

2.2.5.1. Financial assets measured at fair value through profit and loss

Current financial investments measured at fair value through profit or loss comprise of money market funds that are readily convertible to cash and are subject to a marginal risk of changes in value. These financial assets are used by the Company in the management of short-term commitments.

2.2.5.2. Financial assets measured at amortized cost

Financial assets measured at amortized cost include cash and cash equivalents, other financial assets, and non-current assets (i.e., trade receivables and other receivables).

Cash and cash equivalents measured at amortized cost comprise cash at banks and on-hand, that are readily convertible to a known amount of cash and subject to an insignificant risk of changes in value.

Other financial assets comprise cash balances that are not available for use by the Company (i.e., guarantees) and deposit accounts with an original maturity of more than three months.

Trade receivables are initially measured at the transaction price and are subsequently measured at amortized cost using the effective interest rate method, less any loss allowance.

The Company determines the value of the allowance for losses (impairment) on each reporting date. It recognizes this impairment for credit losses to be expected during the term of all financial instruments for which the credit risk—whether on an individual or collective basis—has increased significantly since initial recognition, considering all reasonable and substantiated information, including forward-looking information. In the case that the credit risk is low, the twelve month expected credit losses are recognized.

2.2.6. Financial liabilities

The Company has financial liabilities measured at amortized cost which include trade payables and other payables.

These financial liabilities are recognized initially at fair value minus directly attributable transaction costs and are measured at amortized cost using the effective interest rate method. Gains and losses are recognized in the income statement when the liabilities are derecognized as well as through the effective interest rate method amortization process.

The Company has a contingent consideration payable classified as a financial liability relating to a business combination. The amount classified as a financial liability is subsequently remeasured to fair value with changes in fair value through profit or loss.

A financial liability is derecognized when the obligation under the liability is discharged or cancelled or expires.

2.2.7. Offsetting of financial instruments

Financial assets and financial liabilities are offset and the net amount is reported in the statement of financial position, if there is a currently enforceable legal right to offset the recognized amounts and there is an intention to settle on a net basis, to realize the assets and settle the liabilities simultaneously.

2.2.8. Share-based payments

2.2.8.1. Share-based payments

The Company issued ESOP warrants giving employees and consultants the right to acquire newly issued ESOP common shares. There is no obligation for the Company to deliver cash or another financial asset. The related plans are classified as equity-settled share-based payment transactions. Refer to note 19.1 for more information.

The fair value of warrants granted under the ESOP plan is measured at grant date using the Black-Scholes model and is recognized as an employee benefits expense, with a corresponding increase in equity (share-based payment reserves). The total amount to be expensed is determined by reference to the fair value of the options granted. The ESOP plan has service performance vesting conditions which are further detailed in note 19.1.

The total expense is recognized over the vesting period, which is the period over which all of the specified vesting conditions are to be satisfied. At the end of each period, the entity revises its estimates of the number of options that are expected to vest based on the service conditions. It recognizes the impact of the revision to original estimates, if any, in profit or loss, with a corresponding adjustment to equity.

Where vesting of ESOPs is conditional upon the occurrence of an IPO, and the timing of the qualified IPO is uncertain at grant date, the Group determines the expected vesting period based on the best estimate of when the qualified IPO is expected to occur. This estimate is reassessed at each reporting date and adjusted based on current information regarding the probability and expected timing of the qualified IPO.

Upon reassessment of the variable vesting period, the cumulative expense will be calculated based on the revised vesting period and the impact will be recorded in the reporting period when the reassessment is performed.

2.2.8.2. Profit share certificate

The Company has granted a profit share certificate (PSC) towards a third-party company in return for a research and commercialization license on certain patent rights and know-how. The profit share certificate qualifies as an equity-settled share-based payment transaction. Information relating to this profit share certificate is set out in note 19.2.

The fair value of the profit share certificate is measured at the grant date at fair value (refer to note 4.2.2) and is initially recognized as an intangible asset with a corresponding increase in equity (share-based payment reserves). The profit share certificate is immediately vested at the effective date of the research and commercialization license agreement as the third-party company is not required to deliver any service other than granting the license. No subsequent remeasurement shall be made to total equity in accordance with IFRS 2.23 after the vesting date.

The profit share certificate entitles the third-party to 20% of all distributions to the Company's shareholders (which shall be reduced to 10% following the filing of an Investigational New Drug application ("IND") and is subject to further adjustment upon the occurrence of certain financings).

As at December 31, 2024, the Company has obtained the IND and additionally as a result of the Series D financing round in November 2024, the percentage of the profit share certificate was further adjusted.(i.e., the percentage was reduced to 4.84% of all distributions to the Company's shareholders, subject to further adjustment upon the occurrence of certain financings.).

Upon the occurrence of a qualified initial public offering of the Company, the profit share certificate will automatically be converted into the equivalent number of common shares in the Company.

2.2.9. Anti-dilution warrants

The Company has issued anti-dilution warrants A, B, C and D to each of the preferred A, B, C and D investor shareholders. The anti-dilution warrants are granted to shareholders, in their capacity as shareholder, to protect the investors against future dilutive capital increases. The warrants are only exercisable upon a dilutive capital increase and will grant the right to the holder to obtain an additional variable number of preferred A, B, C or D shares. As the warrants will result in a variable number of shares to be issued upon exercise, they do not meet the definition of an equity instrument. The anti-dilutive warrants are classified as derivative financial liabilities and recorded against accumulated loss upon initial recognition and subsequently measured at fair value through profit and loss.

Refer to note 18 below for further information.

2.2.10. Other income—Grants and R&D incentives

As the Company carries out extensive research & development (R&D) activities, it benefits from various grants and R&D incentives from certain governmental agencies. These grants and incentives generally aim to partly reimburse eligible R&D costs incurred.

All incoming cash from grants is presented as a liability in deferred income on the balance sheet for as long as the grant is not recognized as income. A partial deduction of the withholding tax on salaries of research employees is also recognized as other income in the period in which the deduction is granted. This deduction is treated as a reduced payment of withholding tax to the government and has therefore no direct impact on the cash flow. The Company has not received grants related to assets.

2.2.10.1. VLAIO grants

These amounts relate to R&D innovation grants issued by Flanders Innovation and Entrepreneurship (VLAIO). In line with IAS 20 "Government grants", VLAIO grants are recognized as government grant income over the term of the project for which the grant was given when there is reasonable assurance that the Company will comply with the conditions attached to them and the grants will be received. Grants that compensate the Company for expenses incurred are recorded in other operating income on a systematic basis in the same period in which the expenses are incurred. Grants are provided to the Company in order to support certain R&D activities and costs that are defined in the grant agreement. Over the course of the project, the Company reports on the status of activities and incurred expenditure to VLAIO on a regular basis in order to receive grant advances. A final assessment is performed by VLAIO at the end of the project in order to determine the final grant amount. Projects can take on average between two and three years. Over the course of funded projects, the Company is confident that all activities performed will not deviate from the agreed scope, and that the final grant amount will not deviate from the initially agreed amount. The Company is confident that reasonable assurance as defined in the standard is reached over the course of the project for the amounts spent up to that moment. The only condition attached to the grant is the performance of R&D activities in line with the agreed-upon scope and in line with the set budget. There are no other conditions attached to the grants and the scientific result of R&D activities does not impact the decision of VLAIO as to whether the final grant will be received or not. Contracts with these grant bodies also typically include clauses that require the Company to maintain a presence in the Flemish region for a number of years and that define the need for future validation of the project results after completion of the initial grant term during which the subsidized expenses or investments have been incurred and for which the grant was earned. These government institutions may however subsequently perform an audit which may result in a (partial) claw back of the grant. The Company deems that the claw back risk is remote in view of the continuous monitoring of the contractual conditions. There are no other conditions attached to the grants and the scientific result of R&D activities does not impact the decision of VLAIO as to whether the final grant will be received or not.

2.2.10.2. R&D tax credits

The Company applies for R&D tax credits, a tax incentive measure for European Small and Medium-sized Enterprises (SMEs) established by the Belgian federal government. When capitalizing its R&D expenses for tax filing, the Company may either:

- Receive a reduction of its taxable income (at the current income tax rate applicable); or
- If no sufficient taxable income is available, apply for a refund of the unutilized tax credits, calculated on the R&D expenses for the year.

Such settlement occurs, at the earliest, four financial years after the tax credit application is filed by the Company. Considering that R&D tax credits are ultimately paid by public authorities, the related benefit is treated as a government grant and recognized as other income, to match the R&D expenses subsidized by the grant.

2.2.11. Property, plant and equipment

Property, plant and equipment, including leasehold improvements, is measured at cost less accumulated depreciation and impairment losses. Costs included are the purchase price and any costs directly attributable to bringing the asset to the location and condition necessary for it to be capable of operating as intended by management. The assets' residual values and useful lives have to be reviewed, and adjusted if appropriate, at the end of each reporting period.

Depreciation is calculated on a straight-line basis over the estimated useful lives of the assets. For the non- removable leasehold improvements, if the lease term of the related lease is shorter than the economic life of those leasehold improvements, the Group considers whether it expects to use the leasehold improvements beyond that lease term. If not, the useful life of the non-removable leasehold improvements is equal to the lease term.

The estimated useful lives of the assets are as follows:

Asset class	Useful life in years
Leasehold improvements	9
IT equipment	3
Furniture and fixtures and other equipment	5

An item of property, plant and equipment is derecognised upon disposal or when no future economic benefits are expected from its use or disposal. Any gain or loss arising on derecognition of the asset, calculated as the difference between the net disposal proceeds and the carrying amount of the asset, is included in the statement of profit or loss and other comprehensive income when the asset is derecognised. This either as an operating expense or operating income in case of a net loss or net gain respectively.

2.2.12. Leases

The company assesses whether a contract is or contains a lease at inception of a contract. The company recognizes a right-of-use asset and a corresponding lease liability with respect to all lease agreements in which it is the lessee, except for short-term leases (defined as leases with a lease term of 12 months or less) and leases of low value assets. For these leases, the company recognizes the lease payments as an operating expense on a straight-line basis over the term of the lease, and payments for these leases are presented in cash flow from operating activities.

The lease liability is initially measured at the present value of the lease payments that are not paid at the commencement date, discounted by using the rate implicit in the lease. If this rate cannot be readily determined, the company uses its incremental borrowing rate specific to the country, term and currency of the contract. In addition, the company considers its recent debt issuances as well as publicly available data for instruments with similar characteristics when calculating the incremental borrowing rates.

Lease payments include fixed payments, less any lease incentives, variable lease payments that depend on an index or a rate known at the commencement date, and purchase options or extension option payments if the company is reasonably certain to exercise these options. Variable lease payments that do not depend on an index or rate are not included in the measurement of the lease liability and right-of-use asset and are recognized as an expense in the income statement in the period in which the event or condition that triggers those payments occurs.

A lease liability is remeasured upon a change in the lease term, changes in an index or rate used to determine the lease payments or reassessment of exercise of a renewal and/or purchase option. The corresponding adjustment is made to the related right-of-use asset. The right-of-use assets comprise the initial measurement of the corresponding lease liability, lease payments made at or before the commencement day and any initial direct costs. They are subsequently measured at cost less accumulated depreciation and impairment losses. The right-of-use assets are depreciated starting at the commencement date over the shorter period of useful life of the underlying asset and lease term.

2.2.13. Deferred offering expenses

The Group defers the incremental directly attributable expenses with respect to the in-process equity financing as deferred offering expenses, until such financing is received. If the equity financing is received, these deferred expenses are reclassified and recorded as a deduction of the equity financing generated as a result of the offering. In case the in-process equity financing would no longer be probable, the deferred offering expenses will immediately be expensed as an operating expense in the consolidated statement of profit or loss and other comprehensive income.

3. New and revised standards not yet adopted

New and amended Standards and interpretations applicable for annual period beginning on January 1, 2025, did not have any material impact on our consolidated financial statements. The Group has not early adopted any of the new and amended standards which have been issued but are not yet effective.

The new and amended standards and interpretations that have been issued, but are not effective yet, are disclosed below. The Company intends to adopt these new and amended standards and interpretations, if applicable, when they become effective:

The following amendments are effective for the period beginning January 1, 2026:

- Amendments to IFRS 9 and IFRS 7: Classification and Measurement of Financial instruments
- Annual Improvements: Volume 11
- Amendments to IFRS 9 and IFRS 7: Contracts referencing Nature-dependent Electricity

The following amendments are effective for the period beginning January 1, 2027:

- IFRS 18: Presentation and Disclosure in Financial Statements

The Company is currently assessing the effect of these new accounting standards and amendments.

In April 2024, the IASB issued IFRS 18, which replaces IAS 1 Presentation of Financial Statements. IFRS 18 introduces new requirements for presentation within the statement of profit or loss, including specified totals and subtotals. Furthermore, entities are required to classify all income and expenses within the statement of profit or loss into one of five categories: operating, investing, financing, income taxes and discontinued operations, whereof investing and financing are new.

The standard requires disclosure of newly defined management-defined performance measures, subtotals of income and expenses, and it also includes new requirements for aggregation and disaggregation of financial information based on the identified ‘roles’ of the primary financial statements (PFS) and the notes.

In addition, narrow-scope amendments have been made to IAS 7 Statement of Cash Flows, which include changing the starting point for determining cash flows from operations under the indirect method, from ‘profit or loss’ to ‘operating profit or loss’ and removing the optionality around classification of cash flows from dividends and interest. In addition, there are consequential amendments to several other standards.

The Group is currently working to identify all impacts the amendments will have on the primary financial statements and notes to the financial statements.

IFRS 18 is effective for reporting periods beginning on or after 1 January 2027, but earlier application is permitted and must be disclosed. IFRS 18 will apply retrospectively.

Although the adoption of IFRS 18 will have no impact on the group’s net profit, the following changes are likely to be reflected:

- Loss before financing and income tax will be introduced as [a] new subtotal[s] in the statement of profit or loss.
- Interest income on cash and cash equivalents will be removed from financial result and classified as part of the investing category.
- The interest result with respect to our defined benefit plans currently presented as part of operating profit will be presented as part of the financial result.

- Foreign exchange difference will be classified in the category where the related income and expense form the item giving rising to the foreign exchange difference.

- Remeasurement of the contingent consideration will be removed from financial result and classified as part of the operating result.

Classifications subject to pending IFRIC decisions:

- Foreign exchange on intercompany transactions are currently presented as part of our financial result, pending final IFRIC decisions, it might be that this will have to be presented as part of operating result.

Changes to the cash flow statement:

- Interest received currently classified as part of operating cash flows will have to be presented as part of investing cash flows

- Interest paid currently classified as part of operating cash flows will have to be presented as part of financing cash flows

We have not early adopted any standard, interpretation, or amendment that has been issued but is not yet effective.

4. Key judgements and major sources of estimation uncertainty

The preparation of the Group's consolidated financial statements requires management to make judgments, estimates and assumptions that affect the reported amounts of income, expenses, assets and liabilities, and the accompanying disclosures. Uncertainty about these assumptions and estimates could result in outcomes that require significant adjustments to the carrying amount of assets or liabilities in future periods.

On an ongoing basis, the Group evaluates its estimates, assumptions, and judgments.

The Group based its assumptions and estimates on parameters available when the consolidated financial statements were prepared. Existing circumstances and assumptions about future developments, however, may change due to market changes or circumstances arising beyond the control of the Group. Such changes are reflected in the assumptions when they occur.

4.1. Key judgements

4.1.1. Going concern

The Group regularly monitors its cash position and its ability to continue as a going concern at each reporting period. When assessing going concern, the Group mainly considers the following:

- Cash and cash equivalents available at the reporting date;

- Cash use projected in accordance with the approved budget for next 12-month period as from the issuance date of the financial statements; and

- Availability of grant funding;

Whilst the current cash position is sufficient for the Group to operate as a going concern for next 12 months, the executive management committee and the Board regularly assess if the Company's research and development activities continue to deliver added value. The Company may seek additional funding to support the continuing development of its portfolio of products or to allow it to be able to execute other business opportunities.

Based on the above and the actions the Company has taken, management has concluded that the substantial doubt about its ability to continue as a going concern has been alleviated beyond 12 months from issuance of these financial statements, and these financial statements have been prepared on a going concern basis.

4.2. Key sources of estimation uncertainty

4.2.1. Share-based payment transactions—ESOP warrants

The Company measures the cost of equity-settled transactions with employees and consultants by reference to the fair value of the equity instruments at the date at which they are accepted by the beneficiary. Estimating fair value for share-based payment transactions requires determining the most appropriate valuation model, which is dependent on the terms and conditions of the grant. This estimate also requires determining the most appropriate inputs to the valuation model including the expected life of the share option, volatility, dividend yield and fair value of the underlying common shares (which itself relies on probability of exit scenarios and volatility) determined by using an OPM valuation approach.

As the Group progressed further toward an initial public offering, the fair value determination of the ESOP common shares was updated to a combination of probability weighted scenarios under an option pricing model and a net present value analysis taking into account last capital round(s), changes in the value since the last capital round(s) and different exit scenarios of an IPO and M&A transaction.

The assumptions and models, using the Black-Scholes valuation approach for estimating the fair value of share- based payment transactions and other estimates, are disclosed in note 20.1.

In measuring the expense for ESOP share-based payment transactions, the Company must estimate the vesting period. This estimation is based on the vesting schedule outlined in the plans, and on certain liquidity events, such as an initial public offering (IPO). Accelerated or delayed vesting may occur leading to a revision of the estimated vesting period. The corresponding assumptions regarding vesting period are also disclosed in note 20.1.

4.2.2. Profit share certificate

The Company has a profit share certificate granted to a third party. Refer to note 2.2.8.2. for information on the accounting policy in this respect. The Company measures the profit share certificate by reference to the fair value of the equity instruments at the date at which the profit share certificate was granted. Refer to note 20.2 for a description of the valuation of the profit share certificate and key inputs. Estimating fair value for the profit share certificate requires determining the applicable profit share percentage at grant date based on the contractual terms of the profit share certificate and determination of the volatility and potential exit scenarios as part of the fair value calculation of the underlying common share values.

No subsequent revaluation shall be made to total equity in accordance with IFRS 2.23 after the vesting date.

4.2.3. Identification and valuation of intangible assets in a business combination

The Company has acquired and may continue to acquire significant intangible assets in connection with business combinations that the Company measures at fair value. The fair value of in-process R&D has been estimated based on “Relief from Royalty” (RfR), which is an income approach valuation method. It calculates the value based on the hypothetical royalty payments the Company would save by owning the intangible asset itself compared to paying license fees or royalties to a third party for using the asset. The RfR calculation involves assumptions for both the royalty rate used and the discounted future economic benefits or cashflows (future revenue projections, discount rate equal to the Weighted Average Cost of Capital (WACC) and the applicable statutory tax rate). The royalty rate used within the calculation is based upon the average rate from ten similar transactions within the pharmaceutical and biotech industry.

In-process R&D acquired in a business combination is capitalized as an intangible asset not yet available for use until regulatory approval is obtained, at which time it is accounted for as a definite-lived asset and amortized over its estimated useful life.

4.2.4. Impairment of intangible assets not available for use and goodwill

Goodwill and intangible assets not yet available for use are tested for impairment annually on December 31 or when an event occurs that could indicate that the asset may be impaired. See notes 10 and 11 to the consolidated financial statements for additional information.

As goodwill and intangible assets recognized result from the acquisition of Agomab Spain and relate to the R&D activities in Spain, goodwill and intangible assets are allocated to the same CGU (Agomab Spain). For the impairment test of intangible assets not yet available for use and goodwill, the Company applies the value in use approach (discounted cash flows) that requires significant estimates with respect to future sales volume, revenue and expense growth rates, changes in working capital, appropriate discount rate and other assumptions and estimates. The estimates and assumptions used are consistent with the Company's business plans and a market participant view. The use of alternative estimates and assumptions could increase or decrease the estimated value in use of the CGU and could potentially impact the Group's profit or loss. Actual results may differ from the Group's estimates.

4.2.5. Measurement of contingent considerations

The fair value measurement of the contingent consideration liabilities is determined as of the acquisition date based on significant unobservable inputs, including the discount rate, the estimated probabilities and timing of achieving specified development and regulatory milestones. Contingent consideration liabilities are remeasured to fair value at each subsequent reporting date until the related contingency is resolved. The potential contingent consideration payments are estimated by applying a probability-weighted expected payment model for contingent milestone payments which are then discounted to present value. Changes to the fair value of the contingent consideration liabilities can result from changes to one or a number of inputs, including discount rates, the probabilities of achieving the milestones and the time required to achieve the milestones. Significant judgment is employed in determining the appropriateness of certain of these inputs. Changes to the inputs described above could have a significant impact on the Group's financial position and profit or loss in any given period. Refer to note 23 for more information on the contingent consideration key inputs.

4.2.6 Anti-Dilution warrants

The Company has issued anti-dilution warrants that are measured at fair value on each reporting date. The fair value of such derivatives is estimated by applying valuation models in which the Company uses market data to the extent available. The description of the valuation models and unobservable inputs applied, as well as the impact on the fair value of reasonably possible changes in the value of the respective significant unobservable inputs at the end of the reporting period, is provided in note 18.

5. Segment information

Segment information is determined consistent with the internal reporting to the chief operating decision makers (CODM) of the Group, i.e., the person or persons who take decisions about the allocation of resources and evaluate financial performance. Currently the CODM is the key management personnel, please refer to note 25.1. The CODM reviews information at the consolidated level for resource allocation and evaluation of the Group's financial performance and considers one segment whilst reviewing this information.

As the Group currently has no marketable products, no revenue generated from external customers can be presented based on product or service categories, geographical location or the extent of key customers that constitute total revenue.

The below table presents the non-current assets per country:

	For the year ended December 31	
(In thousands of €)	**2025**	**2024**
AgomAb Belgium	5,267	5,364
Agomab Spain	27,202	27,204
Total non-current assets	**32,469**	**32,568**

6. Overview of consolidation scope

6.1. Subsidiaries

The consolidated financial statements of the Company include:

Company name	Registration number	Location	Financial interest (%)	
AgomAb Therapeutics NV	674527310	Antwerp, Belgium	Parent	
Agomab Spain S.L.U.	B32478414	Fonte Díaz-A Coruña, Spain	100	%
Agomab US Inc.	99-332612	Delaware, USA	100	%

7. Income and expenses

7.1. Operating expenses

The research and development expenses and general and administrative expenses consist of the following expenses:

(In thousands of €)	2025	2024	2023
Clinical trial expenses	36,921	30,057	19,131
Employee benefits	7,267	5,557	3,290
Consulting	2,091	2,121	1,786
Share-based payments	1,506	143	1,009
Chemicals and small materials	78	1,001	191
Patent related charges	249	431	891
Regulatory	101	—	14
Facility rent and expenses	64	—	—
Other R&D expenses	600	—	—
Total research and development expenses	**48,877**	**39,310**	**26,311**
Employee benefits	5,171	3,868	2,243
Share-based payments	3,848	928	1,150
Professional service fees	1,861	3,183	1,185
Office materials and services	559	627	549
Travel and meeting expenses	754	561	483
Facility rent and expenses	211	137	178
Board fees	63	63	67
Depreciation and amortization	219	311	99
Recruitment	25	245	20
Other G&A expenses	80	210	122
Total general and administrative expenses	**12,791**	**10,133**	**6,097**
Total operating expenses	**61,668**	**49,443**	**32,408**

Increases in research and development (R&D) expenses are mainly related to clinical trial expenses, which are outsourced activities, specifically for the two lead programs AGMB-129 and AGMB-447. These increases mainly relate to progress being made within the clinical testing phase for both lead programs as at December 31, 2025. Employee benefits increased due to an increase in full-time equivalent (FTE) employees compared to the December 31, 2024 and December 31, 2023. Expenses for chemicals and small materials decreased during the period ended December 31, 2025, reflecting the advancing pipeline activities of our two lead pipeline programs AGMB-129 and AGMB-447. Other R&D expenses comprise specific meeting and travel expenses, as well as membership fees. Professional service fees for the IPO that was completed on February 9, 2026 are mainly incurred in 2026 prior to the IPO.

Increases within General and Administrative (G&A) expenses mainly relate to increased employee benefits, reflecting organizational scaling to support company growth (see note 7.2). Fees for professional services such as legal, audit and advisory decreased during the year ended December 31, 2025 as the period year December 31, 2024 included significant one-off costs related to the IPO process. Professional fees for the IPO that was completed in 2026, are mainly incurred in 2026.

Increases within share-based payments expenses for both R&D and G&A are primarily due to the increase in the value of the underlying common share and the timing and amount of ESOPs issued during the period ended December 31, 2025 and 2024 (see note 19) and due to accelerated vesting of the ESOPs issued under 2024 ESOP plans (refer to note 26).

7.2. Employee benefit expenses

The employee benefit expenses consist of the following:

(In thousands of €)	2025	2024	2023
Employee salaries and wages - R&D	5,681	3,800	2,337
Employee salaries and wages - G&A	3,626	2,739	1,684
Social security contributions	1,915	1,521	782
Employee provisions	339	763	560
Other employee benefits	877	602	170
Total employee benefit expenses[(1)]	**12,438**	**9,425**	**5,533**

(1) Total employee benefit expenses exclude share-based payment expenses which are included in note 7.1.

Employee benefit expenses is in line with the increase in full-time equivalents ("FTEs") with market standard salary increases. The Group had an average of 60.5 FTEs as at December 31, 2025 compared to 57.8 FTEs as at December 31, 2024 and 34 FTEs as at December 31, 2023.

The employee provisions relate to accrued bonuses and unused holiday provision, representing obligations expected to be settled within twelve months after the reporting date.

The Company offers post-employment retirement benefits to its Belgian employees. The plan is a defined contribution plan with an employer contribution equal to 5% of the employee's gross salary. Although the plan qualifies as a defined contribution plan under Belgian law, it is accounted for as a defined benefit plan under IFRS, due to the guaranteed minimum return provided by the insurance company. Please refer to note 21.

The Group also offers an insurance death coverage to its Belgian and Spanish employees. The coverage amounts to one time the annual salary of the employee and is funded through annual premiums to the insurance company.

7.3. Financial expenses and income

The financial expenses and income consist of the following:

(In thousands of €)	2025	2024	2023
Interest expenses	(60)	(67)	(31)
Exchange rate losses	(64)	(280)	(51)
Bank charges	(9)	(10)	(4)
Total financial expenses	**(133)**	**(357)**	**(86)**
Interest income	1,609	1,218	245
Exchange rate gains	7	49	58
Fair value gains current assets	96	—	—
Other financial income	6	—	—
Total financial income	**1,718**	**1,267**	**303**
Net financial (expenses) income	**1,585**	**910**	**217**

7.4. Other operating income

The other operating income consist of:

(In thousands of €)	2025	2024	2023
Grants received	1,072	380	595
R&D tax credit	512	398	331
R&D personnel credit	774	607	291
Other income	35	37	—
Other operating income	**2,393**	**1,422**	**1,218**

The Company received two new VLAIO grants to support R&D activities during the period ended December 31, 2025. No conditions related to the above government grants were unfulfilled, nor were there any related material contingencies at the date of the approval of the consolidated financial statements.

In conjunction with the two new grants, grants received increased by €0.6 million, grants receivables increased by €1.4 million and deferred income increased by €0.7million as of December 31, 2025, compared to December 31, 2024, reflecting the main movement in respectively other current assets and deferred income and accrued charges (refer to note 15 and 20).

R&D tax credit relates to a tax credit on incurred research and development expenses. The R&D tax credit will be paid to the Group in cash after four years, to the extent it is not offset against the taxable basis over the respective period.

R&D personnel credits relates to a government incentive to support innovation via a reduction in withholding income taxes for qualified personnel employed in research and development. The received incentive increased due to more R&D staff being qualified to apply for such government incentive.

8. Current and deferred taxes

The Group incurred tax losses in current and prior years. It is not assessed as probable that future taxable profits will be available against which the tax losses can be utilized. Therefore, the Group has not recognized deferred tax assets in excess of deferred tax liabilities, relating to the same taxation authority and the same taxable entity.

The breakdown of the income tax expenses by origin is as follows:

(in thousands of €)	2025	2024	2023
Current income tax expense	—	(4)	(3)
Deferred tax income	—	—	622
Income tax (expense)/income	**—**	**(4)**	**619**

The decrease in deferred tax income is due to deferred tax assets on the carryforward of tax losses, most of which cannot be recognized in 2025 and 2024 as they exceed the amount of deferred tax liabilities. The domestic tax rate is 25% for both 2025, 2024 and 2023.

The following table details the source of deferred tax assets and liabilities:

	December 31, 2025			December 31, 2024		
(in thousands of €)	Assets	Liabilities	Net	Assets	Liabilities	Net
Intangible assets	—	(4,637)	(4,637)	—	(4,637)	(4,637)
Property, plant and equipment	1	—	1	1	—	1
Right of use assets	—	(271)	(271)	—	(343)	(343)
Lease liabilities	313	—	313	386	—	386
Other current assets & other liabilities	—	(5)	(5)	2	—	2
Deferred tax assets and liabilities related to temporary differences	**314**	**(4,913)**	**(4,599)**	**389**	**(4,981)**	**(4,592)**
Tax loss carried forwards	4,599	—	4,599	4,592	—	4,592
Deferred tax assets related to unused tax losses	**4,599**	**—**	**4,599**	**4,592**	**—**	**4,592**
Set off of tax	(4,913)	4,913	—	(4,981)	4,981	—
Net deferred tax assets/liabilities	—	—	—	—	—	—

The largest position within temporary differences is relating to intangible assets for which a deferred tax liability was recognized as a result of the fair value adjustment in the acquisition of Agomab Spain.

The Company has tax losses amounting to €38.2 millions for which deferred tax assets have not been recognized. These relate to deductible temporary differences, unused tax losses, and unused tax credits, and have no expiry date.

The movements of deferred tax balances during 2025 and 2024 are disclosed within the table below.

(in thousands of €)	December 31, 2025	Recognized in profit or loss	December 31, 2024
Intangible assets	(4,637)	—	(4,637)
Property, plant and equipment	1	—	1
RoU assets	(271)	72	(343)
Lease liabilities	313	(73)	386
Other current assets & other liabilities	(5)	(7)	2
Deferred tax assets and liabilities related to temporary differences	**(4,599)**	**(8)**	**(4,592)**
Tax loss carry-forwards	4,599	8	4,592
Deferred tax assets/liabilities	—	—	—

The following table represents the reconciliation between the theoretical and effective tax rates of 2025 and 2024.

(in thousands of €)	2025	2024	2023
IFRS profit/(loss) before income taxes	(62,547)	(46,264)	(12,009)
Theoretical income tax (expense)/income	(15,639)	11,568	3,002
Theoretical tax rate*	**25 %**	**25 %**	**25 %**
Non-deductible expenses	(2,950)	(569)	(1,409)
Non-taxable income	128	339	5,636
Tax losses of the year for which no deferred tax asset has been recognized	(12,828)	(11,341)	(6,610)
Income tax (expense)/income	**—**	**(4)**	**619**
Effective tax rate	**— %**	**— %**	**(5)%**

**The theoretical tax rate (25%) is based on the blended average tax rate of the domestic tax rate applicable for both the Company in Belgium and its subsidiary in Spain and the theoretical tax rate (26%) is the domestic tax rate applied for the US subsidiary (21% Federal tax rate and 5% State Corporation Tax).*

9. Loss per share

The calculation of the basic and dilutive loss per share on December 31, 2025,December 31, 2024 and December 31, 2023 is based on the holders of common shares attributable (loss) or profit and the weighted average number of common shares outstanding during the year.

On February 9, 2026 upon the closing of the IPO the Company effected a share split, each common share was split into 21.645 shares (rounded). All references to common shares and per common share data have been retrospectively adjusted to reflect this split. On that basis, the weighted average number of common shares for the period December 31, 2025, 2024 and 2023 has been retrospectively increased to 541,126.

(in thousands of €)	2025	2024	2023
Basic loss			
Loss for the year	(62,547)	(46,267)	(11,390)
Loss attributable to the holder of the profit share certificate (1)	3,027	2,239	752
Cumulative dividend on preferred shares (Series A, B, C and D) (2)	(17,981)	(13,923)	(8,644)
Loss attributable to common shareholders	**(77,501)**	**(57,951)**	**(19,282)**
Diluted loss			
Dilution effect of ESOP warrants, preferred shares, anti-dilutive warrants and profit share certificate	—	—	—
Loss attributable to common shareholders, after dilution effect	**(77,501)**	**(57,951)**	**(19,282)**

(1) Reflects the impact of the liquidation interest profit share in relation to the profit share certificate (4.84% in 2025 and 2024 and 6.6% in 2023). Refer to notes 2.2.8.2 and 19.2.

(2) The cumulative dividend (i.e., a fixed cumulative cash preferential dividend at 6% p.a. of the issue price of the preferred shares) is calculated on the issue price of the preferred shares over the period they were outstanding. In the event of an IPO, the preferred shares will automatically convert into common shares, on a 1:1 basis (before stock split), without any pay-out in the form of cash or common shares relating to the cumulative dividend.

Number of shares	2025	2024	2023
Weighted average number of **common shares** outstanding during the period for basic and diluted EPS	541,126	541,126	541,126
Total weighted average number of common shares outstanding during the period	**541,126**	**541,126**	**541,126**

(in €)	2025	2024	2023
Basic loss per share	(143.22)	(107.09)	(35.63)
Diluted loss per share	(143.22)	(107.09)	(35.63)

Although the Company has common shares that could be issued upon the potential exercise of ESOP warrants, the conversion of preferred shares, conversion of anti-dilutive warrants and the profit share certificate, they have non-dilutive effect, since the Group is in loss-making position during 2025, 2024 and 2023.

Refer to note 26 for more detailed information on the effect of the IPO on the financial statements of the Group.

10. Goodwill

The below table presents the carrying value for the goodwill.

(In thousands of €)	Goodwill	Total
As at January 1, 2025	8,612	8,612
Impairment loss	—	—
Carrying amount as at December 31, 2025	**8,612**	**8,612**
As at January 1, 2024	8,612	8,612
Impairment loss	—	—
Carrying amount as at December 31, 2024	**8,612**	**8,612**

On December 14, 2021, the Company acquired 100% of Agomab Spain, a Spanish biotech company with a pipeline of organ-restricted small molecule drug candidates targeting the transforming growth factor beta (TGF-β) pathway. Through this acquisition, the Company has broadened its clinical-stage pipeline, taking a step closer to bringing meaningful treatments to patients with fibrotic diseases. The synergies between Agomab Spain's unique small molecule platform and the Company's pre-existing antibody capabilities, combined with collective expertise in targeting growth factors, is expected to allow the Group to accelerate the development of novel therapeutic candidates.

The consideration transferred to acquire Agomab Spain amounted to €24.3 million and includes a contingent consideration with a fair value at acquisition date of €3.95 million (see note 22). These assets acquired and liabilities assumed have been measured on a fair value basis at acquisition date, resulting in net assets acquired amounting to €15.7 million, including in-process R&D for €18.55 million (see note 11). The positive difference between the total consideration transferred to acquire 100% of Agomab Spain (€24.3 million) and the fair value of the net assets acquired (€15.7 million) was recognized as goodwill, which is tested for impairment at least annually together with the acquired in-process R&D (see note 11).

The goodwill has been allocated in full to the "Agomab Spain" CGU as this is the level at which the synergies from the combination are expected to materialize. The recoverable amount of the Agomab Spain CGU is based on its value in use, i.e. net present value of the expected future cash flows. No impairment was recorded as the recoverable amount is not lower than the carrying amount of the cash-generating unit.

The cash flow projections are based on the management business plan for each of the R&D projects in Agomab Spain (i.e., AGMB-129 and AGMB-447) that extend over a period of 22 years. The key assumptions made by management within the business plan relate to the:

- Probability of reaching commercialization stage as well as the associated timing, based on external scientific methodologies, reputable scientific literature and internal estimates. In that respect, expected revenues are based on management's best estimation of the timing of obtaining the necessary approvals from the European Union and United States authorities.

- Duration of the patent after reaching commercialization stage, which is estimated by management at 15 years.

- Amount of R&D costs expected to be incurred to reach the commercialization stage and the revenues expected to be generated during the commercialization phase; and

- Discount rates to be applied to the future expected cash flows, which are derived from the Company's weighted average cost of capital, taking into account the cost of equity and debt. The pre-tax discount rate is 21.6%.

Based on the key assumptions above, the recoverable amount of the Agomab Spain CGU significantly exceeds its carrying amount (including allocated goodwill and in-process R&D) and a 'reasonably possible change' in a key assumption would not cause an impairment loss.

11. Intangible assets

The below table presents the movements in the carrying amount of intangible assets.

(In thousands of €)	In-process R&D	Research and commercialization license	Total
Acquisition cost			
As at January 1, 2025	18,550	1,560	20,110
Additions	—	—	—
Disposals	—	—	—
As at December 31, 2025	18,550	1,560	20,110
Accumulated Amortization and impairment losses			
As at January 1, 2025	—	—	—
Amortization	—	—	—
Impairment losses	—	—	—
Disposals	—	—	—
As at December 31, 2025	—	—	—
Carrying amount as at December 31, 2025	**18,550**	**1,560**	**20,110**
Acquisition cost			
As at January 1, 2024	18,550	1,560	20,110
Additions	—	—	—
Disposals	—	—	—
As at December 31, 2024	18,550	1,560	20,110
Accumulated Amortization and impairment losses			
As at January 1, 2024	—	—	—
Amortization	—	—	—
Impairment losses	—	—	—
Disposals	—	—	—
As at December 31, 2024	—	—	—
Carrying amount as at December 31, 2024	**18,550**	**1,560**	**20,110**

In-process R&D is the intangible that has been acquired as part of the business combination with Agomab Spain during 2021 (see note 10). In-process R&D is an intangible not available for use and will therefore not be amortized until one or more corresponding underlying R&D projects have obtained regulatory approval to launch the product on the market. Instead, the Company performs an impairment test at each reporting date. As the related projects are not expected to generate cash inflows independently from the Agomab Spain GCU, the in-process R&D has been fully allocated to the Agomab Spain CGU. The impairment test on the Agomab Spain CGU has been performed based on the principles and key assumptions described in note 10.

The research and commercialization license relates to a third-party research and commercialization license for acquired patent rights and know-how. The license is an intangible asset not yet available for use and will not be amortized until one or more products that use the license have obtained regulatory approval. The Company reviews this intangible asset annually for impairment or when an event occurs during the reporting period that could result in an impairment. During 2025, the Company has decided to pause the start of any further development on one of its preclinical stage assets, relating to the research and commercialization license. This strategic decision has been made because the Company will focus its efforts on other therapeutic areas. No impairment was recorded as the recoverable amount is higher than the carrying amount of the research and commercialization license.

No impairment was recognized on intangible assets.

12. Leases

The following note provides an overview of the right-of-use (RoU) assets and the lease liabilities where the Group is a lessee.

The table below presents the movements in the carrying amount of the RoU assets.

(In thousands of €)	Office leases	Car leases	Total
Acquisition cost			
As at January 1, 2025	1,318	424	1,742
Additions	*34*	—	*34*
Disposals	*(2)*	*(45)*	*(47)*
As at December 31, 2025	1,350	379	1,730
Accumulated depreciation and impairment			
As at January 1, 2025	(236)	(134)	(370)
Depreciation	(162)	(97)	(259)
Disposals	(5)	(12)	(17)
As at December 31, 2025	(403)	(243)	(647)
Carrying amount as at December 31, 2025	**947**	**136**	**1,083**
Acquisition cost			
As at January 1, 2024	1,407	321	1,728
Additions	11	120	131
Disposals	(21)	(17)	(38)
Lease remeasurement	(78)	—	(78)
As at December 31, 2024	1,319	424	1,743
Accumulated depreciation and impairment			
As at January 1, 2024	(71)	(51)	(122)
Depreciation	(168)	(87)	(255)
Disposals	3	4	7
As at December 31, 2024	(236)	(134)	(370)
Carrying amount as at December 31, 2024	**1,083**	**290**	**1,373**

During 2025, AgomAb entered into two short-term office lease agreements that meet the exemption criteria for recognition as RoU assets. The lease payments for both short-term leases have been recorded in the consolidated statement of profit or loss.

This Other than office leases, the Group has several car leases for their Belgian employees. As at December 31, 2025, there are 11 car leases recognized on the balance sheet. As at December 31, 2024, there were 14 car leases with a lease term of four years, which was therefore recognized as a RoU asset.

The below table presents the movements in the lease liabilities.

(In thousands of €)	Office leases	Car leases	Total
As at January 1, 2025	**1,259**	**286**	**1,545**
Additions	34		34
Lease payments	(220)	(118)	(338)
Derecognition of lease liability due to termination	(2)	(45)	(47)
Interest expenses	52	8	60
As at December 31, 2025	**1,123**	**131**	**1,254**
As at January 1, 2024	**1,350**	**270**	**1,619**
Additions	11	120	131
Lease payments	(62)	(101)	(163)
Derecognition of lease liability due to termination	(18)	(13)	(31)
Interest expenses	57	10	67
Lease remeasurement	(78)	—	(78)
As at December 31, 2024	**1,259**	**286**	**1,545**

The weighted average incremental borrowing rate used for the car leases is 3.5% and for the office leases 4.6%. The underlying leased assets are the pledges for the lease liabilities.

The lease liabilities can be split within current and non-current liabilities as follows.

	For the year ended December 31	
(In thousands of €)	2025	2024
Current	249	273
Non-current	1,005	1,272
Total Lease liabilities	**1,254**	**1,545**

The following table provides an overview of the expenditure for the short-term leases.

(In thousands of €)	2025	2024
Expenses short term office leases	15	62
Expenses short term car leases	—	45
Total short term lease expenses	**15**	**107**

13. Property, plant and equipment

The below table presents the movements in the carrying amount of property, plant and equipment

(In thousands of €)	Leasehold improvements	IT equipment	Furniture and fixtures	Other equipment	Total
Acquisition cost					
As at January 1, 2025	**359**	**127**	**179**	**10**	**675**
Additions	—	—	4	—	4
Disposals	—	—	—	—	—
As of December 31, 2025	359	127	183	10	679
Accumulated depreciation and impairment losses					
As at January 1, 2025	**(13)**	**(26)**	**(16)**	**(1)**	**(56)**
Depreciation	(40)	(42)	(36)	(2)	(120)
Impairment losses	—	—	—	—	—
Disposals	—	—	—	—	—
As of December 31, 2025	(53)	(68)	(52)	(3)	(176)
Carrying amount as of December 31, 2025	**306**	**59**	**131**	**7**	**503**
Acquisition cost					
As at January 1, 2024	—	—	—	—	—
Additions	359	127	179	10	675
Disposals	—	—	—	—	—
As of December 31, 2024	359	127	179	10	675
Accumulated depreciation and impairment losses					
As at January 1, 2024	—	—	—	—	—
Depreciation	(13)	(26)	(16)	(1)	(56)
Impairment losses	—	—	—	—	—
Disposals	—	—	—	—	—
As of December 31, 2024	(13)	(26)	(16)	(1)	(56)
Carrying amount as of December 31, 2024	**345**	**101**	**163**	**10**	**619**

14. Other non-current assets

The following table provides a split of other non-current assets:

	For the year ended December 31	
(In thousands of €)	2025	2024
R&D tax credit receivables	2,150	1,787
Total non-current assets	**2,150**	**1,787**

R&D tax credit receivables are future expected refunds or tax deductions resulting from tax incentives on research and development expenses incurred in Belgium. The increase in these tax credits is linked to the increase in R&D activities (note 7.1) in 2025 compared to previous reporting periods. The Group has met the conditions to recognize the benefits as other operating income (note 7.4).

15. Other current assets

The other current assets consist out of the following balances.

(In thousands of €)	For the year ended December 31 2025	2024
Grant receivables	1,672	446
Supplier credit notes received	15	55
VAT receivables	200	381
Other receivables	2,122	1,126
Total trade and other receivables	**4,009**	**2,008**
Deferred charges	638	267
Accrued Income	76	111
Total deferred charges and accrued income	**714**	**378**
Total other current assets	**4,723**	**2,386**

The grant receivables relate to the VLAIO grants received. For further information refer to note 7.4 above. The increase in other receivables is mainly related to the unused R&D tax credit of tax year 2023 that will be paid-out in cash by the Belgian tax authorities.

As at December 31, 2025, deferred charges are mainly related to incremental costs directly attributable to completion of the issuance of new shares on the stock market, which have incurred prior to the initial public offering on February 9, 2026. These expenses amount to € 0.4 million and are initially recognized as deferred charges on the balance sheet and were reclassified to equity upon the close of the IPO (refer to note 26– and section 2.2.13)

16. Current financial investments and cash and cash equivalents

Current financial investments and cash and cash equivalents are as follows.

(In thousands of €)	For the year ended December 31 2025	2024
Money market fund	30,096	—
Total current financial investments	**30,096**	—
Cash at bank and in hand	86,418	26,459
Term deposit	—	145,000
Total cash and cash equivalents	**86,418**	**171,459**
Total current financial investments and cash and cash equivalents	**116,514**	**171,459**

Current financial investments consists of a money market fund that is readily convertible to cash and is subject to a insignificant risk of change in value. We refer to section 2.2.5 and note 23 for more detailed information on the money market fund.

Cash and cash equivalents consist of unrestricted cash held at banks and term accounts held at reputable European banks with credit rating ‘A’ with an original maturity not exceeding 3 months. The carrying amount of the cash and cash equivalents is a reasonable approximation of their fair value.

17. Equity

17.1. Capital management

The Company manages its capital to ensure that it will be able to continue as a going concern. The capital structure of the Company consists of equity attributed to the holders of equity instruments of the Company, such as capital, reserves and accumulated losses as mentioned in the consolidated statement of changes in equity. The Company considers its financing needs in light of changes in economic circumstances, risks associated with its different assets, and the projected cash needs of the current and projected research activities. On December 31, 2025, cash and cash equivalents amounted to €86.5 million. The Company's objective is to maintain its capital structure at a level to enable it to finance its activities for at least 12 months.

17.2. Share capital and share premium

The Company has the following categories of shares: common shares, preferred A shares, preferred B shares, preferred C shares, preferred D shares and, upon exercise of ESOP warrants, ESOP common shares. Upon a liquidity event and after complete fulfillment of the liquidation interest profit share in relation to the profit share certificate (i.e., 4.84% of all amounts that would be distributable to the shareholders of the Company), the remaining amount will be further distributed to the remaining shareholders: firstly (and in priority to any other classes of shares), to the holders of preferred D shares equal to their investment and preferential return (i.e., a fixed cumulative cash preferential dividend at 6% p.a. of the issue price of the preferred shares ("Preferred Dividend")), secondly (and in priority to any other classes of shares), to the holders of preferred C shares equal to their investment and preferential return, thirdly (and in priority to any other classes of shares), to the holders of preferred B shares equal to their investment and preferential return, fourthly (and in priority to any other classes of shares), to the holder of preferred A shares equal to their investment and preferential return and lastly, (and in priority to any other classes of shares, other than the preferred A, B, C and D shareholders), the holders of the common shares will receive a fixed amount of €40 per share. Any remaining amount, will be distributed to all shareholders on a fully diluted basis. A liquidity event is defined as:

a. A payment of dividends, capital reduction, or share buy-back;

b. A bankruptcy, liquidation, dissolution or reorganization of the Company;

c. A sale of all, or substantially all, of the assets (including intellectual property rights) of the Company;

d. Any merger, consolidation, schemes of arrangement or acquisition, involving the Company or its subsidiaries, in which the Company or its subsidiaries are not the surviving entity;

e. The sale of all or such number of the shares of the Company that results in any person acquiring a controlling interest in the Company; or

f. Any other event with substantially the same economic effect as the events set out in (a) to (e) above.

All share and per share data have been revised to give effect to the share split as explained in note 2.1, note 9 and note 26.

The below table provides the overview of the Company's share structure:

	Number of common	Number of preferred A	Number of preferred B	Number of preferred C	Number of preferred D	Total common shares		Total preferred A shares		Total preferred B shares		Total preferred C shares		Total preferred D shares		Total share capital and share premium	
(In thousands of €, except as indicated otherwise)	shares	shares	shares	shares	shares	Share capital	Share premium	Share capital	Share premium	Share capital	Share premium	Share capital	Share premium	Share capital	Share premium	Share capital	Share premium
Outstanding at December 31, 2023	**541,126**	**277,272**	**479,040**	**455,004**	**—**	**25**	**—**	**22,873**	**—**	**87,514**	**12,368**	**64,300**	**30,571**	**—**	**—**	**174,712**	**42,939**
November 4, 2024 – Series D	—	—	—	—	**342,206**	—	—	—	—	—	—	—	—	**48,360**	**33,695**	**48,360**	**33,695**
Outstanding at December 31, 2024	**541,126**	**277,272**	**479,040**	**455,004**	**342,206**	**25**	**—**	**22,873**	**—**	**87,514**	**12,368**	**64,300**	**30,571**	**48,360**	**33,695**	**223,072**	**76,634**
Outstanding at December 31, 2025	**541,126**	**277,272**	**479,040**	**455,004**	**342,206**	**25**	**—**	**22,873**	**—**	**87,514**	**12,368**	**64,300**	**30,571**	**48,360**	**33,695**	**223,072**	**76,634**

The split between share capital and share premium has been recorded in accordance with the local Belgian corporate law based on the difference between the issue price of the preference shares and their par value. On initial recognition, the anti-dilutive warrants are recognized as a financial liability and recorded against accumulated loss.

The above results into following weighted average issue prices for the different classes of shares, and with the respect to the preferred A, B, C and D shares, the concurrently issued anti-dilutive warrants.

	Weighted average issue price per common share in € per share[1]	Weighted average issue price per pref. A share in € per share[1]	Weighted average issue price per pref. B and C shares in € per share[1]	Weighted average issue price per pref. D share in € per share[1]
Outstanding at December 31, 2023	**0.05**	**82.49**	**208.50**	**—**
November 4, 2024—Series D	—	—	—	239.78
Outstanding at December 31, 2024	**0.05**	**82.49**	**208.50**	**239.78**
Outstanding at December 31, 2025	**0.05**	**82.49**	**208.50**	**239.78**

(1) Including concurrently issued anti-dilutive warrants.

The common shares outstanding at January 1, 2022 consist of the 541,126 common shares issued at an issue price of €0.05.

The preferred A shares outstanding at January 1, 2022 consist of 277,272 preferred A shares, of which 15,450 preferred A shares were issued at an issue price of €40 and 261,822 preferred A shares were issued at an issue price of €85. The stated issue prices also include the consideration received for the concurrently issued anti-dilution warrants.

The preferred B shares outstanding at January 1, 2022 consist of 294,954 preferred B shares issued at an issue price of €208.5. The stated issue prices also include the consideration received for the concurrently issued anti-dilution warrants.

On June 28, 2022, the Company raised €38.4 million of share capital by issuing 184,086 preferred B shares at an issue price of €208.5 to existing and three new investors. On October 10, 2023, the Company raised an additional €94.9 million of share capital by issuing 455,004 preferred C shares at an issue price of €208.5 to existing and four new investors. On November 4, 2024, the Company raised an additional €82.1 million of share capital by issuing 342,206 preferred D shares at a share price of €239.78 to existing and new investors. The stated issue prices also include the consideration received for the concurrently issued anti-dilution warrants.

The share capital has been fully paid for all classes of shares.

No ESOP common shares have been issued yet.

With regard to the preferred shares A, B, C, D and the profit share certificate, the Company has assessed that it has no contractual obligation to deliver cash or another financial asset under conditions that are not under the discretionary control of the Company, or to exchange or deliver a variable number of equity instruments of the Company.

Refer to note 26 for more detailed information on the effect of the IPO on the financial statements of the Group.

17.3. Other reserve

Other reserves relate to transaction costs incurred for the capital increases which are deducted directly from equity.

18. Anti-dilution warrants

The Company issued 60 anti-dilution warrants (ADW) to the preferred A shares investors that expire initially after a period of 5 years (i.e., 45 at March 14, 2024, 5 at June 21, 2024 and 10 at October 9, 2024) and were re- issued in 2024 with a new term of 10 years. In the event of a dilutive issuance of new shares at a price lower than the subscription price of the preferred A shares (i.e., €85), holders of the anti-dilution warrants are entitled to subscribe to additional preferred A shares. The number of additional shares they can subscribe to is calculated such that the weighted average price for the total number of shares held by a preferred A shareholder, after exercising the warrants, would be equal to the share price applied in the dilutive issuance. The exercise price for the anti-dilution warrants is €1. The anti-dilution warrants were issued at the same time as the preferred shares.

The Company issued 250 anti-dilution warrants to the preferred B shares investors that expire after a period of 10 years (i.e., 200 at March 5, 2031 and 50 at June 28, 2032). In the event of a dilutive issuance of new shares at a price lower than the subscription price of the preferred B shares (i.e., €208.5), holders of the anti-dilution warrants are entitled to exercise their warrants. Upon exercising one anti-dilution warrant, the holder can subscribe to an additional number of preferred B shares. The number of additional shares is calculated such that the weighted average price for the total number of shares held by a preferred B shareholder, after exercising the warrants, would be equal to the share price applied in the dilutive issuance. The exercise price for the anti-dilution warrants is €1. The anti-dilution warrants were issued at the same time as the preferred shares.

The company issued 210 anti-dilution warrants to the preferred C shares investors that expire after a period of 10 years (i.e., October 10, 2033). In the event of a dilutive issuance of new shares at a price lower than the subscription price of the preferred C shares (i.e., €208.5), holders of the anti-dilution warrants are entitled to exercise their warrants. Upon exercising one anti-dilution warrant, the holder can subscribe to an additional number of preferred C shares. The number of additional shares is calculated such that the weighted average price for the total number of shares held by a preferred C shareholder, after exercising the warrants, would be equal to the share price applied in the dilutive issuance. The exercise price for the anti-dilution warrants is €1. The anti-dilution warrants were issued at the same time as the preferred shares.

The company issued 240 anti-dilution warrants to the preferred D shares investors that expire after a period of 10 years (i.e., November 4, 2034). In the event of a dilutive issuance of new shares at a price lower than the subscription price of the preferred C shares (i.e., €239.78), holders of the anti-dilution warrants are entitled to exercise their warrants. Upon exercising one anti-dilution warrant, the holder can subscribe to an additional number of preferred D shares. The number of additional shares is calculated such that the weighted average price for the total number of shares held by a preferred D shareholder, after exercising the warrants, would be equal to the share price applied in the dilutive issuance. The exercise price for the anti-dilution warrants is €1. The anti- dilution warrants were issued at the same time as the preferred shares.

The anti-dilution warrants protection expires on the earlier of:

- The expiration of the term of the shareholders agreement (amended from time to time), or termination of the shareholders agreement; or

- The completion of an initial public offering (IPO) or liquidity event.

Each warrant can only be exercised once. However, for each series every beneficiary received multiple warrants protecting them against multiple dilutive issuances.

The fair value measurement of the anti-dilution warrants is classified as Level 3, as the valuation requires estimates of the timing of future capital rounds as well as estimates of future capital needs and the probability of non-occurrence of a qualified IPO.

A Monte-Carlo simulation was used to calculate the valuation of the ADW for each occurrence of an expected funding round. The total fair value is the sum of the separate Monte-Carlo simulations multiplied by the probability of occurrence. As at December 31, 2025 and as at December 31, 2024, the fair value of the anti-dilution warrants amounts to zero reflecting the assumption that the exit probability without intermediate funding round was 100%.

The Monte-Carlo simulation is multiplied by the probability of occurrence of a next expected funding round, considering that there is a chance of an exit (i.e., IPO or liquidity event) without an intermediate funding round. In case of such an exit, the ADW would expire and would have no remaining value.

Exit probabilities without intermediate funding round	12/31/2025	12/31/2024
Series A, Series B, Series C and Series D	100 %	100 %

The anti-dilution warrants expired following the completion of the IPO on February 9, 2026, (refer to note 26), no sensitivity analysis has been performed for 2025.

The below sensitivity analysis presents the significant unobservable inputs used and the impact of reasonable changes in the value of the respective significant unobservable inputs at the end of the reporting period of December, 2024, while holding all other assumptions constant. The volatility used as an input in the valuation model was determined based on a peer group defined by management, which is composed of five companies active in the same industry and being at a similar stage of development to the Company. The median of the historical volatilities over 18 months for each valuation date was used as the volatility parameter in the Monte-Carlo simulation.

(in thousands of €)

Sensitivity analysis		12/31/2024
Series A	**Base value**	**—**
	Exit probability -5%	**30**
Series B	**Base value**	**—**
	Exit probability -5%	**456**
Series C	**Base value**	**—**
	Exit probability -5%	**446**
Series D	**Base value**	**—**
	Exit probability -5%	**521**

19. Share-based payments

The Group has two share-based payment plans: employee stock option plan (ESOP) and profit share certificate.

19.1. ESOP warrant plan

The Group has implemented an ESOP warrant plan for its employees, key managers, directors and/or outside consultants and advisors of the Company ("Beneficiaries") with grants made each year, since 2019. In accordance with the terms of the plan, as approved by the shareholders. Beneficiaries are granted free of charge the right to exercise their warrants under certain conditions.

The ESOP warrants carry neither rights to dividends nor voting rights.

The ESOP warrants are classified as equity-settled and have a maximum term of 10 years as from the issue date of the ESOP warrants.

The ESOP warrants vest based on the following schedule:

- 25% will vest 12 months after the date of the offer;
- the remaining 75% of the warrants will vest monthly over a period of 36 months (i.e., 2.083% vested per month).

However, the terms and conditions of the ESOP warrants include conditions under which the ability to exercise the warrants may be accelerated (i.e., in case of a liquidity event or IPO (note 17.2)).

On that basis, management made the following assessment about the most-likely outcome of a liquidity event at the different reporting dates:

- As at December 31, 2023, an IPO was expected to occur in October 2024. Based on this expectation, accelerated vesting of the ESOP warrants was recognized, resulting in a corresponding expense being recorded in the consolidated statement of profit or loss. However, the planned IPO was subsequently not completed in 2024. As a result, the previously recognized acceleration has been reversed in 2024 and the revised expectation was that an IPO was considered probable as from October 2025. The vesting has been adjusted accordingly as at December 31, 2024.

- As at December 31, 2025, the revised expectation is that an IPO was expected in February 2026, to which vesting has been adjusted accordingly. This change has led to an increase in the share-based payment expenses being part of line item "Operating expenses" in the consolidated statement of profit or loss for the year ended December 31, 2025. The remaining expense related to the ESOP warrants will be recognized over the updated vesting period.

The changes of the year for the ESOP warrant plan are as follows (presented on a post-stock split basis, see note 2.1):

	2025		2024		2023	
	Number of warrants	Weighted average exercise price (EUR)	Number of warrants	Weighted average exercise price (EUR)	Number of warrants	Weighted average exercise price (EUR)
Outstanding at January 1st	4,771,450	1.10	2,594,177	0.67	2,519,978	0.67
Granted	1,468,810	1.00	2,488,637	1.43	102,900	0.80
Forfeited	34,242	2.11	311,364	0.10	28,701	2.43
Outstanding at December 31st	6,206,018	1.07	4,771,450	1.10	2,594,177	0.66
Exercisable at December 31st	1,761,472	0.98	399,351	0.98	300,952	0.97

No warrants have been exercised.

The fair value of the warrants is estimated at the grant date using the Black-Scholes option pricing model, considering the terms and conditions upon which the warrants were granted.

The following table provides the input to the Black-Scholes model for the different warrant plans:

ESOP warrants granted in	December 2025	January 2025	November 2024	October 2024
Number of ESOP warrants granted	231,797	1,237,013	308.810	51,472
Fair value (€)	4.58/3.68	4.05 / 4.03 / 4.01	0.30	0.30
Share price (€)	4.58	4.50	0.43	0.43
Exercise price (€)	0 / 4.58	0 /2.77 / 2.98	2.77	2.41
Expected volatility (%)	81.66	91.22	92.07	93.22
Expected life time of a warrant (years)	8.89	9.83	10.00	9.72
Risk-free rate (%)	2.69	2.32	2.24	0.02
Expected dividends (%)	—	—	—	—

ESOP warrants granted in	September 2024	March 2024	February 2024	July 2023
Number of ESOP warrants granted	861,234	938,332	183,507	31,854
Fair value (€)	0.30 - 0.42	1.00 - 1.28	1.02	3.31 - 3.69
Share price (€)	0.43	1.28	1.28	3.69
Exercise price (€)	0 - 2.45	0 - 2.70	2.41	0 - 2.41
Expected volatility (%)	91.80 - 91.86	87.29 - 87.51	87.77	92.04
Expected life time of a warrant (years)	9.83 - 9.85	9.56 - 9.59	9.66	9.87
Risk-free rate (%)	0.02	2.45 - 2.59	2.58	2.40
Expected dividends (%)	—	—	—	—

ESOP warrants granted in	March 2023	January 2023
Number of ESOP warrants granted	35,325	28,138
Fair value (€)	3.34 -3.69	3.69
Share price (€)	3.69	3.69
Exercise price (€)	0 - 2.41	0
Expected volatility (%)	94.88	95.54
Expected life time of a warrant (years)	9.86	9.83
Risk-free rate (%)	2.66	2.37
Expected dividends (%)	—	—

The above inputs for the Black-Scholes model have been determined based on the following parameters and assumptions:

- The price of a ESOP common share has been estimated on the basis of an option pricing model ("OPM") approach calibrated on the latest capital round(s) taking into account the probability of different exit scenarios of IPO and M&A;
- The expected volatility, determined on the basis of volatility of the share price, is not available as the Company is not a listed company. Therefore, the volatility has been determined using a peer group of listed companies for which historical volatility data of the share price was available. The peer group is composed of five companies active in the same industry and being at a similar stage of development compared to the Company;
- The expected life term of an ESOP warrant represents the period between the grant date (valuation date) and the anticipated exercise date
- The risk-free interest rate is based on the Overnight Index Swap (OIS) rate on each valuation date over the lifetime of the warrant; and
- The dividend return is estimated to be zero as no dividend has been paid since inception and the Company has no intention to pay dividends over the life-time of the ESOP warrants.

The expense arising from share-based payment transactions for the warrant plans mentioned above was €5.4 million for 2025 (2024: €1.1 million and 2023: €2.1 million).

The following ESOP warrants were in plthrough ace during the current and prior period (presented on a post-stock split basis, see note 2.1):

Expiry date	Exercise price per warrants (in €	December 31, 2025	December 31, 2024	December 31, 2023
2029	0.98	364,134	364,134	367,100
2030	0.98	349,848	349,848	359,848
2031	2.41	285,043	288,853	288,853
2031	—	956,039	956,039	1,058,593
2032	2.41	115,952	120,065	127,338
2032	2.57	9,156	9,156	9,156
2032	—	339,740	339,740	383,290
2033	2.70	94,437	94,437	—
2033	—	842,922	842,922	—
2033	2.41	173,139	184,740	—
2034	2.45	811,948	811,948	—
2034	2.41	330,195	340,476	—
2034	—	1,006,688	49,286	—
2034	2.77	364,372	19,805	—
2034	2.98	140,758	—	—
2034	4.58	21,645	—	—
Total	—	**6,206,018**	**4,771,449**	**2,594,177**

19.2. Profit share certificate

On March 14, 2019, the Company issued a PSC to a third-party company in return for a research and commercialization license on certain patent rights and know-how (the "IP rights").

In exchange for the IP rights acquired under the license, the Company has issued a PSC that meets the definition of an equity instrument under IFRS. As a result, the transaction qualifies as an equity-settled share-based payment in accordance with IFRS 2.

The PSC immediately vested at the effective date of the research and commercialization license agreement (i.e., March 14, 2019 or 'grant date') as there was no service or other vesting condition to be met. Hence, the fair value was measured at grant date and recognized as an intangible asset (see note 12) with a corresponding increase in equity (share-based payment reserve). No subsequent adjustments are made to equity in accordance with IFRS 2.23 after vesting date.

The Company measures the fair value by reference to the equity instrument issued. In accordance with the terms of the license agreement, the fair value of the PSC at grant date is calculated as 20% of the total equity fair value. The total equity fair value is obtained by multiplying the outstanding number of each class of shares by the corresponding latest share price at the same date (i.e., preferred share price of €85 and common share price of €1.71 as of March 14, 2019) and by subsequently dividing by 80% to gross up the amount to the total equity value (to appropriately take the profit share certificate into account). Refer to note 2.2.8.2 and note 17.2 for more details on the terms and conditions of the profit share certificate.

Refer to note 26 for the for the consequences of the events after the reporting period on the profit share certificate.

20. Other current liabilities

The following table provides an overview of the other current liabilities.

	For the year ended December 31	
(In thousands of €)	**2025**	**2024**
Trade payables	7,628	5,952
Payroll-related liabilities	2,370	1,923
Social tax payables	266	177
Other current liabilities	2	—
Total trade and other payables	**10,266**	**8,052**
Deferred income	1,461	801
Accrued charges	87	—
Total deferred income and accrued charges	**1,548**	**801**
Total other current liabilities	**11,814**	**8,853**

The increase in trade payables is primarily due to the nature and timing of contracted activities certain clinical and non-clinical milestones (AGMB-129 and AGMB-447) were achieved and invoiced close to year-end, together with invoices of professional service providers for offering costs that were incurred for the initial public offering on February 6, 2026 (see note 26).

The advancement of several projects during the period has resulted in an increased need for recruitment, leading to a corresponding rise in payroll-related liabilities as at the reporting date. Deferred income relates to outstanding receivables for VLAIO grants provided by the Flemish government (see section 2.2.10.1 above). The grant matches the period of recognition of the related R&D expenses. Refer to note 16 for the related deferral of these expenses.

21. Pensions and other post-employment benefit plans

The Company offers post-employment retirement benefits to its employees. The plan is a defined contribution plan with an employer contribution equal to 5% of the employee's gross salary. The plan is individually funded through an insurance company that offers a guaranteed minimum return.

Belgian legislation requires a company sponsoring a defined contribution plan to guarantee a minimum level of return. If the return obtained on the individual accounts, in our case via the insurance company, is lower than the minimum return defined by the legislation, the employer would be required to make additional contributions to cover the shortfall.

The employee will receive its accrued individual account at retirement, including the potential additional contribution paid by the employer. Typically, these benefits are paid as a lump sum at retirement for tax reasons.

Due to this obligation, a Belgian defined contribution plan is treated as a Defined Benefit plan under IFRS Accounting Standards. An IAS 19 valuation has been performed as at December 31, 2025 and has been concluded that no net liability exists for the Company, the gross liability being equal to the assets of €0.5 million as at December 31, 2025.

The principal assumptions used in determining post-employment benefit obligations for the Group's plans are shown below:

Assumptions	2025	2024
Discount rate	4.25 %	3.40 %
Salary increase (incl. inflation)	4.00 %	4.00 %
Legal minimum rate of return	2.50 %	2.50 %
Turnover rate	5% until age 55; 0% thereafter	5% until age 55; 0% thereafter
Mortality table (pre-retirement)	MR-5 / FR-5	MR-5 / FR-5

The following table provides the present value of the defined benefit obligation (DBO) and the fair value of the plan assets.

(In thousands of €)	2025	2024
Present value of defined benefit obligation (DBO)	464	255
Fair value of plan assets (FVPA)	(464)	(255)
Net defined benefit liability/(asset)	—	—

The DBO is floored at the value of plan assets due to the legal minimum return guarantee. Therefore, changes in assumptions such as discount rate, inflation, or turnover do not impact the recognized DBO for 2024 and 2025.

The following table presents the reconciliation of the net liability for financial year 2025 and 2024.

(In thousands of €)	2025	2024
Net defined benefit liability at January 1	—	—
Current service cost	249	104
Net interest cost	(4)	(2)
Employer contributions	(254)	(175)
Remeasurements (OCI)	6	73
Net defined benefit liability at December 31	—	—

The below tables present the net benefit expense recognized in profit and loss and in other comprehensive income

(In thousands of €)	2025	2024
Current service cost	249	104
Net interest (expense)/income	(4)	(2)
Total pension costs	**245**	**103**

Total pension costs recognized in the statement of profit or loss and are included within 'Employee benefits expense', under other employee benefits.

(In thousands of €)	2025	2024
Actuarial loss–experience adjustment	6	73
Total recognized in OCI	**6**	**73**

22. Contingent considerations—earn out

Contingent consideration in business combinations, which are classified as financial liabilities, represent additional payments that are contingent upon the occurrence of future events, such as the achievement of specified development milestones.

The contingent consideration as a result of the acquisition of Agomab Spain consists of maximum future contingent milestone payment to Agomab Spain's former equity holders of €20 million if all the targets are achieved. The contingent consideration is payable upon the occurrence of the following earn-out events:

- €10 million shall be paid upon the first dosing of the first subject in the first qualifying Phase 2 Clinical Trial with the first Agomab Spain product on or before December 31, 2030;
- €5 million shall be paid upon the first dosing of the first subject in the first qualifying Phase 3 Clinical Trial with the first Agomab Spain product on or before December 31, 2035;
- €5 million shall be paid upon obtaining Regulatory Approval for the first Agomab Spain product in the United States on or before December 31, 2040.

The fair value of the contingent consideration was estimated at €3.95 million at acquisition date (i.e., December 14, 2021). This estimation was based on the cash outflow associated with each of the potential scenarios, the likelihood of achieving each of the potential scenarios and the timing of any cash payments following the achievement of these scenarios assessed at the time of the acquisition. Management's estimate regarding the achievement of the different scenarios and corresponding phases in the clinical processes are based on a combination of internal data, historical experience based on scientific studies, and industry knowledge.

At each reporting date, the fair value of the contingent consideration is re-measured based on the present value of expected future cash flows, adjusted for risk, and discounted using the WACC. The WACC is considered an appropriate discount rate as it takes into account only the cost of equity.

	For the year ended December 31	
(In thousands of €)	**2025**	**2024**
Probability weighted average of different scenarios	13,170	8,800
WACC (%)	16.50	16.60
Contingent consideration	**(9,736)**	**7,879**
of which current	(6,526)	—
of which non-current	(3,210)	—

During 2025, the Company signed an amendment to the existing Share Purchase Agreement relating to the acquisition of Agomab Spain S.L.U, resulting in new information regarding the contingent earn-out consideration. Based on these new contractual terms that were agreed, the first initial earn-out milestone has changed from a €10 million payment to a €3 million payment upon contract signature and a second payment of €7 million contingent on the first dosing of the first subject with the first Agomab Spain product in either a phase 2 or proof-of-concept clinical trial that (A) has safety and efficacy as its primary and/or secondary endpoints and (B) meets the other contractually agreed criteria on or before 31 December 2030. €3.0 million was paid in 2025 for achieving the first tranche of the first milestone.

If the likelihood of achieving the first milestone (Phase 2) is increased by 10% without changing the timing of the achievement or the WACC, the impact on the contingent consideration would be an increase of €0.962 million as at December 31, 2024 and €0.925 million as at January 1, 2024. Since the likelihood of achieving the first milestone (Phase 2) is 100% as at December 31, 2025, there is no impact on the contingent consideration as at December 31, 2025.

If the timing for reaching the different earn-out milestones were delayed by 1 year without changing the likelihood of achieving the milestones or the WACC, the impact on the contingent consideration would be a decrease of €0.925 million as at December 31, 2025, €1.262 million as at December 31, 2024 and €1.081 million as at January 1, 2024.

If the WACC was increased by 1% without the likelihood of achieving the milestones or the timing of their achievement, the impact on the contingent consideration would be a decrease of €0.139 million as at December 31, 2025, €0.039 million as at December 31, 2024 and €0.054 million as at January 1, 2024.

23. Fair value

23.1. Financial assets and liabilities

The following table provides an overview of the financial assets.

(In thousands of €)	Category	For the year ended December 31 2025	2024
Financial assets			
Other non-current assets	FAAC*	11	12
Cash and cash equivalents	FAAC*	86,418	171,459
Current financial investments (level 1)	FLAFVTPL***	30,096	—
Total		**116,525**	**171,472**

The carrying value of cash and cash equivalents and other current assets approximate their fair value.

Cash and cash equivalents measured at amortized cost comprise cash at banks and on-hand, that are readily convertible to a known amount of cash and subject to an insignificant risk of changes in value.

Current financial investments equivalents measured at fair value through profit or loss comprise a money market fund that is readily convertible to cash and are subject to a marginal risk of changes in value. These financial assets are used by the Company in the management of short-term commitments.

The following table provides an overview of the financial liabilities:

(In thousands of €)	Category	For the year ended December 31 2025	2024
Financial liabilities			
Contingent considerations - earn out (level 3)	FLAFVTPL***	9,736	7,879
Anti-dilution warrants (level 3)	FLAFVTPL***	—	—
Trade and other payables	FLAC**	7,628	8,052
Total		**17,364**	**15,931**

(*) Financial assets measured at amortized cost
(**) Financial liabilities measured at amortized cost
(***) Financial assets and liabilities measured at fair value through profit and loss

The carrying value of trade and other payables approximates their fair value.

During the 2025 reporting period, there were no transfers performed between level 1 and 2, or between level 2 and level 3 for assets and liabilities measured at fair value on a recurring basis. The absence of transfers reflects the stability and consistency in valuation methods and inputs.

The following table provides a reconciliation from the opening to closing balances of 2025 for the recurring fair value measurements categorized within level 3 of the fair value hierarchy.

(in thousands of €)	Contingent considerations – earn out	Anti-dilution warrants
As at January 1, 2023	(4,373)	(23,318)
Total gains or (losses) for the period		
included in profit or (loss)	(3,127)	22,092
include in OCI	—	—
As at December 31, 2023	(7,500)	(1,226)
Total gains or (losses) for the period		
included in profit or (loss)	(379)	1,226
include in OCI	—	—
As at December 31, 2024	**(7,879)**	**—**
Total gains or (losses) for the period		
included in profit or (loss)	(4,857)	—
include in OCI	—	—
Settlements	3,000	—
As at December 31, 2025	**(9,736)**	**—**

Since the probability of an exit without intermediate funding round has increased to 100% as of December 31, 2024, the fair value of these ADWs, are reduced to €0.0 million. No changes in fair value have been recognized within the statement of comprehensive income during the year ended 2025 (2024: gain of €1.2 million) as the probability of an exit without intermediate funding round remained unchanged as of December 31, 2025. This reflects management's assessment that an exit will occur without any further intermediate funding, making the ADWs no longer exercisable (see note 18).

The earn-out liability increased from €7.9 million as of December 31, 2024 to €9.7 million as of December 31, 2025. The increase for the year ended December 31, 2025 is the effect of increased probability of meeting the contractually agreed milestones pursuant to which the earn-out is calculated. This resulted in an additional cost recognized within the statement of comprehensive income of €4.9 million for the year ended December 31, 2025. The increase has been offset by a €3.0 million payment made for achieving the first tranche of the first milestone (refer to note 22).

24. Financial risk management

24.1. Market risks

The Company is not significantly exposed to market risks such as interest rate risk, foreign currency risks and other market risks that may impact the fair value or future cash flows of its financial instruments. As such, sensitivity analysis is not provided.

24.2. Interest rate risk

The Company is only subject to changes in variable interest rates on cash and cash equivalents. The Company is not subject to immediate changes in interest rates from borrowings.

24.3. Foreign exchange risk

The Group does not currently have any customers and purchases the majority of its materials and services in Euros, which is the functional currency of the Group entities. The Group is however exposed to limited purchase contracts in USD, CHF, and GBP. On that basis, the Group is not subject to significant foreign exchange risks. Any purchases in foreign currencies are settled at the spot rate at the time of payment, which is within one month of the invoice date. As such, sensitivity analysis is not provided.

24.4. Liquidity risk

The Company manages liquidity risk by maintaining adequate reserves, by continuously monitoring forecast and actual cash flows, and by matching the maturity profiles of financial assets and liabilities. The Company's main sources of cash inflows are through capital increases and government grants. All cash is held in immediately accessible current accounts with reputable banks and, if deemed appropriate, term deposit accounts with maturity of one year or less in duration and money market funds that are readily convertible to cash and subject to a marginal risk of changes in value. The Company does not have any unused credit lines available.

24.5. Credit risk

Credit risk is the risk that third parties may not meet their contractual obligations resulting in a loss for the Group. The Group is exposed to credit risk from its operating activities, which are currently only cash held, short-term deposits and money market funds with high-creditworthy financial institutions. The Group limits this exposure by contracting with credit-worthy business partners or with financial institutions which meet high credit rating requirements. Grant receivables are from the government and are considered a very low credit risk.

25. Related party disclosures

Transactions between the Company, its directors and key management personnel for the reporting period 2025, 2024 and 2023 are described below. Balances and transactions between the Company and its subsidiary, which is a related party of the Company, have been eliminated on consolidation and are not disclosed in this note. There were no other related party transactions.

During 2025, the Group paid a milestone consideration of €3 million to the former shareholders of Origo Biopharma, S.L., in accordance with the terms of the acquisition agreement. These payments reflect consideration for the business acquired and are not related to services provided to the Group. One beneficiary subsequently invested in the share capital of the Group during our Series B Extn, C and Series D capital raise and another beneficiary joined the Group's management team; however, the earn-out terms were not linked to employment.

The payments to these related parties were made on the same terms and conditions as those applicable to the other former shareholders and formed part of the total consideration recognized under IFRS 3 Business Combinations.

25.1. Remuneration of key management personnel

As at December 31, 2025 the key management team included six members:

- Chief Executive Officer, Mr. Tim Knotnerus
- Chief Medical Officer, Mr. Philippe Wiesel
- Chief Development Officer, Mrs. Andrea Sáez
- Chief Finance Officer, Mr. Pierre Kemula
- Chief Business Officer, Mr. Paul van der Horst
- General Counsel, Mrs. Ellen Lefever

Their combined remuneration package, including employer taxes, amounted to the following:

(In thousands of €)	2025	2024	2023
Number of key management personnel	6	6	6
Short-term employee benefits	3,082	2,224	2,022
Post employment benefits	—	—	—
Other long-term benefits	—	—	—
Termination benefits	—	—	—
Share-based payments	1,087	171	822
Total	**4,169**	**2,395**	**2,844**
Of which outstanding at year-end	—	573	1,465
ESOP warrants granted during the year	1,324,054	1,067,618	—
ESOP warrants outstanding	3,704,852	2,380,798	1,571,838

No loans, quasi-loans or other guarantees are outstanding with members of the executive management team.

25.2. Remuneration of the Board

The total remuneration of the Board of Directors in 2025 was €0.5 million (2024: €0.2 million; 2023: €0.6 million). No advances or credits have been granted to any member of the Board of Directors. None of the members of the Board of Directors have received any non-monetary remuneration other than ESOP warrants.

26. Events after the reporting period

On February 9, 2026, the Company successfully completed an IPO on the NASDAQ Global Select Market under the symbol "AGMB", issuing 12,500,000 American Depositary Shares (ADSs) representing 12,500,000 of its common shares. All of the ADSs are being offered by the Company. The gross proceeds of the issuance of new shares amounted $200 million (€169 million). On March 4, 2026, The Company issued an additional 482,967 ADSs representing 482,967 of its common shares with total gross proceeds of $7.7 million. The completion and closing of the IPO triggered the following events ("IPO events"):

- The conversion of all preferred shares into common shares on 1:1 basis (before stock split), without any pay-out in the form of cash or common shares relating to the cumulative dividend immediately prior to the consummation of the public offering;
- the profit share certificate has been automatically converted into the equivalent number of common shares (2,069,611 common shares, before stock split) in the Company, immediately prior to the consummation of the public offering;
- Expiration of the anti-dilution warrant protection before expiration of the term of the shareholders agreement, and the derecognition of the anti-dilutive warrant liability immediately prior to the public offering;
- A stock split of our common and preferred shares effected upon the consummation of the offering; and
- Accelerated vesting of ESOPs: 50% of ESOPs issued under 2024 ESOP plans have vested immediately and become exercisable, the remainder 50% of ESOPs will follow the original vesting scheme. All ESOPs issued under the other plans have vested immediately and become exercisable.
- Share split of the common shares (25,000) into an aggregate of 541,126 common shares.

28,229 ESOPs were exercised after reporting date and before authorization of the financial statements, representing 28,229 common shares.

No other events have occurred after the balance sheet date that could have a material impact on the consolidated financial statements as at December 31, 2025.

FREE ENGLISH TRANSLATION FOR INFORMATION PURPOSES ONLY

"**AgomAb Therapeutics**"
Limited liability company
Established in the Flemish Region
With registered address at 2600 Antwerp, Posthoflei 1, box 6
RLE Antwerp (Section Antwerp) VAT BE 0674.527.310
(the "**Company**")

Articles of association after the notarial deed of March 12, 2026

CHAPTER I. LEGAL FORM – NAME – REGISTERED OFFICE – PURPOSE – TERM.

Article 1.- LEGAL FORM – NAME.

1.1 The Company is a limited liability company ("naamloze vennootschap" / "*société anonyme*"), abbreviated "*NV*" / "*SA*".

1.2 Its name is "AgomAb Therapeutics".

1.3 Its name has to be preceded or followed by the designation of the company form, or the abbreviation of such form.

Article 2.- REGISTERED OFFICE.

2.1 The registered office of the Company is established in the Flemish Region.

2.2 It may be transferred to any other place in Belgium by decision of the board of directors, subject to the application of the laws on the use of languages.

2.3 The Company may, by decision of the board of directors, establish administrative offices and operating offices, branches, agencies and warehouses in Belgium or abroad.

Article 3.- OBJECT.

The Company has as its object, in Belgium as well as abroad, on its own behalf as well as on behalf of third parties, alone or in participation with third parties:

(a) the scientific research, the clinical study, the identification, the testing, analysis and evaluation, of biological, chemical or natural products with therapeutic or diagnostic potential in the life science area in general and in the pharmaceutical, medical, chemical, veterinary sectors in particular, and the production, the marketing, the exploitation, the granting or taking of a license and in general performing all possible transactions regarding any pharmaceutical or affiliated products and formulations;

(b) the worldwide distribution of, selling of and providing services with regard to the products of the Company directly to clients and also via third parties;

(c) the setting up of, participating in, managing of, monitoring of and collaborating with companies and other enterprises, obtaining, maintaining, selling or by other means managing of participations and interests in other companies and enterprises;

(d) the financing of companies and other enterprises, borrowing, lending and collecting of funds, the participation in financial transactions, including the issuance of bonds, debentures or other securities, and concluding of all agreements somehow related thereto, to enterprises and companies connected to the Company in a group and to third parties;

(e) providing guarantees, binding of the Company and encumbering assets of the Company for the benefit of enterprises and companies with which the Company is affiliated in a group and for the benefit of third parties;

(f) to acquire, manage, exploit and dispose of movable goods, immovable property and all asset values in general;

(g) to trade in currencies, securities, movable goods, immovable property and asset values in general;

(h) to acquire, exploit and trade in patents, trademarks, licenses, know-how and other industrial property rights;

(i) to perform all types of industrial, financial and commercial activities.

The Company may perform all civil, industrial, commercial, movable or immovable operations, directly or indirectly, totally or partially related to any section of its purpose, or that are of such a nature to enlarge the realization of its purpose or to facilitate it.

The Company may in any way, participate in all companies or enterprises with a similar or a related purpose, or whose purposes are of such a nature to facilitate the realization of its own purpose.

The Company may also enter into any agreement of cooperation, rationalization, association or other with such companies or enterprises.

The Company may provide a guarantee or provide security, both by providing personal rights or rights in rem for the benefit of any physical or legal person, whether or not affiliated. It may execute the role of director, managing director ("*zaakvoerder*"/"*gérant*") and liquidator.

Article 4.- TERM.

The Company is incorporated for an indefinite term.

CHAPTER II. COMPANY'S SHARE CAPITAL AND SHARES.

Article 5.- SHARE CAPITAL.

5.1 The share capital of the Company amounts to three hundred three million, fifty-seven thousand, eight hundred thirteen euros, and ninety-one cents (EUR 303,057,813.91). It is represented by forty-nine million, two hundred forty-seven thousand, nine hundred seventy-five (49,247,975) ordinary shares, without designation of nominal value, each share representing an equal part of the share capital.

5.2. The share capital is entirely and unconditionally subscribed for and fully paid up.

Article 6.- AUTHORISED CAPITAL.

6.1 The board of directors is authorised to increase the share capital of the company on one or several occasions by a maximum aggregate amount of three hundred two million, nine hundred ninety-three thousand, three hundred forty-six euros, and seventy-two cents (EUR 302,993,346.72).

6.2 The board of directors may increase the share capital by contributions in cash or in kind, by capitalisation of reserves, whether available or unavailable for distribution, and capitalisation of issue premiums, with or without the issuance of new shares, for no consideration or for consideration with an issue price below, at, or above the fractional value of the then existing shares, with or without voting rights, that will have the rights as will be determined by the board of directors. The board of directors is also authorised to use this authorisation for the issuance of convertible bonds or subscription rights, bonds with subscription rights or other securities.

6.3 This authorisation is valid for a period of five years as from the date of publication in the Annexes to the Belgian Official Gazette of an extract of the minutes of the extraordinary general shareholders' meeting of the company held on 15 January 2026.

6.4 In the event of a capital increase decided by the board of directors within the framework of the authorised capital, all issue premiums booked, if any, will be accounted for in accordance with the provisions of these articles of association.

6.5 The board of directors is authorised, when exercising its powers within the framework of the authorised capital, to restrict or cancel, in the interest of the company, the preferential subscription rights of the shareholders. This restriction or cancellation of the preferential subscription rights can also be done in favour of members of the personnel of the company or of its subsidiaries, or in favour of one or more persons other than members of the personnel of the company or of its subsidiaries.

6.6 The board of directors is authorised, with the right of substitution, to amend the articles of association, after each capital increase that has occurred within the framework of the authorised capital, in order to bring them in conformity with the new situation of the share capital and the shares.

Article 7.- PROFIT-SHARING CERTIFICATES, SUBSCRIPTION RIGHTS (WARRANTS), CONVERTIBLE BONDS AND CERTIFICATES.

The Company can issue profit-sharing certificates, certificates, subscription rights (warrants), convertible bonds, or other securities. The Company can, for the benefit of the Company, collaborate with a third party for the issuance by this third party of certificates which represent the securities of the Company according to the provisions of article 7:61 of the Belgian Companies and Associations Code (*Wetboek van vennootschappen en verenigingen*) of 23 March 2019, as amended from time to time (the "**Belgian Companies and Associations Code**"). The Company can decide to take charge of the costs connected to the certification and to the incorporation and functioning of the issuer of the certificates. The certificate-holders, the issuer of the certificates or third parties may only rely upon the collaboration of the Company for the issuance of the certificates, if the Company confirms its collaboration by writing to the issuer. The issuer of the certificates has to make himself known to the Company in this respect. The Company takes notice of this mentioning in the concerned register of securities.

Article 8.- SHARES IN UNDIVISION.

8.1 The shares are indivisible with regard to the Company.

8.2 In case shares belong to multiple holders of rights in rem, are pledged, or in case the rights attached to the shares are subject to an undivided ownership, usufruct or any other manner of division of the rights attached to such shares, joint owners must be represented with regard to the Company by one single person; as long as this is not the case, the rights attached to these shares shall be suspended until one person has been identified towards the Company as the holder of those securities or as their joint representative. If no agreement can be reached between the titleholders, a competent judge may, upon request of the first party (including the Company, as the case may be) to take action, appoint an interim administrator to exercise the concerned rights in the interest of the joint titleholders. All notices, writs and other notifications by the Company will occur validly and exclusively, as the case may be, to the person appointed as owner vis-à-vis the Company, or to the joiny representative so appointed.

8.3 Notwithstanding the foregoing, if the shares belong to bare owners and usufructuaries all rights, including voting rights, shall be exercised by the usufructuary(ies), unless stipulated otherwise in a will or an agreement.

Article 9.- NO SERIES OF SHARES.

All of the shares belong to the same series or classes of shares and shall benefit from the same rights and privileges. There are no distinct series or classes of shares as referred to in article 7:60 of the Belgian Companies and Associations Code.

Article 10.- SHARES NOT FULLY PAID-UP – OBLIGATION TO PAY UP.

10.1 The commitment to pay up a share in full is unconditional and indivisible. Each payment called is accounted to all of the shares of which the shareholder is the owner.

10.2 If shares not fully paid up belong to several persons undividedly, each of them is responsible for the payment of the full amount of the called up payments due.

10.3 Any additional or full payment shall be requested by the board of directors at a time to be determined by it. The shareholders shall be notified of this by means of a public announcement or press release or by means of a registered letter or, for shareholders who have communicated their e-mail address to the Company in accordance with the provisions of the Belgian Companies and Associations Code, by e-mail, stating a bank account to which payment, to the exclusion of any other means of payment, must be made by bank transfer or cash deposit. The shareholder shall be in default by the mere expiry of the period specified in the notification and interest shall be due by operation of law to the Company at the statutory interest rate specified at that time, as from the date such payment call was originally payable.

10.4 As long as the requested payments due on a share have not been made in accordance with this provision, the exercise of all associated membership rights attached to the share concerned shall remain suspended by operation of law. In addition, if the shareholder fails to comply with the notice of default sent by the board of directors after the expiry of the period determined by the board of directors, the board of directors may have the shares concerned sold in the most appropriate manner, without prejudice to the Company's right to claim from the shareholder the outstanding payment as well as any damages and interests may apply.

10.5 In addition, in the event of a transfer of shares that are not fully paid up, the transferor and transferee shall, notwithstanding any provision to the contrary, be jointly and severally liable for full payment. In the case of successive transfers, all successive transferees shall be jointly and severally liable in accordance with the provisions of article 7:77 of the Belgian Companies and Associations Code.

10.6. Early payments on shares may not be made without the prior consent of the board of directors.

Article 11.- SHARE CAPITAL INCREASE.

11.1 The share capital of the Company can be increased in accordance with the applicable legal provisions of the Belgian Companies and Associations Code.

11.2 With respect to any specific capital increase, in the event of a capital increase by contribution in cash, each shareholder has, in accordance with the provisions of the Belgian Companies and Associations Code, a statutory preferential subscription right to subscribe to the newly issued shares in proportion to his participation in the capital ("*pro rata participationis*"). The terms and conditions for the exercise of this statutory preferential subscription right are laid down in the Belgian Companies and Associations Code. The general shareholders' meeting or the board of directors, acting within the framework of the authorised capital, may, in the interest of the Company, restrict or dis-apply the aforementioned statutory preferential subscription right in accordance with the applicable legal provisions of the Belgian Companies and Associations Code, including to the benefit of one or more specified persons other than members of the personnel of the Company or of its subsidiaries.

Article 12.- SHARE CAPITAL DECREASE.

The share capital of the Company can be descreased in accordance with the applicable legal provisions of the Belgian Companies and Associations Code.

CHAPTER III. SHARES – OTHER SECURITIES.

Article 13.- TRANSFER OF SHARES ISSUED BY THE COMPANY

Unless provided otherwise by law, the transfer of shares or other securities issued by the Company is not subject to any transfer restriction.

Article 14.- NATURE OF SHARES ISSUED BY THE COMPANY

14.1 Shares (whether fully paid-up or not) are in registered form.

14.2 A share register is kept at the registered office of the Company and may be split by decision of the board of directors in accordance with applicable law. The board of directors can appoint a third party of its choice to keep any part of the split share register. Subject to applicable provisions of companies, financial and securities laws, and unless decided otherwise by the board of directors in accordance with these articles of association, dividends and other distributions (as the case may be) by the Company on shares can be made in euro (EUR) or United States dollars (USD) depending on the component of the (split) share register on which the shares are reflected.

The (split) register of registered shares and the registers of other registered securities, as the case may be, can be kept electronically, in accordance with applicable law.

Each holder of securities can consult the (split) register with respect to his, her or its securities. The board of directors can appoint a third party of its choice to keep this (split) electronic register.

All recordings in the (split) share register and the registers of other registered securities, including transfers and conversions, can be validly made on the basis of documents or instructions submitted electronically or via any other means by the transferor, the transferee and/or the holder of the securities, as applicable.

14.3 The general shareholders' meeting of the Company can resolve to proceed with a share split or a share consolidation in accordance with the applicable law.

Article 15.- TRANSPARENCY OBLIGATIONS

15.1 Each natural or legal person acquiring or transferring voting securities of the Company, whether or not representing the share capital of the Company, must comply with the relevant notification and information obligations that are imposed by applicable law.

15.2 Non-compliance with the relevant notification and information obligations that are imposed by applicable law in relation to the acquisition or transfer of voting securities of the Company, whether or not representing the share capital of the Company, may result, in accordance with applicable law, a suspension of the voting rights attached to the relevant voting securities or such other consequence as provided for by applicable law.

Article 16.- ISSUE OF BONDS, SUBSCRIPTION RIGHTS AND OTHER SECURITIES GIVING RIGHT TO SHARES.

16.1 The Company may issue bonds by resolution of the board of directors and on such conditions as it shall determine.

16.2 The general shareholders' meeting or the board of directors, acting within the framework of the authorized capital, may issue convertible bonds, bonds repayable into shares, subscription rights, profit-sharing certificates or any other financial instrument giving an entitlement to shares, subject to compliance with the relevant legal provisions.

16.3 In accordance with applicable law, holders of shares without voting rights, profit certificates without voting rights, convertible bonds, subscription rights or certificates which were issued with cooperation of the Company have the right to attend general shareholders' meetings, but only in a consultative capacity.

Article 17.- SUCCESSORS IN TITLE AND EXERCISE OF RIGHTS.

17.1 The rights and obligations attached to a security follow that security, regardless of whom it is transferred to.

17.2 The heirs, the creditors, and/or other beneficiaries of a shareholder cannot, on any grounds whatsoever, interfere with the management of the Company, cause seals to be laid on the goods and values of the Company, or pursue the liquidation of the Company and the distribution of its assets.

17.3 In exercising their rights shareholders are bound by the balance sheets and inventories of the Company, and must comply with and conform to the resolutions of the general shareholders' meeting of the Company.

Article 18. - ACQUISITION AND DISPOSAL OF OWN SHARES.

The Company can acquire and dispose of its own shares in accordance with the relevant legal provisions.

CHAPTER IV. BODIES OF THE COMPANY.
SECTION 1. General shareholders' meeting

Article 19.- COMPOSITION AND AUTHORITIES

The regularly composed general shareholders' meeting represents the entirety of the shareholders. The resolutions of the general shareholders' meeting are binding upon all shareholders, even those absent or those who voted against.

Article 20.- ANNUAL, SPECIAL AND EXTRAORDINARY GENERAL SHAREHOLDERS' MEETING.

20.1 The annual general shareholders' meeting of the Company shall be held each year on the last Tuesday of the month May at 4:00 PM (Brussels time).

However, should this day be a legal holiday, the annual general shareholders' meeting of the Company will take place on the next Business Day at the same time. A special or extraordinary general shareholders' meeting can be convened at any time in the interest of the Company, to discuss any matter falling within its powers.

20.3 The annual general shareholders' meeting of the Company is held at the registered office of the Company or in the commune of the registered office of the Company or at any other location as set out in the invitation notice.

The extraordinary or special general shareholders' meetings of the Company are held at the place indicated in the invitation notice.

Article 21.- CONVENING NOTICES.

General shareholders' meetings shall be convened in accordance with the applicable law.

Article 22.- ADMISSION TO THE MEETING.

22.1 In order to be admitted to and participate to a general shareholders' meeting, shareholders must comply with the relevant registration, notice, filing and other formalities as required by applicable law or as shall be set out (subject to applicable law) in the notice convening the meeting.

22.2 The board of directors shall have the ability to determine that the right to attend the general shareholders' meetings and to exercise the voting right at such meetings (as the case may be) is determined by the registration of the ownership of the securities concerned in the name of the holder of such securities on the third (3rd) Business Day prior to the date of the relevant general shareholders' meeting (or such other date as shall be set out in the notice convening the general shareholders' meeting, but which cannot be earlier than the 15th calendar date before the relevant general shareholders' meeting), at midnight at the end of such day (Brussels time) (such date and hour being the relevant registration date), by means of the registration of such securities in the relevant (portion of the split) register book for such securities, or in the accounts of a certified account holder or relevant central securities depositary for the securities concerned, irrespective of the number of shares the shareholder possesses at the day of the general shareholders' meeting.

22.3 The board of directors may make participation to the general shareholders' meetings dependent on a requirement of notification by the securities holders concerned to the Company, or to the person appointed for this purpose by the Company, on a date to be determined by the board of directors before the date of the scheduled meeting, that such securities holder intends to attend the meeting, stating the number of securities with which such securities holder wishes to participate. The manner in which such notification must be made (as the case may be) must be set out in the notice convening the general shareholders' meeting.

22.4 Natural persons, corporate bodies or proxy holders who participate in the general shareholders' meeting must be able to provide proof of their identity. The representatives of legal entities have to provide documents showing their capacity as corporate body or special proxy holder.

22.5 Holders of non-voting shares, non-voting profit-sharing certificates, convertible bonds, subscription rights, or certificates issued with the cooperation of the Company may attend the general meeting, but only in an advisory capacity. If they wish to participate, they will be subject to the same formalities of prior deposit and notice, of the form and the deposit of a proxy, and of admission, as those to which the shareholders are subject.

Article 23.- REPRESENTATION.

23.1 Notwithstanding applicable law with respect to legal representation, each security holder who can participate in the general shareholders' meeting, can be represented at a general shareholders' meeting by a proxy holder, who needs not be a shareholder, who has been granted a handwritten proxy or a proxy on another durable medium recognized by law. A person acting as proxy holder may carry a proxy of more than one shareholder; in such case he may vote differently for one shareholder than for another shareholder.

23.2 Such proxies must be granted and submitted to the company in accordance with the applicable law and/or as set out (in accordance with the applicable law) in the convening notice, as the case may be.

23.3 The holders of a proxy must comply with the relevant legal provisions concerning proxies for general shareholders' meetings, as relevant. The board of directors can establish a form for the proxies. The proxy forms will be made available to the security holders.

Article 24.- ATTENDANCE LIST.

The shareholders or their proxyholders are obliged, before being admitted to the general shareholders' meeting, to sign the attendance list indicating their surname, first name(s) and domicile or the corporate name and registered office and the number of shares they represent.

Article 25.- COMPOSITION OF THE BUREAU.

25.1 The general shareholders' meetings shall be chaired by the chairperson, or, in the latter's absence, by his, her or its substitute or by a member of the meeting appointed by the meeting.

25.2 The chairperson of the meeting appoints the secretary, who may be or may not be a shareholder or director. Should the number of persons allow or require this, the meeting will appoint two vote counters upon proposal of the chairperson, who may be or may not be a shareholder. Both roles may be performed by one person.

25.3 The persons mentioned in articles 25.1 and 25.2 constitute the bureau of the meeting.

25.4 The chairperson can assemble the bureau prior to the general shareholders' meeting and, as such, the assembled bureau can proceed with the verification of the proxies granted to the participants of the general shareholders' meeting prior to the opening of the meeting.

Article 26.- VOTING RIGHTS.

Each share carries one vote, unless determined otherwise by applicable law.

Article 27.- REMOTE VOTING OR PARTICIPATION.

27.1 If the convening notice so provides, a shareholder may, prior to the general shareholders' meeting, vote by mail or via electronic means using forms, the draft text of which shall be determined by the board of directors. The voting forms will be made available to the shareholders.

27.2 These votes by mail or by electronic means must be cast in accordance with the applicable law and/or as will be set out (in accordance with applicable law) in the convening notice.

27.3 In accordance with applicable law, the board of directors can also organise a remote voting by means of other electronic means of communication such as one or more websites. The board of directors is authorised to organise the practical procedures to facilitate such electronic voting.

27.4 In accordance with applicable law, the board of directors can offer security holders the possibility to participate remotely in the general shareholders' meeting via a means of communication made available by the company. The board of directors is authorised to organise the practical procedures to facilitate such remote participation by a means of communication made available by the company.

Article 28.- DELIBERATION, DECISION MAKING AND QUORUM REQUIREMENTS.

28.1 The general shareholders' meeting cannot deliberate on items that are not on the agenda or contained therein implicitly, unless all shareholders are present or represented at the meeting and unanimously consent to do so and if, in the event of a vote by mail, the form authorises a proxy holder to take such a decision. The required consent is given if no objection is recorded in the minutes of the meeting.

28.2 The general shareholders' meeting can validly deliberate and pass resolutions regardless of the number of shares present or represented, except in cases in which applicable law requires a specific attendance quorum.

28.3 The resolutions of the general shareholders' meeting are validly adopted by a simple majority of the votes validly cast at the meeting, except in cases in which applicable law requires a specific majority. In the event votes are tied, the proposal is rejected.

28.4 Voting will be by show of hands unless, in view of the number of participants or otherwise, the chairperson of the meeting thinks it preferable to vote by another method, such as voting slips or electronic means.

28.5 General shareholders' meetings may be transmitted or broadcast live by telephone conferencing or video conferencing, or any other means of transmission and/or telecommunication. By participating in general shareholders' meetings that are transmitted or broadcast, the natural persons participating in the general shareholders' meeting consent to their image being transmitted or broadcast through these transmission or telecommunication means.

Article 29.- ADJOURNMENT.

29.1 The board of directors has the right, during the annual general shareholders' meeting, to adjourn the resolution relating to the approval of the annual accounts for three (3) weeks. This adjournment does not affect the other decisions already taken, unless the general shareholders' meeting decides otherwise in this respect. The next general shareholders' meeting has the right to definitively adopt the annual accounts.

29.2 The board of directors also has the right, during the general shareholders' meeting, to adjourn any other general shareholders' meeting once by three (3) weeks. This adjournment does not affect the resolutions already passed by this meeting, unless the general shareholders' meeting decides otherwise in this respect.

29.3 At the next general shareholders' meeting, the items on the agenda on which no final decision was taken at the previous general shareholders' meeting will be dealt with further.

29.4 Subject to applicable law, additional items on the agenda may be added to the agenda of the next general shareholders' meeting.

29.5 Subject to applicable law, the formalities completed in order to attend the first general shareholders' meeting, including registration for the general shareholders' meeting, and, as the case may be, the deposit of proxies, shall remain valid for the second general shareholders' meeting.

29.6 Shareholders who were not present or represented at the previous (adjourned) general shareholders' meeting will be admitted to the next general shareholders' meeting, provided that they have complied with the formalities set out in the applicable legal provisions and these articles of association.

Article 30 - MINUTES.

30.1 Minutes shall be drawn up for each general shareholders' meeting, and the attendance list and any reports, proxies and written votes shall be attached thereto. The minutes shall be kept in a special register.

30.2 The minutes are signed by the members of the bureau and by the shareholders who wish to do so.

30.3 Except when provided otherwise by law, the copies and/or excerpts of the minutes of the general shareholders' meetings addressed to third parties are signed by the chairperson, by a managing director, by the chief executive officer, or by two directors. Their signature must be preceded by an indication of the capacity in which they act.

SECTION 2. Management

Article 31.- POWERS OF THE BOARD OF DIRECTORS.

31.1 The Company has opted for a one tier governance model whereby the board of directors has the authority to take all actions necessary or useful for the realisation of the corporate purpose of the Company, save for those actions for which only the general shareholders' meeting has authority by applicable law.

31.2 The Company, acting through the board of directors, can, to greatest extent permitted by applicable law, take out insurance coverage in order to cover liability of the directors and agents of the Company and its subsidiaries.

Article 32.- COMPOSITION OF THE BOARD OF DIRECTORS.

32.1 The Company is governed by a board of directors, acting as a collective body, and consisting of at least three (3) and maximum nine (9) directors, who need not be shareholders. They shall be appointed by simple majority of the general shareholders' meeting.

32.2 The directors may be either natural persons or legal persons. When a legal person is appointed as a director, it appoints a natural person as permanent representative in accordance with the applicable legal provisions, subject to acceptance of this person by the other members of the board of directors. The permanent representative is charged with the execution of the assignment in the name and on behalf of the legal person. The legal person may not dismiss its representative without at the same time appointing a successor. The appointment and termination of the mandate of the permanent representative shall be subject to the same rules of disclosure as if it was carrying out this mandate in its own name and for its own account.

32.3 The duration of their assignment may not exceed six (6) years. The assignments end immediately after the annual meeting in the financial year in which the term of their mandate expires in accordance with the appointment resolution.

32.4 The directors may be dismissed at any time by the general shareholders' meeting without notice or compensation in accordance with the applicable legal provisions and without prejudice to applicable contractual arrangements.

32.5 The directors may be reappointed when their mandate expires.

32.6 Should the mandate of a director become vacant, for any reason whatsoever, the remaining directors shall have the right to temporarily fill such vacancy (co-optation). The next general shareholders' meeting must confirm the mandate of the co-opted director; if confirmed, the co-opted director completes the mandate of his, her or its predecessor, unless the general shareholders' meeting decides otherwise. In the absence of confirmation, the mandate of the co-opted director ends at the end of the general shareholders' meeting, without prejudice to the regularity of the composition of the board of directors up to that moment in time. In case of more than one vacancy, the remaining directors shall have the right to fill all such vacancies simultaneously. As long as the general shareholders' meeting or the board of directors, for any reason whatsoever, does not fill the vacancy, the directors of whom the mandate has ended will remain in function if this is needed for the board of directors to maintain the minimum number of directors as required by applicable law and these articles of association.

Article 33.- REIMBURSEMENT.

The Company will reimburse the directors for the reasonable costs and out of pocket expenses incurred by them in respect of attending meetings of the Company or carrying out authorised business on behalf of the Company.

Article 34.- CHAIRPERSON.

34.1 The chairperson of the board of directors is appointed by the board of directors from among its members. The chairperson of the board of directors can elect one or more vice-chairpersons.

34.2 The chairperson or, in case he, she or it is absent or hindered, a vice-chairperson, if any, or, in the absence of the latter, a director designated by the other board members present, shall chair the meetings of the board of directors.

Article 35.- CONVOCATION OF BOARD MEETINGS.

35.1 The board of directors shall meet at least four (4) times per year at any location acceptable to the members of the board of directors, with such greater frequency as the directors may require in the interest of the Company or any time two directors or the chairperson so requests. Unless determined otherwise by the board of directors, at least one (1) meeting per year shall be held in person.

35.2 The board of directors shall meet when convened by and under the presidency of the chairperson or, in case he, she or it is absent or hindered, a vice-chairperson, if any, or, in the absence the latter, a director appointed by the other directors. A board meeting must be called upon the request of one or more directors.

35.3 The notice of the meeting shall mention the place, date, hour and agenda for the meeting. Unless all directors agree otherwise, notices to attend the board meeting must be in writing and delivered to each director at the latest three (3) calendar days prior to the meeting, except in case of emergency. In case of emergency, the convening notice must be given within not less than twenty-four (24) hours, and the reasons for the emergency should be specified in the notice. The notice shall be sent out by letter, telefax, email or any other written (or electronic) means of communication specified by applicable law. The board of directors may validly deliberate and decide without furnishing proof of the compliance with this formality with respect to the calling of the meeting, provided that all directors are present or have waived their right in writing to be formally invited to the meeting.

35.4 When all directors are present or validly represented, the valid convening of the meeting cannot be challenged.

Article 36.- REPRESENTATION AND REMOTE PARTICIPATION.

36.1 Each director may, by any written form of communication bearing his, her or its signature (including an electronic signature), authorise another member of the board of directors to represent him, her or it at a specific meeting of the board of directors and to vote for him, her or it in his, her or its place. Such authorisation must be notified to the board of directors by simple letter or any other means of written (or electronic) communication. A director giving such instructions is regarded as being present at the meeting. Without prejudice to the rules of collegiality, a director may represent several of his, her or its colleagues and may, in addition to his, her or its own vote, cast as many votes as he, she or it has received proxies.

36.2 Meetings can be held by using any telecommunication means permitting a joint discussion, such as telephone conferencing or video conferencing. Directors taking part in a meeting held by conference call or video conference shall be deemed present at the meeting.

Article 37.- DELIBERATIONS.

37.1 The board of directors shall be validly constituted to decide on the items listed on the agenda provided that a majority of the directors is present or validly represented at the meeting. If at a meeting of the board of directors, the quorum is not met, a second meeting of the board of directors with the same agenda shall be convened within twenty (20) Business Days following the first meeting which can validly decide only on the items on the first meeting's agenda whatever the number of directors present or validly represented.

37.2 Unless provided otherwise by law, every decision of the board of directors shall be valid if approved by a majority of directors present or represented at the relevant meeting. Blank and invalid votes are not included in the numerator, nor in the denominator. In case of abstentions, the resolutions shall be adopted by a simple majority of the votes of the other directors present or represented at the meeting.

37.3 The board of directors can only validly deliberate and resolve on matters not appearing on the agenda if all members of the board of directors are present or represented at the meeting and have unanimously consented thereto. This consent is assumed to have been given if no objection is recorded in the minutes.

37.4 Each director has one (1) vote, but may cast, in addition to his, her or its own vote, as many votes as he, she or it has powers of attorney from his, her or its fellow directors.

37.5 In case votes are tied, the chairperson of the meeting shall not have a casting vote.

37.6 The board of directors may pass resolutions by unanimous written consent of all directors in accordance with applicable law.

Article 38.- CONFLICTS OF INTEREST

38.1 If a director has a direct or indirect financial interest which is contrary to the interest of the Company at the occasion of a decision or transaction that falls within the powers of the board of directors, the provisions of Article 7:96 of the Belgian Companies and Associations Code must be complied with by the director concerned, as well as by the board of directors in its deliberations and resolutions.

38.2 If more than one director finds himself, herself or itself in this position, the resolutions can be validly passed by the remaining directors, even if in these circumstances more than half of the directors are no longer present or validly represented.

38.3 If all directors have a conflict of interest, the decision or the transaction shall be submitted to the general shareholders' meeting. If the general shareholders' meeting approves the decision or the transaction, the board of directors may execute it.

Article 39.-MINUTES

39.1 The decisions of the board of directors are recorded in minutes signed by the chairperson, or, in the latter's absence, by his, her or its substitute or by a member of the board of directors appointed to act as chairman of the meeting by the board of directors, the secretary and the members who so desire.

39.2 Any proxy received by a director shall be attached to the minutes of the meeting for which they were given.

39.4 The minutes shall be recorded in a special register kept at the registered office of the Company.

39.5 The copies or extracts to be submitted to a court of law or elsewhere are validly signed by the chairperson, by two directors, by the chief executive officer, by a managing director, or by a special proxyholder.

Article 40.- ALLOCATION OF DUTIES WITHIN THE BOARD OF DIRECTORS.

40.1 The board of directors shall have the power and, to the extent required by applicable law, the obligation to establish, in its midst and under its responsibility, one or more advisory committees, such as (but not limited to) an audit committee, a nomination committee and a remuneration committee (which can be combined with the nomination committee). The board of directors determines the composition and duties of these committees.

40.2 The board of directors may delegate the daily management of the Company, the management of one or more sectors of its activities or the implementation of the decisions of the board of directors to one or more directors, managers or proxy holders, whether or not shareholders. If a director is charged with the daily management, he, she or it bears the title of "managing director". If a non-director is charged with the daily management, he, she or it shall bear the title of manager or general manager or any other title to which he, she or it are referred in the appointment decision.

40.3 The board of directors, within the limits of its authority, as well as the proxies for the daily management within the framework of this daily management, may also grant specific and limited powers for a specific legal act or a series of specific legal acts to one or more persons of their choice, directors or not.

Article 41.-REPRESENTATION AUTHORITY.

41.1 The board of directors shall represent the Company as a body in and out of court. It shall act through the majority of its members.

41.2 Without prejudice to the general representative powers of the board of directors as a collective body, the Company shall be validly represented vis-à-vis third parties, before the court and in the documents, including those requiring the intervention of a public official or a notary public, by two (2) directors acting jointly.

41.3 Within the framework of the daily management, the Company is also validly represented by a person charged with daily management (director or non-director), acting alone or jointly in accordance with the delegation resolution of the board of directors.

41.4 The Company is also, within the framework of their mandate, validly represented by a special proxyholder, without prejudice to the responsibility of the directors in the event of excess of power of attorney.

41.5 Furthermore, the Company may be represented abroad by any person expressly appointed for this purpose by the board of directors.

SECTION 3. Control

Article 42.- CONTROL.

42.1 The auditing of the financial situation, the annual accounts and the regularity of the transactions to be reported on in the annual accounts is conferred to one or more statutory auditors, or, in the absence of a statutory auditor, to each shareholder, in each case in accordance with applicable law.

42.2 The statutory auditors are appointed and remunerated in accordance with applicable law.

CHAPTER V. FINANCIAL YEAR – ANNUAL ACCOUNTS – DISTRIBUTION OF PROFITS.

Article 43.- FINANCIAL YEAR.

The financial year of the Company starts on the first of January and shall end on the thirty-first of December of each year.

Article 44.- DISTRIBUTION OF PROFITS.

44.1 The net profits of the financial year are constituted in accordance with the applicable legal provisions.

44.2 From the net profits of the Company, at least five percent (5%) shall be set aside each year to constitute the legal reserve. Such deduction shall no longer be required as soon as this legal reserve reaches one tenth of the Company's capital.

44.3 Upon proposal of the board of directors, the general shareholders' meeting shall annually decide on the allocation of the balance of the net profits by simple majority vote, subject to applicable law.

44.4 The board of directors shall be entitled to determine whether any profits legally available for distribution with respect to any financial year of the Company will be distributed among the holders of the shares, as well as the place, timing and manner (including applicable currency) thereof. In such case, such profits shall be distributed to shareholders pro rata to their respective holdings of shares.

44.5 The dividends will be paid at the times and places as determined by the board of directors. All dividends not claimed within five years are time-barred and remain acquired by the Company. They will be allocated to the legal reserve.

Article 45.- INTERIM DIVIDENDS.

The board of directors is authorised to pay an interim dividend on the result of the financial year and to determine the amount (including applicable currency) and the date of their payment, subject to compliance with applicable law.

Article 46.- PROHIBITED DISTRIBUTION.

Any distribution of dividends made contrary to the law or the terms of these articles of association must be repaid by the shareholder who received it.

CHAPTER VI. DISSOLUTION AND LIQUIDATION.

Article 47.- DISSOLUTION.

The general shareholders' meeting may at any time dissolve the Company, respecting the quorum and majority requirements for modifications of the by-laws.

Article 48.- DISSOLUTION AND LIQUIDATION.

48.1 Subject to the relevant legal provisions with respect to dissolution, the Company can only be dissolved by a decision of the general shareholders' meeting, deliberating in accordance with the applicable legal provisions.

48.2 The general shareholders' meeting shall have the broadest powers to determine the powers of the liquidators, determine their remuneration and grant them release from liability.

CHAPTER VII. GENERAL PROVISIONS.

Article 49. ELECTION OF DOMICILE.

49.1 Every director, person delegated to the daily management, statutory auditor or liquidator residing abroad, is deemed, for the duration of their function, to have elected domicile at the registered office of the Company, for all matters affecting the performance of their duties, where all communications, notifications and summons can be validly served on them, whereas the Company has no other obligation than to keep them available to the recipient.

49.2 The registered security holders are obliged to notify the Company of any change to their elected domicile. In absence of such notification, they are assumed to have elected domicile at their previous domicile, where all acts may be validly served or notified to them, whereas the Company has no other obligation than to keep them available to the recipient.

Article 50.- GOVERNING LAW.

All matters not expressly determined in these articles of association, or to the legal provisions from which is not validly derogated in these articles of association are subject to the provisions of the Belgian Companies and Associations Code and other provisions of Belgian law.

Article 51.- CHOICE OF FORUM.

All disputes relating to corporate matters and the implementation of these articles of association between the Company, its shareholders, holders of bonds, holders of subscription rights, or holders of other securities or certificates issued by or with the cooperation of the Company, its directors, statutory auditors, or liquidators, shall be subject to the exclusive jurisdiction of the courts of the jurisdiction of the registered office of the Company, unless otherwise determined by the applicable law.

Article 52.- PERSONNEL.

Unless the context requires otherwise or unless otherwise defined in these articles of association, for the purposes of these articles of association, "personnel" has the meaning as defined in Article 1:27 of the Belgian Companies and Associations Code.

Article 53.- BUSINESS DAY.

For the purposes of these articles of association, "Business Day" means any day from Monday to Friday (included), excluding statutory or banking holidays in Belgium or New York, the United States of America.

Exhibit 2.3

Description of rights of common shares and American Depositary Shares registered under Section 12 of the Securities Exchange Act of 1934 (the "Exchange Act")

The following description is a summary of certain information relating to our share capital, certain provisions of our restated articles of association, the Belgian Companies and Associations Code and the deposit agreement governing the American Depositary Shares, or ADSs, each representing one common share. Common shares underlying the ADSs are held by The Bank of New York Mellon, as depositary. We last amended our articles of association on March 12, 2026.

Because this description is a summary, it may not contain all information which is important to you. Accordingly, this description is qualified entirely by references to our articles of association and the Belgian Companies and Associations Code. Copies of our articles of association are publicly available as Exhibit 1.1 to our Annual Report on Form 20-F, or the Annual Report.

The following also includes comparisons of certain provisions of our articles of association and the Belgian Companies and Associations Code applicable to us, and the Delaware General Corporation Law, or the DGCL, the law under which many publicly listed companies in the United States are incorporated. Because such statements are summaries, they do not address all aspects of Belgian law that may be relevant to us and our shareholders or all aspects of the DGCL which may differ from Belgian law. This summary is not intended to be a complete discussion of the respective rights and it is qualified entirely by reference to the Belgian Companies and Associations Code applicable to us and the DGCL.

Share capital

Our share capital is represented by registered common shares without nominal or par value. Our share capital is fully paid-up. Following the closing of our IPO, there are no separate classes of shares.

In connection with the closing of our IPO, all outstanding preferred shares converted into common shares, we issued common shares to argenx BV upon the conversion of the profit-sharing certificate and we effected a stock split of our outstanding common shares.

As of March 31, 2026, our share capital consists of 49,247,975 common shares, without nominal or par value.

Our ADSs have been approved for listing on the Nasdaq Global Select Market under the symbol "AGMB."

Common shares

The following summarizes the main rights of holders of our common shares:

- each holder of common shares is entitled to one vote per share on all matters to be voted on by shareholders generally, including the appointment of directors;
- there are no cumulative voting rights;
- the holders of our common shares are entitled to dividends and other distributions as may be declared from time to time by us out of funds legally available for that purpose, if any;
- upon our liquidation and dissolution, the holders of common shares will be entitled to share ratably in the distribution of all of our assets remaining available for distribution after satisfaction of all our liabilities; and
- the holders of our common shares have pre-emption rights in case of share issuances or the grant of rights to subscribe for shares, except if such rights are limited or excluded by the corporate body authorized to do so and except in such cases as provided by Belgian law and our articles of association.

Options/Warrants

Vested ESOP warrants granted under the Company's Employee Stock Option Plans are exercisable into common shares subject to the terms and conditions of such plans.

Articles of association and other share information

Corporate profile

Our legal and commercial name is "AgomAb Therapeutics." We are a limited liability company incorporated in the form of a *naamloze vennootschap / société anonyme* under Belgian law. We are registered with the Register of Legal Entities of Antwerp (section Antwerp) under the registration number 0674.527.310. Our registered office and our headquarters are located at Posthoflei 1/ 6, 2600 Antwerpen, Belgium. We were incorporated on April 13, 2017 for an unlimited duration. Our financial year runs from January 1 through December 31.

Corporate purpose

According to Article 3 of our articles of association, our corporate purpose is as follows:

"The Company has as its object, in Belgium as well as abroad, on its own behalf as well as on behalf of third parties, alone or in participation with third parties:

(a) the scientific research, the clinical study, the identification, the testing, analysis and evaluation, of biological, chemical or natural products with therapeutic or diagnostic potential in the life science area in general and in the pharmaceutical, medical, chemical, veterinary sectors in particular, and the production, the marketing, the

exploitation, the granting or taking of a license and in general performing all possible transactions regarding any pharmaceutical or affiliated products and formulations;

(b) the worldwide distribution of, selling of and providing services with regard to the products of the Company directly to clients and also via third parties;

(c) the setting up of, participating in, managing of, monitoring of and collaborating with companies and other enterprises, obtaining, maintaining, selling or by other means managing of participations and interests in other companies and enterprises;

(d) the financing of companies and other enterprises, borrowing, lending and collecting of funds, the participation in financial transactions, including the issuance of bonds, debentures or other securities, and concluding of all agreements somehow related thereto, to enterprises and companies connected to the Company in a group and to third parties;

(e) providing guarantees, binding of the Company and encumbering assets of the Company for the benefit of enterprises and companies with which the Company is affiliated in a group and for the benefit of third parties;

(f) to acquire, manage, exploit and dispose of movable goods, immovable property and all asset values in general;

(g) to trade in currencies, securities, movable goods, immovable property and asset values in general;

(h) to acquire, exploit and trade in patents, trademarks, licenses, know-how and other industrial property rights;

(i) to perform all types of industrial, financial and commercial activities.

The Company may perform all civil, industrial, commercial, movable or immovable operations, directly or indirectly, totally or partially related to any section of its purpose, or that are of such a nature to enlarge the realization of its purpose or to facilitate it.

The Company may in any way, participate in all companies or enterprises with a similar or a related purpose, or whose purposes are of such a nature to facilitate the realization of its own purpose.

The Company may also enter into any agreement of cooperation, rationalization, association or other with such companies or enterprises.

The Company may provide a guarantee or provide security, both by providing personal rights or rights in rem for the benefit of any physical or legal person, whether or not affiliated. It may execute the role of director, managing director (zaakvoerder/gérant) and liquidator."

Board of directors

Belgian law does not specifically regulate the ability of directors to borrow money from our company.

Article 7:96 of the Belgian Companies and Associations Code provides that if one of our directors has a direct or indirect interest of a patrimonial nature that conflicts with the interest of the Company in connection with a resolution or transaction that falls within the powers of our board of directors, the director concerned must inform our other directors of this matter before our board of directors makes any decision on the relevant resolution or transaction. The statutory auditor must also be notified. The director may neither participate in the deliberation nor vote on the conflicting resolution or transaction. An excerpt from the minutes of the meeting of our board of directors that sets forth the financial impact of the matter on us and justifies the decision of our board of directors must be published in our annual report. The statutory auditor's report to the annual accounts must contain a description of the financial impact on us of each of the decisions of our board of directors where director conflicts arise. If all directors have a conflict of interest, the resolution or transaction shall be submitted for approval to the shareholders' meeting.

There are no outstanding loans granted by our Company to any of the members of the board of directors and members of the executive management, nor are there any guarantees provided by our Company for the benefit of any of the members of the board of directors and members of the executive management.

Our articles of association provide that the Company can, to the greatest extent permitted by applicable law, take out insurance coverage in order to cover liability of the directors and agents of the Company and its subsidiaries.

None of the members of the board of directors and members of the executive management has a family relationship with any other of the members of the board of directors and members of the executive management.

The DGCL generally permits transactions involving a Delaware corporation and an interested director of that corporation if (i) the material facts as to the director's relationship or interest and as to the transaction are disclosed and a majority of disinterested directors consent, (ii) the material facts are disclosed as to the director's relationship or interest and a majority of shares entitled to vote thereon consent or (iii) the transaction is fair to the corporation at the time it is authorized by the board of directors, a committee of the board of directors or the stockholders.

We rely on a provision in the Listing Rules of Nasdaq that allows us to follow Belgian corporate law with respect to certain aspects of corporate governance. This allows us to continue following certain corporate governance practices that differ in significant respects from the corporate governance requirements applicable to U.S. companies listed on Nasdaq. In particular, the Listing Rules of Nasdaq require a majority of the directors of a listed U.S. company to be independent, whereas pursuant to Belgian law, we are not subject to any legal requirement to have any independent directors. Our board of directors currently comprises five independent directors and one non-independent director. See Item 6 ("Directors, Senior Management and Employees") of the Annual Report. The Listing Rules of Nasdaq further require that each of the nominating, compensation and audit committees of a listed U.S. company be comprised entirely of independent directors. All members of our Audit Committee are independent as determined under Rule 10A-3 under the Exchange Act and the applicable rules of Nasdaq. See Item 6 ("Directors, Senior Management and Employees") of the Annual Report.

Limitations on director liability

Under Belgian law, our company's directors may be liable for damages to our company in the case of improper performance of their duties. Our company's directors may be liable to our company and to third parties for infringement of our company's articles of association, Belgian company law (including the Belgian Companies and Associations Code) and, under certain circumstances, pursuant to Belgian tort, bankruptcy, social security or tax laws. Under certain circumstances, directors may be criminally liable.

The company maintains liability insurance for the company's directors and officers, including insurance against liability under the Securities Act.

The Belgian Companies and Associations Code includes a cap on liability for directors (including persons in charge of daily management) for any damages they cause due to mismanagement, including breaches of the articles of association and the Belgian Companies and Associations Code. This liability cap applies towards the company and third parties. For the company, the cap currently amounts to EUR 12,000,000.00 (subject to indexation). The cap applies irrespective of the number of claimants or defendants for the same (set of) facts. However, the cap does not apply to repetitive minor misconduct, serious error or cases of fraud or intent to harm. Furthermore, the cap does not apply to directors' liability under the special liability regimes relating to payment of withholding tax, VAT and social security contributions, and in certain other technical cases provided for by the Belgian Companies and Associations Code.

Certain of the company's non-executive directors may, through their relationships with their employers or partnerships, be insured and/or indemnified against certain liabilities in their capacity as members of the company's board of directors.

Under Delaware law, a corporation's certificate of incorporation may generally include a provision eliminating or limiting the personal liability of a director to the corporation and its stockholders for monetary damages arising from a breach of fiduciary duty as a director. However, no provision can limit the liability of a director for:

- any breach of the director's duty of loyalty to the corporation or its stockholders;
- acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law;
- intentional or negligent payment of unlawful dividends or stock purchases or redemptions;
- claims with respect to unlawful payment of dividends and unlawful stock purchases and redemptions; or
- any transaction from which the director derives an improper personal benefit.

Form and transferability of our shares

All of our shares rank *pari passu* in all respects with all other existing and outstanding shares of the Company.

All of our shares belong to the same class of securities and are in registered form.

All of our outstanding shares are fully paid-up and freely transferable, subject to any contractual restrictions.

Currency

Our share capital, which is represented by our outstanding common shares, is denominated in Euros.

Changes to our share capital

In principle, changes to our share capital are decided by our shareholders. Our shareholders may at any time at a shareholders' meeting decide to increase or decrease our share capital. Such resolution must satisfy the quorum and majority requirements that apply to an amendment of the articles of association, as described below in "—Description of the rights and benefits attached to our shares—Right to attend and vote at our shareholders' meeting—Quorum and majority requirements." No shareholder is liable to make any further contribution to our share capital other than with respect to shares held by such shareholder that are not fully paid-up.

Share capital increases by our board of directors

Subject to the quorum and majority requirements described below in "—Description of the rights and benefits attached to our shares—Right to attend and vote at our shareholders' meeting—Quorum and majority requirements," our shareholders' meeting may authorize our board of directors, within certain limits, to increase our share capital without any further approval of our shareholders. A capital increase that is authorized in this manner is referred to as "authorized capital". This authorization needs to be limited in time, meaning that it can only be granted for a renewable period of a maximum of five years.

By virtue of the resolution of the extraordinary general shareholders' meeting of the Company held on January 15, 2026, as published by excerpt in the Annexes to the Belgian Official Gazette (*Belgisch Staatsblad/ Moniteur belge*) on April 8, 2026, the board of directors of the Company has been granted certain powers to increase our share capital in the framework of the authorized capital. The powers under the authorized capital have been set out in article six of the Company's articles of association, and currently provide that the board of directors is authorized to increase the share capital of the company on one or several occasions by a maximum aggregate amount of EUR 302,993,346.72.

Within the framework of the authorized capital, the board of directors may increase the share capital by contributions in cash or in kind, by capitalization of reserves, whether available or unavailable for distribution, and capitalization of issue premiums, with or without the issuance of new shares, for no consideration or for consideration with an issue price below, at, or above the fractional value of the then existing shares, with or without voting rights, that will have the rights as will be determined by the board of

directors. The board of directors is also authorized to use this authorization for the issuance of convertible bonds or subscription rights, bonds with subscription rights or other securities. The board of directors is also authorized, when exercising its powers within the framework of the authorized capital, to restrict or cancel, in the interest of the company, the preferential subscription rights of the shareholders. This restriction or cancellation of the preferential subscription rights can also be done in favor of members of the personnel of our company or of its subsidiaries, or in favor of one or more persons other than members of the personnel of our company or of its subsidiaries.

Preferential subscription rights

In the event of a share capital increase for cash through the issuance of new shares, or in the event we issue convertible bonds or subscription rights (warrants), our then existing shareholders will have a preferential right to subscribe, pro rata, to the new shares, convertible bonds or subscription rights (warrants). These preferential subscription rights are transferable during the subscription period. Our board of directors can decide that preferential subscription rights that were not exercised by any shareholders shall accrue proportionally to the other shareholders that have already exercised their preferential subscription rights, and can fix the practical terms for such subscription.

Our shareholders may, at a shareholders' meeting, decide to limit or cancel this preferential subscription right, subject to special reporting requirements. Such decision by the shareholders must satisfy the same quorum and majority requirements as the decision to increase our share capital.

Shareholders may also decide to authorize our board of directors to limit or cancel the preferential subscription right within the framework of the authorized capital, subject to the terms and conditions set forth in the Belgian Companies and Associations Code and the relevant authorization. As mentioned above, our board of directors has the authority to increase the share capital within the framework of the authorized capital, and the right to limit or cancel the preferential subscription right within the framework of the authorized capital. The powers under the authorized capital have been set out in article six of the articles of association. See also "—Share capital increases by our board of directors" above.

Generally, unless expressly authorized in advance by the shareholders' meeting, the authorization of our board of directors to increase the share capital through contributions in cash with cancellation or limitation of the preferential subscription right of the existing shareholders is suspended as of the notification to us by the Belgian Financial Services and Markets Authority, or the FSMA, of a public takeover bid on our financial instruments.

Our shareholders' meeting did not grant such express authorization to our board of directors. See also "—Share capital increases by our board of directors" above.

Under the DGCL, stockholders of a Delaware corporation have no preemptive rights to subscribe for additional issues of stock or to any security convertible into such stock unless, and to the extent that, such rights are expressly provided for in the corporation's certificate of incorporation.

Purchases/acquisitions and sales of our own shares

We may acquire, pledge and dispose of our own shares, profit certificates or associated certificates at the conditions provided for by articles 7:215 and following of the Belgian Companies and Associations Code. These conditions include a prior shareholders' resolution approved by at least 75% of the votes validly cast at a general shareholders' meeting (whereby abstentions are not included in the numerator nor in the denominator) where at least 50% of the share capital are present or represented. In the event where the aforementioned 50% quorum is not present or represented at the first general shareholders' meeting, a second general shareholders' meeting needs to be convened through a new notice. The second general shareholders' meeting may validly deliberate and decide regardless of the number of shares present or represented. The special 75% majority requirements, however, remain applicable.

Furthermore, shares can only be acquired with funds that would otherwise be available for distribution as a dividend to the shareholders and the transaction must relate to fully paid-up shares or associated

certificates. Furthermore, an offer to purchase shares must be made by way of an offer to all shareholders under the same conditions.

Generally, the general shareholders' meeting or the articles of association determine the amount of shares, profit certificates or certificates that can be acquired, the duration of such an authorization which cannot exceed five years as from the publication of the proposed resolution as well as the minimum and maximum price that the board of directors can pay for the shares. The prior approval by the shareholders is not required if we purchase the shares to offer them to our personnel, in which case the shares must be transferred within a period of 12 months as from their acquisition.

We may, without prior authorization by the general shareholders' meeting, dispose of the Company's own shares, profit certificates or associated certificates in the limited number of situations set out in article 7:218 of the Belgian Companies and Associations Code.

As of the date of our Annual Report, our Company does not hold any own shares.

Under the DGCL, a Delaware corporation may purchase or redeem its own shares unless the capital of the corporation is impaired or the purchase or redemption would cause an impairment of the capital of the corporation.

Description of the rights and benefits attached to our shares

Right to attend and vote at our shareholders' meetings

Annual shareholders' meeting

Our annual general shareholders' meeting will be held at the registered office of our Company (in Belgium) or at the place determined in the notice convening the general shareholders' meeting. The meeting will be held every year on the last Tuesday of May at 04:00 p.m. (Belgian time). If this day would be a Belgian public holiday, the annual general shareholders' meeting shall be held on the next business day. At our annual general shareholders' meeting, the board of directors submits to the shareholders the audited non-consolidated and consolidated annual financial statements and the reports of the board of directors and of the statutory auditor with respect thereto.

The general shareholders' meeting then decides on the approval of the statutory annual financial statements, the proposed allocation of the Company's profit or loss, the release from liability of the directors and the statutory auditor, and, when applicable, the (re-)appointment or dismissal of the statutory auditor and/or of all or certain directors. In addition, as relevant, the general shareholders' meeting must also decide on the approval of the remuneration of the directors and statutory auditor for the exercise of their mandate (see also "—Voting rights attached to the common shares" below).

Special and extraordinary shareholders' meetings

Our board of directors or the statutory auditor (or the liquidators, if appropriate) may, whenever our interests so requires, convene a special or extraordinary shareholders' meeting. Pursuant to article 7:126 of the Belgian Companies and Associations Code, such general shareholders' meeting must also be convened when one or more shareholders holding, alone or together, at least 10% of our company's share capital so request. Shareholders that do not hold at least 10% of our share capital do not have the right to have the general shareholders' meeting convened.

Under the DGCL, special meetings of the stockholders of a Delaware corporation may be called by such person or persons as may be authorized by the certificate of incorporation or by the bylaws of the corporation, or if not so designated, as determined by the board of directors. Stockholders generally do not have the right to call meetings of stockholders unless that right is granted in the certificate of incorporation or the bylaws.

Notices convening shareholders' meetings

Notices convening our shareholders' meeting must state the place, date and hour of the meeting, must include an agenda indicating the items to be discussed and the proposed resolutions that will be submitted at the meeting, and will be published at least 15 calendar days prior to the general shareholders' meeting on our company's website. At the same time as its publication, the convening notice must also be sent to the holders of registered shares, holders of registered convertible bonds, holders of registered subscription rights (warrants), holders of registered certificates issued with the co-operation of the Company (if any), and, as the case may be, to the directors and statutory auditor of the Company. This communication needs to be made by e-mail unless the addressee has informed the Company that it wishes to receive the relevant documentation by another equivalent means of communication. If the relevant addressee does not have an e-mail address or if it did not inform the Company thereof, the relevant documentation will be sent by ordinary mail. The aforementioned convening rules apply for as long as the company's shares and subscription rights remain in registered form.

See also "—Voting Rights attached to the common shares" below. The term of 15 calendar days prior to the general shareholders' meeting for the publication and distribution of the convening notice can be reduced to 10 calendar days for a second meeting if, as the case may be, the applicable quorum for the meeting is not reached at the first meeting, the date of the second meeting was mentioned in the notice for the first meeting and no new item is put on the agenda of the second meeting. See also further below under "—Quorum and majority requirements."

Notices of all our shareholders' meetings and all documents submitted to such meetings, such as special board and auditor's reports, will also be published on our website.

Under the DGCL, unless otherwise provided in the certificate of incorporation or by-laws, written notice of any meeting of the stockholders of a Delaware corporation must be given to each stockholder entitled to vote at the meeting not less than 10 nor more than 60 days before the date of the meeting and shall specify the place, date, hour, and, in the case of a special meeting, the purpose of the meeting.

Admission to meetings

All holders of shares, subscription rights (warrants), profit-sharing certificates, non-voting shares, convertible bonds, or other securities issued by our Company, as the case may be, and all holders of certificates issued with the co-operation of our Company (if any) can attend the general shareholders' meetings insofar as the law or the articles of association entitle them to do so and, as the case may be, give them the right to participate in voting. The articles of association determine the formalities that shareholders need to fulfill to be admitted to the general shareholders' meeting. As the case may be, the formalities for the registration of securities holders, and the notification of our Company must be described in the notice convening the general shareholders' meeting.

The board of directors shall have the ability to determine that the right to attend the general shareholders' meetings and to exercise the voting right at such meetings (as the case may be) is determined by the registration of the ownership of the securities concerned in the name of the holder of such securities on the third business day prior to the date of the relevant general shareholders' meeting (or such other date as shall be set out in the notice convening the general shareholders' meeting, but which cannot be earlier than the 15th calendar date before the relevant general shareholders' meeting), at midnight at the end of such day (Brussels time) (such date and hour being the relevant registration date), by means of the registration of such securities in the relevant (portion of the split) register book for such securities, or in the accounts of a certified account holder or relevant settlement institution for the securities concerned. The board of directors may also make participation to the general shareholders' meetings dependent on a requirement of notification by the securities holders concerned to the Company, or to the person appointed for this purpose by the Company, on a date to be determined by the board of directors before the date of the scheduled meeting, that such securities holder intends to attend the meeting, stating the number of securities with which such securities holder wishes to participate. The manner in which such notification must be made (as the case may be) must be set out in the notice convening the general shareholders' meeting.

Electronic participation

Our board of directors has the possibility to organize the general shareholders' meeting by means of electronic communication which must (i) allow our company to verify the capacity and identity of the shareholders using it; (ii) at least enable (a) the securities holders to directly, simultaneously and continuously follow the discussions during the meeting and (b) the shareholders to exercise their voting rights on all points on which the general shareholders' meeting is required to take a decision; and (iii) allow the securities holders to actively participate to the deliberations and to ask questions during the meeting.

Voting by proxy or remote voting

Each shareholder has, subject to compliance with the requirements set forth above under "—Admission to meetings", the right to attend a general shareholders' meeting and to vote at the general shareholders' meeting in person or through a proxy holder, who need not be a shareholder. The appointment of a proxy holder must be made in accordance with the applicable rules of Belgian law, including in relation to conflicts of interest and the keeping of a register.

The notice convening the meeting may allow shareholders to vote remotely in relation to the general shareholders' meeting, by sending a paper form or, if specifically allowed in the notice convening the meeting, by sending a form electronically (in which case the form shall be signed by means of an electronic signature in accordance with applicable Belgian law). These forms shall be made available by our company. The original signed paper form must be received by our company within the term specified by the articles of association. Voting through the signed electronic form may occur until the last calendar day before the meeting.

Our company may also organize a remote vote in relation to the general shareholders' meeting through other electronic communication methods, such as, among others, through one or several websites. Our company shall specify the practical terms of any such remote vote in the convening notice.

When votes are cast electronically, an electronic confirmation of receipt of the votes is sent to the relevant shareholders that cast the vote. After the general shareholders' meeting, shareholders can obtain, at least upon request (which must be made no later than three months after the vote), the confirmation that their votes have been validly recorded and taken into account by the Company, unless that information is already available to them.

Holders of securities who wish to be represented by proxy or vote remotely must, in any case comply with the formalities to attend the meeting, as explained under "—Admission to Meetings." Holders of shares without voting rights, profit-sharing certificates without voting rights, convertible bonds, subscription rights (warrants) or certificates issued with the cooperation of our company may attend the general shareholders' meeting but only with an advisory vote.

Voting rights attached to the common shares

Each shareholder of the Company is entitled to one vote per common share. Shareholders may vote by proxy, subject to the rules described in "—Right to attend and vote at general shareholders' meetings" and "—Voting by proxy or remote voting."

Voting rights can also be suspended in relation to shares:

- which are not fully paid-up, notwithstanding the request thereto of our board of directors;
- to which more than one person is entitled or on which more than one person has rights *in rem* (*zakelijke rechten/ droits réels*), except in the event a single representative is appointed for the exercise of the voting right vis-à- vis our company;
- which entitle their holder to voting rights above the threshold of 25% of the total number of voting rights attached to the outstanding financial instruments of our company on the date of the relevant general shareholders' meeting, in the event that the relevant shareholder has not notified us at least 20 calendar days prior to the date of our general shareholders' meeting in accordance with the applicable rules of the Belgian Companies and Associations Code; or

- of which the voting right was suspended by a competent court.

Pursuant to the Belgian Companies and Associations Code, the voting rights attached to shares owned by the Company, or a person acting in its own name but on behalf of the Company, or acquired by a subsidiary of the Company, as the case may be, are suspended.

Generally, the general shareholders' meeting has sole authority with respect to:

- the approval of the annual financial statements of our company;
- the distribution of profits (except interim dividends (see "—Dividends"));
- the appointment and dismissal of directors of our company;
- the appointment and dismissal of the statutory auditor of our company;
- the granting of release from liability to the directors and the statutory auditor of our company;
- the determination of the remuneration of the directors and of the statutory auditor for the exercise of their mandate;
- the filing of a claim for liability against directors;
- the decisions relating to the dissolution, merger and certain other reorganizations of our company; and
- the approval of amendments to our articles of association.

Quorum and majority requirements

In general, there is no attendance quorum requirement for a general shareholders' meeting and decisions are passed with a simple majority of the votes of the shares present or represented. However, capital increases (other than those decided by the board of directors pursuant to the authorized capital), decisions with respect to our company's dissolution, mergers, de-mergers and certain other reorganizations of our company, amendments to the articles of association (other than an amendment of the corporate purpose), and certain other matters referred to in the Belgian Companies and Associations Code do not only require the presence or representation of at least 50% of the share capital of our company but also a majority of at least 75% of the votes cast (whereby abstentions are not included in the numerator nor in the denominator). An amendment of our company's corporate purpose requires the approval of at least 80% of the votes cast at a general shareholders' meeting (whereby abstentions are not included in the numerator nor in the denominator), which can only validly pass such resolution if at least 50% of the share capital of our company and at least 50% of the profit certificates, if any, are present or represented. In the event where the required quorum is not present or represented at the first meeting, a second meeting needs to be convened through a new notice. The second general shareholders' meeting may validly deliberate and decide regardless of the number of shares present or represented. The special majority requirements, however, remain applicable.

Under the DGCL, the certificate of incorporation or bylaws of a Delaware corporation may specify the number of shares required to constitute a quorum but in no event shall a quorum consist of less than one-third of shares entitled to vote at a meeting. In the absence of such specifications, a majority of shares entitled to vote shall constitute a quorum.

Right to ask questions

Within the limits of Article 7:139 of the Belgian Companies and Associations Code, security holders have a right to ask questions to the directors in connection with the report of the board of directors or the items on the agenda of such general shareholders' meeting. However, directors may, in the interest of our company, refuse to answer questions when the communication of certain information or facts could cause prejudice to our company or is contrary to the obligations of confidentiality entered into by them or by our company.

Shareholders can also ask questions to the statutory auditor in connection with its report. Such questions can

be submitted in writing prior to the meeting or can be asked at the meeting. Written questions to the statutory auditor must be submitted to our company at the same time as questions to the directors. The statutory auditor may, in the interest of our company, refuse to answer questions when the communication of certain information or facts could cause prejudice to our company or is contrary to its professional secrecy or to obligations of confidentiality entered into by our company. The statutory auditor has the right to speak at the general meeting in connection with the performance of its duties.

Written and oral questions will be answered during the meeting concerned in accordance with applicable law. In addition, in order for written questions to be considered, the shareholders who submitted the written questions concerned must comply with the formalities to attend the meeting, as explained under "—Admission to Meetings."

Dividends and other distributions

Under Belgian law, companies can make distributions to shareholders either as dividends of profits or as a return of capital from a reduction of share capital or issue premium.

Dividends of profits

All shares participate equally in our company's profits (if any). Pursuant to the Belgian Companies and Associations Code, the shareholders can in principle decide on the distribution of profits with a simple majority vote at the occasion of the annual general shareholders' meeting, based on the most recent non-consolidated statutory audited financial statements, prepared in accordance with Belgian GAAP and based on a (non-binding) proposal of the Company's board of directors. The Belgian Companies and Associations Code and the Company's articles of association also authorize the board of directors to declare interim dividends without shareholder approval.

The right to pay such interim dividends is, however, subject to certain legal restrictions.

Our ability to distribute dividends is subject to availability of sufficient distributable profits as defined under Belgian law on the basis of our stand-alone statutory accounts prepared in accordance with accounting principles generally accepted in Belgium, or Belgian GAAP (and hence not on the basis of the IFRS consolidated accounts). In particular, dividends can only be distributed if, following the declaration and issuance of the dividends, the amount of our net assets on the date of the closing of the last financial year as shown on the stand-alone statutory financial statements (i.e., summarized, the amount of the assets as shown on the balance sheet, decreased by provisions and liabilities, and, save in exceptional cases, to be mentioned and justified in the notes to the annual accounts, decreased by the non-amortized costs of incorporation and extension and the non-amortized costs for research and development, all in accordance with Belgian GAAP), does not fall below the amount of the paid-up capital (or, if higher, the issued capital), increased by the amount of non-distributable reserves (which include, as the case may be, the unamortized part of any revaluation surpluses).

Furthermore, pursuant to Belgian law and our articles of association, we must allocate each year an amount of at least 5% of our annual net profit under our stand-alone statutory accounts (prepared in accordance with Belgian GAAP) to a legal reserve on our stand-alone statutory accounts, until the legal reserve amounts to 10% of our share capital. Our legal reserve currently does not meet this requirement. Accordingly, 5% of our annual net profit under our stand-alone statutory accounts (prepared in accordance with Belgian GAAP) during future years will need to be allocated to the legal reserve, further limiting our ability to pay out dividends to our shareholders.

In addition, further financial restrictions and other limitations may be contained in future credit agreements.

The right to payment of dividends expires five years after the board of directors declared the dividend payable.

Under the DGCL, a Delaware corporation may pay dividends out of its surplus (the excess of net assets over capital), or in case there is no surplus, out of its net profits for either or both of the fiscal year in which the dividend is declared and the preceding fiscal year (provided that the amount of the capital of the corporation is not less than the aggregate amount of the capital represented by the issued and outstanding stock of all classes having a preference upon the distribution of assets). Dividends may be paid in the form of shares, property or cash.

Return of capital via reduction of share capital or issue premium

All shares will be entitled to participate in the same manner if we return our capital to our shareholders via reducing our share capital or issue premium. Pursuant to the Belgian Companies and Associations Code, reducing our share capital would require an amendment to our articles of association. As described above, such an amendment would be subject to approval of 75% of the votes of our shareholders cast at a shareholders' meeting at which at least 50% of the share capital is represented, or, where quorum was not reached at the first meeting, a subsequent meeting to which quorum requirements will not apply. Subject to the foregoing requirements, we can return our share capital to shareholders as long as it is not reduced to less than a certain *de minimis* amount. A reduction of our issue premium would not constitute an amendment to our articles of association, but would be subject to the same approval and quorum requirements as such an amendment.

Furthermore, if we return capital to shareholders, creditors who have a receivable that has not yet been paid by us, or have an outstanding claim that is subject to arbitration or litigation, can, within two months following the publication of the shareholder approval of the capital return, demand collateral to secure their receivable or claim.

Appointment of directors

Pursuant to the Belgian Companies and Associations Code and the articles of association, the board of directors must consist of at least three directors and no more than nine directors.

Liquidation rights

Our company can only be voluntarily dissolved by a shareholders' resolution passed with a majority of at least 75% of the votes cast at an extraordinary shareholders' meeting where at least 50% of the share capital is present or represented. In the event the required quorum is not present or represented at the first meeting, a second meeting needs to be convened through a new notice. The second meeting of shareholders can validly deliberate and decide regardless of the number of shares present or represented.

Under the DGCL, unless the board of directors approves the proposal to dissolve, dissolution of a Delaware corporation must be approved by stockholders holding 100% of the total voting power of the corporation. Only if the dissolution is initiated by the board of directors may it be approved by a simple majority of the corporation's outstanding shares. The DGCL allows a Delaware corporation to include in its certificate of incorporation a supermajority voting requirement in connection with dissolutions initiated by the board.

In the event of the dissolution and liquidation of our company, the assets remaining after payment of all debts and liquidation expenses will be distributed to the holders of our shares, each receiving a sum on a pro rata basis.

Pursuant to article 7:228 of the Belgian Companies and Associations Code, if, as a result of losses incurred, the ratio of our net assets (determined in accordance with Belgian legal and accounting rules for non-consolidated financial statements) to share capital is less than 50%, the board of directors must convene an extraordinary general shareholders' meeting within two months as of the date upon which the board of directors discovered or should have discovered this undercapitalization. At this general shareholders' meeting the board of directors needs to propose either the dissolution of the Company or the continuation of the Company, in which case the board of directors must propose measures to ensure the Company's continuity. The board of directors must justify its proposals in a special report to the shareholders. Shareholders representing at least 75% of the votes validly cast at this meeting have the right to dissolve the

Company, provided that at least 50% of our share capital is present or represented at the meeting. In the event the required quorum is not present or represented at the first meeting, a second meeting needs to be convened through a new notice. The second shareholders' meeting can validly deliberate and decide regardless of the number of shares present or represented.

If, as a result of losses incurred, the ratio of the Company's net assets to share capital is less than 25%, the same procedure must be followed, it being understood, however, that in that event shareholders representing 25% of the votes validly cast at the meeting can decide to dissolve the Company.

Pursuant to article 7:229 of the Belgian Companies and Associations Code, if the amount of the Company's net assets has dropped below €61,500 (the minimum amount of share capital of a corporation with limited liability organized under the laws of Belgium (*naamloze vennootschap/société anonyme*)), any interested party is entitled to request the competent court to dissolve the Company. The court can order the dissolution of the Company or grant a grace period within which the Company is to remedy the situation.

If the Company is dissolved for any reason, the liquidation must in principle be carried out by one or more liquidators appointed by the general shareholders' meeting and whose appointment has been ratified by the enterprise court. Any balance remaining after discharging all debts, liabilities and liquidation costs must first be applied to reimburse, in cash or in kind, the paid-up capital of the shares not yet reimbursed. Any remaining balance shall be equally distributed amongst all the shareholders.

On the date of this Annual Report, the Company's net equity is positive and does not fall within the scope of the articles 7:228 or 7:229 of the Belgian Companies and Associations Code.

Belgian legislation

Disclosure/notification of significant shareholdings

Pursuant to Article 7:83 of the Belgian Companies and Associations Code, when a natural or legal person directly or indirectly acquires dematerialized voting securities that cause that person to hold 25% or more of the total voting rights of the company as of the date of the transaction, such person must notify the company of the total number of securities held by them within five working days following the day of acquisition. This notification is also compulsory within the same period in case of a transfer of securities when such transfer results in the voting rights falling below the 25% threshold mentioned above.

The obligation to disclose significant shareholdings as well as certain other provisions of Belgian law (e.g., merger control, foreign investment screening and authorized capital) that may apply to the Company, may make an unsolicited tender offer, merger, change in management or other change in control, more difficult. Such provisions could discourage potential takeover attempts that third parties may consider and that other shareholders may consider to be in their best interest and could adversely affect the market price of the shares. These provisions may also deprive shareholders of the opportunity to sell their shares at a premium (which is typically offered in the context of a takeover bid).

The Belgian Act of May 2, 2007 on the disclosure of significant shareholdings in issuers whose securities are admitted to trading on a regulated market and containing various provisions, as amended from time to time, does not apply to us. However, in accordance with U.S. federal securities laws, holders of our common shares and holders of ADSs will be required to comply with disclosure requirements relating to their ownership of our securities. Any person who, after acquiring beneficial ownership of our common shares or ADSs, is the beneficial owners of more than 5% of our outstanding common shares or common shares underlying ADSs must file with the SEC a Schedule 13D or Schedule 13G, as applicable, disclosing the information required by such schedules, including the number of our common shares or common shares underlying ADSs that such person has acquired (whether alone or jointly with one or more other persons). In addition, if any material change occurs in the facts set forth in the report filed on Schedule 13D (including a more than 1% increase or decrease in the percentage of the total shares beneficially owned), the beneficial owner must promptly file an amendment disclosing such change.

Public takeover bids

Public takeover bids in Belgium for the Company's shares and other securities giving access to voting rights (such as subscription rights or convertible bonds, if any) are subject to supervision by the FSMA. Any public takeover bid must be extended to all of the Company's voting securities, as well as all other securities giving access to voting rights. Prior to making a bid, a bidder must publish a prospectus which has been approved by the FSMA prior to publication.

Belgium has implemented the Thirteenth Company Law Directive (European Directive 2004/25/EC of April 21, 2004) by the Belgian Act of April 1, 2007 on public takeover bids, as amended, or the Belgian Takeover Act, and the Belgian Royal Decree of April 27, 2007 on public takeover bids, as amended, or the Belgian Takeover Decree. As the Company does not qualify as a listed company under Belgian law (as the Company's shares are not admitted to trading and listing on a regulated market within the European Economic Area), the requirement, provided for by the Belgian Act of April 1, 2007, to launch a mandatory bid for all of our outstanding shares and securities giving access to shares if a person, as a result of its own acquisition or the acquisition by persons acting in concert with it or by persons acting on their account, directly or indirectly holds more than 30% of the voting securities in a company that has its registered office in Belgium and of which at least part of the voting securities are traded on a regulated market or on a multilateral trading facility designated by the Belgian Royal Decree of April 27, 2007 does not apply. This may allow existing shareholders or new investors to acquire significant influence or control over the Company by acquiring the shares in the market without being required to acquire the other outstanding voting securities, as well as for all other securities that entitle the holders thereof to the subscription to, the acquisition of or conversion into voting securities.

There are several provisions of Belgian company law and certain other provisions of Belgian law, such as merger control, that may apply towards the Company and which may create hurdles to an unsolicited tender offer, merger, change in management or other change in control. These provisions could discourage potential takeover attempts that other shareholders may consider to be in their best interest and could adversely affect the market price of the shares of the Company. These provisions may also have the effect of depriving the shareholders of the opportunity to sell their shares at a premium.

In addition, pursuant to Belgian company law, the board of directors of Belgian companies may in certain circumstances, and subject to prior authorization by the shareholders, deter or frustrate public takeover bids through dilutive issuances of equity securities (pursuant to the authorized capital) or through share buy-backs (i.e. purchase of own shares). In principle, the authorization of the board of directors to increase the share capital of the Company through contributions in kind or in cash with cancellation or limitation of the preferential subscription right of the existing shareholders is suspended as of the notification to the Company by the FSMA of a public takeover bid on the securities of the Company. The general shareholders' meeting can, however, under certain conditions, expressly authorize the board of directors to increase the capital of the Company in such case by issuing shares in an amount of not more than 10% of the existing shares at the time of such a public takeover bid. (see also "—Changes to our share capital" and "—Share capital increases by our board of directors").

Our articles of association do not provide for any specific protective mechanisms against public takeover bids.

Squeeze-out

Pursuant to Article 7:82 of the Belgian Companies and Associations Code or the regulations promulgated thereunder, a person or legal entity, or different persons or legal entities acting alone or in concert, who own, at least 95% of the securities with voting rights in a limited liability company are entitled to acquire the totality of the securities with voting rights in that company following a squeeze-out offer. With the exception of the securities for which the owner has expressly indicated in writing that he does not wish to relinquish them, the securities not offered at the end of the procedure shall be deemed to have passed automatically to the person making a squeeze-out offer with consignment of the price.

Limitations on the right to own securities

Neither Belgian law nor our articles of association impose any general limitation on the right of non-residents or foreign persons to hold our securities or exercise voting rights on our securities other than those limitations that would generally apply to all shareholders. However, investors residing, incorporated or with an ultimate beneficiary owner based outside the European Union may have to obtain the prior approval of the Belgian Inter-Federal Screening Commission in order to hold certain important stakes of the voting rights in the Company, in each case in accordance with, and subject to, the applicable Belgian foreign investment screening regulations.

Transfer Agent and Registrar of Shares

Our share register for the underlying common shares is maintained by the Company. The share register reflects only record owners of our common shares. Holders of our ADSs will not be treated as our shareholders and their names will therefore not be entered in our share register. The depositary, the custodian or their nominees will be the holder of the common shares underlying our ADSs. Pursuant to the terms of the deposit agreement, holders of our ADSs have a right to receive the common shares underlying their ADSs.

American Depositary Shares

The following is a summary of what we believe to be the material terms of the deposit agreement. Notwithstanding this, because it is a summary, it may not contain all the information that the holder may otherwise deem important. For more complete information, the holder should read the entire deposit agreement and the form of the American Depositary Receipt, or ADR, filed as Exhibit 2.2 of our Annual Report. The Bank of New York Mellon serves as the depositary for the ADSs.

Each ADS represents one common share (or a right to receive one common share) deposited with ING Securities Services, Inc., as custodian for the depositary. Each ADS also represents any other securities, cash or other property that may be held by the depositary. The deposited shares together with any other securities, cash or other property held by the depositary are referred to as the deposited securities. The depositary's office at which the ADSs are administered and its principal executive office are located at 240 Greenwich Street, New York, New York 10286.

A holder may hold ADSs either (A) directly (i) by having an American Depositary Receipt, also referred to as an ADR, which is a certificate evidencing a specific number of ADSs, registered in the holder's name, or (ii) by having uncertificated ADSs registered in the holder's name, or (B) indirectly by holding a security entitlement in ADSs through the holder's broker or other financial institution that is a direct or indirect participant in The Depository Trust Company, also called DTC. If the holder holds ADSs directly, the holder is a registered ADS holder, also referred to as an ADS holder. This description assumes the holder is an ADS holder. If the holder holds the ADSs indirectly, the holder must rely on the procedures of the holder's broker or other financial institution to assert the rights of ADS holders described in this section. A holder should consult with the holder's broker or financial institution to find out what those procedures are.

Registered holders of uncertificated ADSs will receive statements from the depositary confirming their holdings.

As an ADS holder, the holder will not be treated as one of our shareholders and the holder will not have shareholder rights. Belgian law governs shareholder rights. The depositary will be the holder of the shares underlying the holder's ADSs. As a registered holder of ADSs, the holder will have ADS holder rights. A deposit agreement among us, the depositary, ADS holders and all other persons indirectly or beneficially holding ADSs sets out ADS holder rights as well as the rights and obligations of the depositary. New York law governs the deposit agreement and the ADSs.

The following is a summary of the material provisions of the deposit agreement. For more complete information, the holder should read the entire deposit agreement and the form of ADR. Directions on how

to obtain copies of those documents are provided in the section of the Annual Report titled “Where you can find additional information.”

Dividends and other distributions

How will a holder receive dividends and other distributions on the shares?

The depositary has agreed to pay or distribute to ADS holders the cash dividends or other distributions it or the custodian receives on shares or other deposited securities, upon payment or deduction of its fees and expenses. The holder will receive these distributions in proportion to the number of shares the holder’s ADSs represent.

- Cash. The depositary will convert any cash dividend or other cash distribution we pay on the shares into U.S. dollars, if it can do so on a reasonable basis and can transfer the U.S. dollars to the United States. If that is not possible or if any government approval is needed and cannot be obtained, the deposit agreement allows the depositary to distribute the foreign currency only to those ADS holders to whom it is possible to do so. It will hold the foreign currency it cannot convert for the account of the ADS holders who have not been paid. It will not invest the foreign currency and it will not be liable for any interest.

  Before making a distribution, any withholding taxes, or other governmental charges that must be paid will be deducted. See “Material income tax considerations”. The depositary will distribute only whole U.S. dollars and cents and will round fractional cents to the nearest whole cent. If the exchange rates fluctuate during a time when the depositary cannot convert the foreign currency, the holder may lose some of the value of the distribution.

- Shares. The depositary may distribute additional ADSs representing any shares we distribute as a dividend or free distribution. The depositary will only distribute whole ADSs. It will sell shares which would require it to deliver a fraction of an ADS (or ADSs representing those shares) and distribute the net proceeds in the same way as it does with cash. If the depositary does not distribute additional ADSs, the outstanding ADSs will also represent the new shares. The depositary may sell a portion of the distributed shares (or ADSs representing those shares) sufficient to pay its fees and expenses in connection with that distribution.

- Rights to purchase additional shares. If we offer holders of our securities any rights to subscribe for additional shares or any other rights, the depositary may (i) exercise those rights on behalf of ADS holders, (ii) distribute those rights to ADS holders or (iii) sell those rights and distribute the net proceeds to ADS holders, in each case after deduction or upon payment of its fees and expenses. To the extent the depositary does not do any of those things, it will allow the rights to lapse. In that case, the holder will receive no value for them. The depositary will exercise or distribute rights only if we ask it to and provide satisfactory assurances to the depositary that it is legal to do so. If the depositary will exercise rights, it will purchase the securities to which the rights relate and distribute those securities or, in the case of shares, new ADSs representing the new shares, to subscribing ADS holders, but only if ADS holders have paid the exercise price to the depositary. U.S. securities laws may restrict the ability of the depositary to distribute rights or ADSs or other securities issued on exercise of rights to all or certain ADS holders, and the securities distributed may be subject to restrictions on transfer.

- Other distributions. The depositary will send to ADS holders anything else we distribute on deposited securities by any means it thinks is legal, fair and practical. If it cannot make the distribution in that way, the depositary has a choice. It may decide to sell what we distributed and distribute the net proceeds, in the same way as it does with cash. Or, it may decide to hold what we distributed, in which case ADSs will also represent the newly distributed property. However, the depositary is not required to distribute any securities (other than ADSs) to ADS holders unless it receives satisfactory evidence from us that it is legal to make that distribution. The depositary may sell a portion of the distributed securities or property sufficient to pay its fees and expenses in connection with that distribution. U.S. securities laws may restrict the ability of the depositary to distribute securities to all or certain ADS holders, and the

securities distributed may be subject to restrictions on transfer.

The depositary is not responsible if it decides that it is unlawful or impractical to make a distribution available to any ADS holders. We have no obligation to register ADSs, shares, rights or other securities under the Securities Act. We also have no obligation to take any other action to permit the distribution of ADSs, shares, rights or anything else to ADS holders. This means that ADS holders may not receive the distributions we make on our shares or any value for them if it is illegal or impractical for us to make them available to the holder.

Deposit, withdrawal and cancellation

How are ADSs issued?

The depositary will deliver ADSs if the holder or the holder's broker deposits shares or evidence of rights to receive shares with the custodian. Upon payment of its fees and expenses and of any taxes or charges, such as stamp taxes or stock transfer taxes or fees, the depositary will register the appropriate number of ADSs in the names the holder request and will deliver the ADSs to or upon the order of the person or persons that made the deposit.

How can ADS holders withdraw the deposited securities?

The holder may surrender the holder's ADSs to the depositary for the purpose of withdrawal. Upon payment of its fees and expenses and of any taxes or charges, such as stamp taxes or stock transfer taxes or fees, the depositary will deliver the shares and any other deposited securities underlying the ADSs to the ADS holder or a person the ADS holder designates at the office of the custodian. Or, at the holder's request, risk and expense, the depositary will deliver the deposited securities at its office, if feasible. However, the depositary is not required to accept surrender of ADSs to the extent it would require delivery of a fraction of a deposited share or other security. The depositary may charge the holder a fee and its expenses for instructing the custodian regarding delivery of deposited securities.

When can ADSs be cancelled by the depositary?

The depositary may cancel ADSs if there are no underlying deposited securities, or those deposited securities have become apparently worthless or to the extent there are insufficient underlying deposited securities because of an increase in the number of shares represented by one ADS.

How do ADS holders interchange between certificated ADSs and uncertificated ADSs?

The holder may surrender the holder's ADR to the depositary for the purpose of exchanging the holder's ADR for uncertificated ADSs. The depositary will cancel that ADR and will send to the ADS holder a statement confirming that the ADS holder is the registered holder of uncertificated ADSs. Upon receipt by the depositary of a proper instruction from a registered holder of uncertificated ADSs requesting the exchange of uncertificated ADSs for certificated ADSs, the depositary will execute and deliver to the ADS holder an ADR evidencing those ADSs.

Voting rights

How does a holder vote?

ADS holders may instruct the depositary how to vote the number of deposited shares their ADSs represent. If we request the depositary to solicit the holder's voting instructions (and we are not required to do so), the depositary will notify the holder of a shareholders' meeting and send or make voting materials available to the holder. Those materials will describe the matters to be voted on and explain how ADS holders may instruct the depositary how to vote. For instructions to be valid, they must reach the depositary by a date set by the depositary. The depositary will try, as far as practical, subject to the laws of Belgium and the provisions of our articles of association or similar documents, to vote or to have its agents vote the deposited shares as instructed by ADS holders. If we do not request the depositary to solicit the holder's voting instructions, the holder can still send voting instructions, and, in that case, the depositary may try to vote as the holder instruct, but it is not required to do so.

Except by instructing the depositary as described above, the holder will not be able to exercise voting rights unless the holder surrenders the holder's ADSs and withdraws the shares. However, the holder may not know about the meeting enough in advance to withdraw the shares. In any event, the depositary will not exercise any discretion in voting deposited securities and it will only vote or attempt to vote as instructed.

We cannot assure a holder that the holder will receive the voting materials in time to ensure that the holder can instruct the depositary to vote the shares represented by the holder's ADSs. In addition, the depositary and its agents are not responsible for failing to carry out voting instructions or for the manner of carrying out voting instructions. *This means that the holder may not be able to exercise voting rights and there may be nothing the holder can do if the shares represented by the holder's ADSs are not voted as the holder requested.*

In order to give a holder a reasonable opportunity to instruct the depositary as to the exercise of voting rights relating to Deposited Securities, if we request the depositary to act, we agree to give the depositary notice of any such meeting and details concerning the matters to be voted upon at least 30 days in advance of the meeting date.

To the extent not prohibited by law or regulations, we and the depositary may, upon notice to ADS holders, agree to modify or adopt additional voting procedures from time to time.

Fees and expenses

Holders or persons depositing or withdrawing shares, surrendering ADSs, or to whom or from whom ADSs are delivered or cancelled, must pay:	For:
$10.00 (or less) per 100 ADSs (or portion of 100 ADSs)	Issuance of ADSs, including issuances resulting from a distribution of shares or rights or other property or in relation to a change in the number of shares represented by ADSs Surrender of ADSs for the purpose of withdrawal or cancellation of ADSs, including if the deposit agreement terminates or in relation to a change in the number of shares represented by ADSs
$.10 (or less) per ADS	Any cash distribution to ADS holders
A fee equivalent to the fee that would be payable if securities distributed to a holder had been shares and the shares had been deposited for issuance of ADSs	Distribution of securities distributed to holders of deposited securities (including rights) that are distributed by the depositary to ADS holders
Fees assessed from time to time, but not exceeding $.10 per ADS during any calendar year	Depositary services
Registration or transfer fees	Transfer and registration of shares on our share register to or from the name of the depositary or its agent when a holder deposits or withdraws shares
Expenses of the depositary	Cable (including SWIFT) and facsimile transmissions (when expressly provided in the deposit agreement) Converting foreign currency to U.S. dollars
Taxes and other governmental charges the depositary or the custodian has to pay on any ADSs or shares underlying ADSs, such as stock transfer taxes, stamp duty or withholding taxes	As necessary
Any charges incurred by the depositary or its agents for servicing the deposited securities	As necessary

The depositary collects its fees for delivery and surrender of ADSs directly from investors depositing shares or surrendering ADSs for the purpose of withdrawal or from intermediaries acting for them. The depositary collects fees for making distributions to investors by deducting those fees from the amounts distributed or by selling a portion of distributable property to pay the fees. The depositary may collect fees for depositary services by deduction from cash distributions or by directly billing investors or by charging the book-entry system accounts of participants acting for them. While aggregate fees for depositary services will not exceed $.10 per ADS in a calendar year, an investor may be charged more than one such fee in a consecutive 12-month period. The depositary may collect any of its fees by deduction from any cash distribution payable (or by selling a portion of securities or other property distributable) to ADS holders that are obligated to pay those fees. The depositary may generally refuse to provide fee-attracting services until its fees for those services are paid.

From time to time, the depositary may make payments to us to reimburse us for costs and expenses generally arising out of establishment and maintenance of the ADS program, waive fees and expenses for services provided to us by the depositary or share revenue from the fees collected from ADS holders. In performing its duties under the deposit agreement, the depositary may use brokers, dealers, foreign

currency dealers or other service providers that are owned by or affiliated with the depositary and that may earn or share fees, spreads or commissions.

The depositary may convert currency itself or through any of its affiliates, or the custodian or we may convert currency and pay U.S. dollars to the depositary. Where the depositary converts currency itself or through any of its affiliates, the depositary acts as principal for its own account and not as agent, advisor, broker or fiduciary on behalf of any other person and earns revenue, including, without limitation, transaction spreads, that it will retain for its own account. The revenue is based on, among other things, the difference between the exchange rate assigned to the currency conversion made under the deposit agreement and the rate that the depositary or its affiliate receives when buying or selling foreign currency for its own account. The depositary makes no representation that the exchange rate used or obtained by it or its affiliate in any currency conversion under the deposit agreement will be the most favorable rate that could be obtained at the time or that the method by which that rate will be determined will be the most favorable to ADS holders, subject to the depositary's obligation to act without negligence or bad faith. The methodology used to determine exchange rates used in currency conversions made by the depositary is available upon request. Where the custodian converts currency, the custodian has no obligation to obtain the most favorable rate that could be obtained at the time or to ensure that the method by which that rate will be determined will be the most favorable to ADS holders, and the depositary makes no representation that the rate is the most favorable rate and will not be liable for any direct or indirect losses associated with the rate. In certain instances, the depositary may receive dividends or other distributions from us in U.S. dollars that represent the proceeds of a conversion of foreign currency or translation from foreign currency at a rate that was obtained or determined by us and, in such cases, the depositary will not engage in, or be responsible for, any foreign currency transactions and neither it nor we make any representation that the rate obtained or determined by us is the most favorable rate and neither it nor we will be liable for any direct or indirect losses associated with the rate.

Payment of taxes

The holder will be responsible for any taxes or other governmental charges payable on the holder's ADSs or on the deposited securities represented by any of the holder's ADSs. The depositary may refuse to register any transfer of the holder's ADSs or allow the holder to withdraw the deposited securities represented by the holder's ADSs until those taxes or other charges are paid. It may apply payments owed to the holder or sell deposited securities represented by the holder's ADSs to pay any taxes owed and the holder will remain liable for any deficiency. If the depositary sells deposited securities, it will, if appropriate, reduce the number of ADSs to reflect the sale and pay to ADS holders any proceeds, or send to ADS holders any property, remaining after it has paid the taxes.

Tender and exchange offers; redemption, replacement or cancellation of deposited securities

The depositary will not tender deposited securities in any voluntary tender or exchange offer unless instructed to do so by an ADS holder surrendering ADSs and subject to any conditions or procedures the depositary may establish.

If deposited securities are redeemed for cash in a transaction that is mandatory for the depositary as a holder of deposited securities, the depositary will call for surrender of a corresponding number of ADSs and distribute the net redemption money to the holders of called ADSs upon surrender of those ADSs.

If there is any change in the deposited securities such as a sub-division, combination or other reclassification, or any merger, consolidation, recapitalization or reorganization affecting the issuer of deposited securities in which the depositary receives new securities in exchange for or in lieu of the old deposited securities, the depositary will hold those replacement securities as deposited securities under the deposit agreement. However, if the depositary decides it would not be lawful and practical to hold the replacement securities because those securities could not be distributed to ADS holders or for any other reason, the depositary may instead sell the replacement securities and distribute the net proceeds upon surrender of the ADSs.

If there is a replacement of the deposited securities and the depositary will continue to hold the

replacement securities, the depositary may distribute new ADSs representing the new deposited securities or ask the holder to surrender the holder's outstanding ADSs in exchange for new ADSs identifying the new deposited securities.

If there are no deposited securities underlying ADSs, including if the deposited securities are cancelled, or if the deposited securities underlying ADSs have become apparently worthless, the depositary may call for surrender of those ADSs or cancel those ADSs upon notice to the ADS holders.

Amendment and termination

How may the deposit agreement be amended?

We may agree with the depositary to amend the deposit agreement and the ADRs without the holder's consent for any reason. If an amendment adds or increases fees or charges, except for taxes and other governmental charges or expenses of the depositary for registration fees, facsimile costs, delivery charges or similar items, or prejudices a substantial right of ADS holders, it will not become effective for outstanding ADSs until 30 days after the depositary notifies ADS holders of the amendment. *At the time an amendment becomes effective, the holders are considered, by continuing to hold the holder's ADSs, to agree to the amendment and to be bound by the ADRs and the deposit agreement as amended.*

How may the deposit agreement be terminated?

The depositary will initiate termination of the deposit agreement if we instruct it to do so. The depositary may initiate termination of the deposit agreement if:

- 90 days have passed since the depositary told us it wants to resign but a successor depositary has not been appointed and accepted its appointment;
- we delist the ADSs from an exchange in the United States on which they were listed and do not list the ADSs on another exchange in the United States or make arrangements for trading of ADSs on the U.S. over-the-counter market;
- the depositary has reason to believe the ADSs have become, or will become, ineligible for registration on Form F-6 under the Securities Act of 1933;
- we appear to be insolvent or enter insolvency proceedings;
- all or substantially all the value of the deposited securities has been distributed either in cash or in the form of securities;
- there are no deposited securities underlying the ADSs or the underlying deposited securities have become apparently worthless; or
- there has been a replacement of deposited securities.

If the deposit agreement will terminate, the depositary will notify ADS holders at least 90 days before the termination date. At any time after the termination date, the depositary may sell the deposited securities. After that, the depositary will hold the money it received on the sale, as well as any other cash it is holding under the deposit agreement, unsegregated and without liability for interest, for the pro rata benefit of the ADS holders that have not surrendered their ADSs. Normally, the depositary will sell as soon as practicable after the termination date.

After the termination date and before the depositary sells, ADS holders can still surrender their ADSs and receive delivery of deposited securities, except that the depositary may refuse to accept a surrender for the purpose of withdrawing deposited securities or reverse previously accepted surrenders of that kind that have not settled if it would interfere with the selling process. The depositary may refuse to accept a surrender for the purpose of withdrawing sale proceeds until all the deposited securities have been sold. The depositary will continue to collect distributions on deposited securities, but, after the termination date, the depositary is not required to register any transfer of ADSs or distribute any dividends or other

distributions on deposited securities to ADS holders (until they surrender their ADSs) or give any notices or perform any other duties under the deposit agreement except as described in this paragraph.

Limitations on obligations and liability

Limits on our obligations and the obligations of the depositary; limits on liability to holders of ADSs

The deposit agreement expressly limits our obligations and the obligations of the depositary. It also limits our liability and the liability of the depositary. We and the depositary:

- are only obligated to take the actions specifically set forth in the deposit agreement without negligence or bad faith, and the depositary will not be a fiduciary or have any fiduciary duty to holders of ADSs;

are not liable if we are or it is prevented or delayed by law or by events or circumstances beyond our or its ability to prevent or counteract with reasonable care or effort from performing our or its obligations under the deposit agreement;

are not liable if we or it exercises discretion permitted under the deposit agreement;

- are not liable for the inability of any holder of ADSs to benefit from any distribution on deposited securities that is not made available to holders of ADSs under the terms of the deposit agreement, or for any special, consequential or punitive damages for any breach of the terms of the deposit agreement;

- have no obligation to become involved in a lawsuit or other proceeding related to the ADSs or the deposit agreement on the holder's behalf or on behalf of any other person;

- may rely upon any documents we believe or it believes in good faith to be genuine and to have been signed or presented by the proper person;

- are not liable for the acts or omissions of any securities depository, clearing agency or settlement system; and

- the depositary has no duty to make any determination or provide any information as to our tax status, and neither we nor the depositary have any liability for any tax consequences that may be incurred by ADS holders as a result of owning or holding ADSs or be liable for the inability or failure of an ADS holder to obtain the benefit of a foreign tax credit, reduced rate of withholding or refund of amounts withheld in respect of tax or any other tax benefit.

In the deposit agreement, we and the depositary agree to indemnify each other under certain circumstances.

Requirements for depositary actions

Before the depositary will deliver or register a transfer of ADSs, make a distribution on ADSs, or permit withdrawal of shares, the depositary may require:

- payment of stock transfer or other taxes or other governmental charges and transfer or registration fees charged by third parties for the transfer of any shares or other deposited securities;

- satisfactory proof of the identity and genuineness of any signature or other information it deems necessary; and

- compliance with regulations it may establish, from time to time, consistent with the deposit agreement, including presentation of transfer documents.

The depositary may refuse to deliver ADSs or register transfers of ADSs when the transfer books of the depositary or our transfer books are closed or at any time if the depositary or we think it advisable to do so.

The holder's right to receive the shares underlying the holder's ADSs

ADS holders have the right to surrender their ADSs and withdraw the underlying shares at any time except:

- when temporary delays arise because: (i) the depositary has closed its transfer books or we have closed our transfer books; (ii) the transfer of shares is blocked to permit voting at a shareholders' meeting; or (iii) we are paying a dividend on our shares;

- when the holder owes money to pay fees, taxes and similar charges; or

- when it is necessary to prohibit withdrawals in order to comply with any laws or governmental regulations that apply to ADSs or to the withdrawal of shares or other deposited securities.

This right of withdrawal may not be limited by any other provision of the deposit agreement.

Direct registration system

In the deposit agreement, all parties to the deposit agreement acknowledge that the Direct Registration System, also referred to as DRS, and Profile Modification System, also referred to as Profile, apply to the ADSs. DRS is a system administered by DTC that facilitates interchange between registered holding of uncertificated ADSs and holding of security entitlements in ADSs through DTC and a DTC participant. Profile is a feature of DRS that allows a DTC participant, claiming to act on behalf of a registered holder of uncertificated ADSs, to direct the depositary to register a transfer of those ADSs to DTC or its nominee and to deliver those ADSs to the DTC account of that DTC participant without receipt by the depositary of prior authorization from the ADS holder to register that transfer.

In connection with and in accordance with the arrangements and procedures relating to DRS/Profile, the parties to the deposit agreement understand that the depositary will not determine whether the DTC participant that is claiming to be acting on behalf of an ADS holder in requesting registration of transfer and delivery as described in the paragraph above has the actual authority to act on behalf of the ADS holder (notwithstanding any requirements under the Uniform Commercial Code). In the deposit agreement, the parties agree that the depositary's reliance on and compliance with instructions received by the depositary through the DRS/Profile system and in accordance with the deposit agreement will not constitute negligence or bad faith on the part of the depositary.

Shareholder communications; inspection of register of holders of ADSs

The depositary will make available for the holder's inspection at its office all communications that it receives from us as a holder of deposited securities that we make generally available to holders of deposited securities. The depositary will send the holder copies of those communications or otherwise make those communications available to the holder if we ask it to. The holder has a right to inspect the register of holders of ADSs, but not for the purpose of contacting those holders about a matter unrelated to our business or the ADSs.

Jury trial waiver

The deposit agreement provides that, to the extent permitted by law, ADS holders waive the right to a jury trial of any claim they may have against us or the depositary arising out of or relating to our shares, the ADSs or the deposit agreement, including any claim under the U.S. federal securities laws. If we or the depositary opposed a jury trial demand based on the waiver, the court would determine whether the waiver was enforceable in the facts and circumstances of that case in accordance with applicable case law.

The holder will not, by agreeing to the terms of the deposit agreement, be deemed to have waived our or the depositary's compliance with U.S. federal securities laws or the rules and regulations promulgated thereunder.

Exchange controls and limitations affecting shareholders

There are no Belgian exchange control regulations that impose limitations on our ability to make, or the amount of, cash payments to residents of the United States. We are in principle under an obligation to report to the National Bank of Belgium certain cross-border payments, transfers of funds, investments and other transactions in accordance with applicable balance-of-payments statistical reporting obligations. Where a cross-border transaction is carried out by a Belgian credit institution on our behalf, the credit institution will in certain circumstances be responsible for the reporting obligations.

Certain identified information has been excluded from this exhibit because it is both not material and is the type that the registrant treats as private or confidential. Information that was omitted has been noted in this document with a placeholder identified by the mark "[***]".

ADDENDUM V
TO THE NON-RESIDENTIAL LEASE AGREEMENT

This Addendum V is made in Touro on February 26, 2026, but shall have retroactive effect as of the 1st of January 2026.

BY AND BETWEEN

On the one hand, **Galchimia, S.A.** (hereinafter, "**Galchimia**"), a Spanish Company, with registered offices at [***], and holder of Spanish Tax Identification number [***], duly represented by Ms. María do Carme Pampín Casal, holding Spanish ID number [***], in her capacity as Managing Director ("*Consejera Delegada*").

And on the other hand, **Agomab Spain, S.L.U.** (hereinafter, "**Agomab**"), a Spanish Company, with registered offices at [***], and holder of Spanish Tax Identification number [***], duly represented by Mr. Tim Knotnerus, individual representing Agomab Therapeutics NV, in its capacity as Sole Director.

Hereinafter, Galchimia and Agomab may be referred to, jointly, as the "**Parties**" and, individually, as the "**Party**".

The Parties mutually recognize each other as having the necessary legal capacity to bind themselves pursuant to the terms of the present Addendum III and, to that effect,

WHEREAS

I. That on October 26th, 2021, Galchimia and Agomab (formerly known as Origo Biopharma, S.L.) entered into a non-residential lease agreement (*"Contrato de arrendamiento para uso distinto del de vivienda*") by virtue of which Galchimia, as lessor leases, to Agomab, as lessee, a specific area of the industrial building ("*nave industrial*") described in the aforementioned agreement (hereinafter, the "**Agreement**").

II. That on July 15th, 2022, the Parties entered into an addendum amending the Agreement (the "**Addendum I**") in which were modified the number of Users ("*Usuarios*") that will have access to the Area ("*Espacio*"), the amount of the Rent ("*Renta*") and the number of square meters of the leased Area.

III. That on March 27th, 2023, the Parties entered into an addendum amending the Agreement (the "**Addendum II**") in which were modified the number of Users ("*Usuarios*") that will have access to the Area ("*Espacio*"), the amount of the Rent ("*Renta*") and the number of square meters of the leased Area.

IV. That on April 18th, 2024, the Parties entered into an addendum amending the Agreement (the "**Addendum III**") in which were modified the number of Users ("*Usuarios*") that will have access to the Area ("*Espacio*"), the amount of the Rent ("*Renta*") and the number of square meters of the leased Area.

V. That on February 6th, 2025, the Parties entered into an addendum amending the Agreement (the "**Addendum IV**") in which were modified the number of Users ("*Usuarios*") that will have access to the Area ("*Espacio*"), the amount of the Rent ("*Renta*") and the number of square meters of the leased Area.

VI. That by virtue of clause 2.1.4 c) of the Agreement, the Parties wish to enter into this addendum to the Agreement for the purpose of modifying *the number of Users who will have access to the Area and the amount of the Rent / the number of Users who will have access to the Area, the amount of the Rent and the number of square meters of the Area to be leased* (hereinafter, the "**Addendum V**"), all in accordance with the following:

CLAUSES

FIRST.- DEFINITIONS AND CONSTRUCTION

Unless otherwise provided in this Addendum V, those terms, definitions or words expressed in capital letters and not expressly defined in this Addendum V, shall be construed as set forth and defined for them in the Agreement.

SECOND.- NUMBER OF USERS AND AMOUNT OF CURRENT RENT

The Parties agree to partially modify clause 2.1 of the Agreement, regarding the rent, effective as of the date of signature of this Addendum V, the wording of which shall hereinafter read as follows:

"2.1. Rent

2.1.1. In consideration for the lease of the Area, AGOMAB shall pay to GALCHIMIA the amounts detailed below:

*a. In consideration for the use of the Office Area, AGOMAB shall pay a monthly rent of **268.00.-€** per User, as this term is defined in Clause 2.1.4 below.*

(...)

*c. In addition, in consideration for the use of the Laboratory Area, AGOMAB shall pay a monthly rent of **793.00.-€** per User, as this term is defined in Clause 2.1.4 below.*

The above amount includes the use of one (1) laboratory cabinet per user, fully equipped for the execution of small-scale chemical synthesis projects. In addition,

the items listed in Clause 2.1.1 (b) above are also provided for AGOMAB 's use of the Laboratory Area.

(...)

2.1.5. The Parties declare that, as of the date of this Agreement, the total number of Users amounts to five (5), which are distributed as follows:

a. ***three(3)*** *Users for the Laboratory Area, and*

b. ***two(2)*** *Users for the Office Area.*

2.1.6. Pursuant to the provisions of this Clause 2, the Parties declare that the current amount to be paid by AGOMAB to GALCHIMIA as Rent, in exchange of the current number of Users of the Area, is set at ***2,379.00.-€*** *for the Laboratory Area, and* ***536.00.-€****, for the Office Area, being the total of both amounts of* ***2,915.00.-€*** *("Renta Actual").*

(...)"

THIRD.- CLOSING CLAUSE

All the provisions of the Agreement, the Addendum I, the Addendum II, Addendum III, and the Addendum IV shall remain in full force and effect, except for those that conflict with this Addendum V, as the latter shall prevail.

The legal regime applicable to this Addendum V in matters of jurisdiction, applicable law or any other circumstance not expressly regulated in this document shall be the same as the one provided for these matters in the Agreement.

In witness whereof, the Parties have signed this Addendum V in duplicate originals and for a single purpose, when applicable, as of the effective date and place indicated in the heading.

/s/ Carme Pampín Casal	/s/ Tim Knotnerus
GALCHIMIA, S.A.	**AGOMAB SPAIN, S.L.U.**
Ms. Carme Pampín Casal	AGOMAB THERAPEUTICS NV
	Mr. Tim Knotnerus

AGOMAB THERAPEUTICS NV

INSIDER TRADING POLICY

AgomAb Therapeutics NV (the "Company") has adopted the following policy and procedures for securities trading by Company directors and employees (our "Insider Trading Policy"). Our Insider Trading Policy is intended to prevent the misuse of material nonpublic information, insider trading in securities, and the severe consequences associated with violations of insider trading laws. It is your obligation to review, understand and comply with this Insider Trading Policy and applicable laws. Our board of directors (the "Board of Directors") has approved this Insider Trading Policy, and we have appointed a Compliance Officer (with their designees, the "Compliance Officer") to administer the policy and to be available to answer your questions.

PART I. OVERVIEW

A. Who Must Comply?

This Insider Trading Policy applies to all of our directors, members of the executive committee, employees and consultants, including anyone employed by or acting as a director of any of the Company's subsidiaries, as well as any other individuals whom the Compliance Officer may designate as Insiders (defined below).

In addition, all of our directors, members of the executive committee and any other employees designated by the Compliance Officer because they have access to material nonpublic information about the Company must comply with the Trading Procedures included in Part II of this Insider Trading Policy (the "Trading Procedures"); we will refer to these individuals in this policy as "Insiders." The Trading Procedures provide rules for when Insiders can trade in our securities and explain the process for mandatory pre-clearance of proposed trades. You will be notified if you are considered to be an Insider who is required to comply with the Trading Procedures.

This Insider Trading Policy and, for Insiders, the Trading Procedures also apply to the following persons ("Affiliated Persons"):

- your "Family Members" ("Family Members" are (a) your spouse or domestic partner, children, stepchildren, grandchildren, parents, stepparents, grandparents, siblings and in-laws who reside in the same household as you, (b) your children or your spouse's children who do not reside in the same household as you but are financially dependent on you, (c) any of your other family members who do not reside in your household but whose transactions are directed by you, and (d) any other individual over whose account you have control and to whose financial support you materially contribute. (Materially contributing to financial support would include, for example, paying an individual's rent but not just a phone bill.).);

- all trusts, family partnerships and other types of entities formed for your benefit or for the benefit of a member of your family and over which you have the ability to influence or direct investment decisions concerning securities;

- all persons who execute trades on your behalf; and

- all investment funds, trusts, retirement plans, partnerships, corporations and other types of entities over which you have the ability to influence or direct investment decisions concerning securities; provided, however, that the Trading Procedures do not apply to any such entity that engages in the investment of securities in the ordinary course of its business (e.g., an investment fund or partnership) if the entity has established its own insider trading controls and procedures in compliance with applicable securities laws and it (or an affiliated entity) has represented to the Company that its affiliated entities: (a) engage in the investment of securities in the ordinary course of their respective businesses; (b) have established insider trading controls and procedures in compliance with securities laws; and (c) are aware the securities laws prohibit any person or entity who has material nonpublic information concerning the Company from purchasing or selling securities of the Company or from communicating such information to any other person under circumstances in which it is reasonably foreseeable that such person is likely to purchase or sell securities.

You are responsible for ensuring compliance with this Insider Trading Policy, including the Trading Procedures contained herein, by all of your Affiliated Persons.

B. What is Prohibited by this Insider Trading Policy?

You and your Affiliated Persons are prohibited from engaging in insider trading and from otherwise trading in securities in violation of this Insider Trading Policy. "Insider trading" is (1) trading (buying or selling) the securities of a company whether for your account or for the account of another, while in the possession of material nonpublic information (see definition below) about that company or (2) disclosing material nonpublic information about a company to others who may trade on the basis of that information. Insider trading can result in criminal prosecution, jail time, significant fines and public embarrassment for you and the Company.

Prohibition on Trading in Company Securities

When you are in possession of material nonpublic information about the Company, whether positive or negative, you are prohibited from trading (whether for your account of for the account of another) in the Company's securities, which includes common shares, options to purchase common shares, any other type of securities that the Company may issue (such as preferred shares, convertible debentures, warrants and exchange-traded options), and any derivative securities that provide the economic equivalent of ownership of any of the Company's securities or an opportunity, direct or indirect, to profit from any change in the value of the Company's securities, except for trades made pursuant to plans approved by the Compliance Officer in accordance with this policy that are intended to comply with Rule 10b5-1 under the Securities Exchange Act of 1934, as amended (the "Exchange Act").

The trading prohibitions in this Insider Trading Policy do not apply to: (1) an exercise of an employee stock option when payment of the exercise price is made in cash or (2) the withholding by the Company of shares upon vesting of restricted stock or upon settlement of restricted stock units to satisfy applicable tax withholding requirements if (a) such withholding is required by the applicable plan or award agreement or (b) the election to exercise such tax withholding right was made by the Insider in compliance with the Trading Procedures.

The trading prohibitions in this Insider Trading Policy do apply, however, to the use of outstanding Company securities to pay part or all of the exercise price of a stock option, any sale of shares as part of a broker-assisted cashless exercise of an option and any other market sale for the purpose of generating the cash needed to pay the exercise price of an option.

Restricted Trading Periods

From time to time, in connection with an announcement of material information about the Company or when significant developments or announcements are anticipated, we may impose a temporary prohibition on trading in our securities that applies to specified groups of employees or, in rare instances, all persons covered by this policy. In such event, you will be notified by e-mail and/or other means of the imposition and expected duration of the trading prohibition. During that period, no person covered by such a notice may trade in our securities (subject to the limited exceptions set forth in this policy).

Prohibition on Tipping

Providing material nonpublic information about the Company to another person who may trade or advise others to trade on the basis of that information is known as "tipping" and is illegal. You are prohibited from providing material nonpublic information about the Company to a friend, relative or anyone else who might buy or sell a security or other financial instrument on the basis of that information, whether or not you intend to or actually do realize a profit (or any other benefit) from such tipping. Additionally, you are prohibited from recommending to any person that such person engage in or refrain from engaging in any transaction involving the Company's securities, or otherwise give trading advice concerning the Company's securities, if you are in possession of material nonpublic information about the Company.

Prohibition on Trading in Securities of Other Companies

This policy's prohibitions against insider trading and tipping also apply to trading in securities of other companies, including the Company's customers, suppliers, partners and other enterprises with which we are working (such as when negotiating an acquisition, investment or other transaction that could be material to the other company). Whenever, during the course of your service to or employment by the Company, you become aware of material nonpublic information about another company, including any confidential information that is reasonably likely to affect the market price of that company's securities (for example, discussions of licensing a product or acquiring that other company), neither you nor your Affiliated Persons may trade in any securities of that company, give trading advice about that company, tip or disclose that information, pass it on to others or engage in any other action to take advantage of that information.

If your work regularly involves handling or discussing confidential information of companies in either of the foregoing categories, you should consult with the Compliance Officer before trading in any of those company's securities.

Additionally, if you believe you may be in possession of nonpublic information about the Company that could potentially have a material effect on the stock price of a company with which the Company does not have an existing business relationship or with which the Company is not discussing a potential transaction or business relationship, you should exercise caution when trading in the securities of that company because the U.S. Securities and Exchange Commission (the "SEC ") has successfully brought an insider trading claim against an insider in those circumstances.

Other Prohibited Transactions

- ***No Short Sales***. You may not at any time sell any securities of the Company that are not owned by you at the time of the sale (a "short sale").

- ***No Purchases or Sales of Derivative Securities or Hedging Transactions***. You may not buy or sell puts, calls, other derivative securities of the Company or any derivative securities that provide the economic equivalent of ownership of any of the Company's securities or an opportunity, direct or indirect, to profit from any change in the value of our securities or engage in any other hedging transaction with respect to our securities.

- ***No Company Securities Subject to Margin Calls***. You may not use the Company's securities as collateral in a margin account.

- ***No Pledges***. The Company strongly discourages pledging Company securities as collateral for a loan (or modifying an existing pledge for the same). Any person who wishes to pledge Company securities as collateral for a loan must submit a request for approval to the Compliance Officer prior to the proposed execution of documents evidencing the proposed pledge and such request shall be considered trading in securities for purposes of the Pre-Clearance Procedures.

See "Transactions in mutual, exchange-traded or index funds" for more information.

Duration of Trading Prohibitions

These trading prohibitions continue whenever and for as long as you know or are in possession of material nonpublic information. Remember, anyone scrutinizing your transactions will be doing so after the fact, with the benefit of hindsight. As a practical matter, before engaging in any transaction, you should carefully consider even the appearance of improper insider trading and how enforcement authorities and others might view the transaction in hindsight.

This Insider Trading Policy applies to you and your Affiliated Persons so long as you are associated with the Company. If you leave the Company for any reason, this Insider Trading Policy, including, if applicable, the Trading Procedures described in Part III, will continue to apply to you and your Affiliated Persons until the first trading day after any material nonpublic information known to you has become public or is no longer material.

C. What is Material Nonpublic Information?

This Insider Trading Policy prohibits you from trading in a company's securities if you are in possession of information about the company that is both "*material*" and "*nonpublic*." If you have a question whether certain information you are aware of is material or has been made public, you should consult with the Compliance Officer.

"Material" Information

Information about our Company or any other company is "material" if it could reasonably be expected to affect the investment decisions of a shareholder or potential investor or if disclosure of the information could reasonably be expected to significantly alter the total mix of information in the marketplace about us or any other company. We speak mostly in this Insider Trading Policy about determining whether information about us is material and nonpublic, but the same analysis applies to

information about other companies covered by this policy that would preclude you from trading in their securities.

In simple terms, material information is any type of information that could reasonably be expected to affect the market price of our securities. Both positive and negative information may be material. While it is not possible to identify all information that would be deemed "material," the following items are examples of the types of information that could be material:

- significant new scientific discoveries or other events, late-stage preclinical development achievements or failures from any lead or other important preclinical programs, clinical program developments, filing of an Investigational New Drug Application or other significant regulatory events or interactions, relevant regulatory changes, data that have been recently generated from ongoing or recently completed clinical trials;

- plans to pursue, entry into, or termination of a major licensing, partnership, collaboration, manufacturing or supply agreement, or changes in relationships, including significant disputes, with major licensors, licensees, partners, collaborators, manufacturers, or suppliers;

- projections of future earnings or losses, or other earnings guidance;

- quarterly financial results that are known but have not been publicly disclosed;

- potential restatements of the Company's financial statements, changes in auditors or auditor notification that the Company may no longer rely on an auditor's audit report;

- pending or proposed corporate mergers, acquisitions, tender offers, joint ventures or dispositions of significant assets;

- changes in senior management or member of our Board of Directors;

- significant actual or threatened litigation or governmental investigations or major developments in such matters;

- cybersecurity risks and incidents, including the discovery of significant vulnerabilities or breaches;

- significant developments regarding products, suppliers, orders, contracts or financing sources (e.g., the acquisition or loss of a contract);

- developments regarding any programs in clinical development or subject to regulatory approval, including recent regulatory interaction and/or data that have been recently generated from ongoing or recently completed clinical trials;

- developments regarding the intellectual property and/or freedom to operate for any of the current programs or product candidates under development;

- changes in dividend policy, declarations of stock splits or proposed securities offerings or other financings;

- potential defaults under our credit agreements or indentures or potential material liquidity issues; and

- bankruptcies or receiverships.

The above items will not always be material. For example, some new products or contracts may clearly be material while others may not be. No "bright-line" standard or list of items can adequately address the range of situations that may arise; information and events should be carefully considered in terms of their materiality to the Company.

"Nonpublic" Information

Material information is "nonpublic" if it has not been disseminated in a manner making it available to investors generally.

To demonstrate that information is public, one must be able to point to some fact that establishes that the information has become publicly available, such as the filing of a report with the SEC, the distribution of a press release, publishing the information on our website or posting on social media if those are regular ways we communicate with investors, or by other means that are reasonably designed to provide broad public access. Before a person with material nonpublic information can trade, the market must have adequate time to absorb the information that has been disclosed. For the purposes of this Insider Trading Policy, information will be considered public after the completion of one full day of trading following our public release of the information. For that purpose, a full day of trading means an entire calendar day in which a session of regular trading hours on Nasdaq between 9:30 a.m. and 4:00 p.m. Eastern Time (or such earlier close time as has been set by exchange rules) has occurred.

For example, if the Company publicly discloses material nonpublic information of which you are aware before trading begins on a Tuesday, the first time you can buy or sell Company securities is the opening of the market on the following Wednesday. However, if the Company publicly discloses material information after trading begins on a Tuesday, the first time that you can buy or sell Company securities is the opening of the market on the following Thursday.

D. What are the Penalties for Insider Trading and Noncompliance with this Insider Trading Policy?

Both the SEC and the national securities exchanges, through the Financial Industry Regulatory Authority ("FINRA"), investigate and are very effective at detecting insider trading. The U.S. government pursues insider trading violations vigorously, successfully prosecuting, for example, trading by employees in foreign accounts, trading by family members and friends of insiders and trading involving only a small number of shares.

The penalties for violating rules against insider trading can be severe and include:

- forfeiting any profit gained or loss avoided by the trading;
- payment of the loss suffered by the persons who, contemporaneously with the purchase or sale of securities that are subject of a violation, have purchased or sold securities of the same class;
- payment of criminal penalties of up to $5,000,000;
- payment of civil penalties of up to three times the profit made or loss avoided; and
- imprisonment for up to 20 years.

The Company and/or the supervisors of the person engaged in insider trading may also be required to pay civil penalties or fines of $2.5 million or more, up to three times the profit made or loss avoided, as

well as criminal penalties of up to $25,000,000, and could under some circumstances be subject to private lawsuits.

Violation of this Insider Trading Policy or any federal or state insider trading laws may subject you to disciplinary action by the Company, including termination of your employment or other relationship with the Company. The Company reserves the right to determine, in its own discretion and on the basis of the information available to it, whether this Insider Trading Policy has been violated. The Company may determine that specific conduct violates this Insider Trading Policy whether or not it also violates the law. It is not necessary for the Company to await the filing or conclusion of a civil or criminal action against an alleged violator before taking disciplinary action.

E. How Do You Report a Violation of this Insider Trading Policy?

If you have a question about this Insider Trading Policy, including whether certain information you are aware of is material or has been made public, you should consult with the Compliance Officer. In addition, if you violate this Insider Trading Policy or any federal or state laws governing insider trading or know of any such violation by any director or employee of the Company, you should report the violation immediately to the Compliance Officer.

PART II. TRADING PROCEDURES

A. Special Trading Restrictions Applicable to Insiders

In addition to needing to comply with the restrictions on trading in our securities set forth above, Insiders and their Affiliated Persons are subject to the following special trading restrictions:

1. Special Closed Trading Periods

The Compliance Officer may designate, from time to time, a "Special Closed Window" during what would otherwise be a permitted trading window. During a Special Closed Window, designated Insiders (which could be all Insiders or a subset of them) may not trade in the Company's securities. The Compliance Officer may also impose a Special Closed Window on Insiders or a subset of them to prohibit trading in the securities of other companies, including specified peers or competitors of the Company. The imposition of a Special Closed Window will not be announced to the Company generally, should not be communicated to any other person, and may itself be considered under this Insider Trading Policy to be material nonpublic information about the Company.

2. Gifts and Other Distributions in Kind.

No Insider may donate or make any other transfer of Company securities without consideration when the Insider is not permitted to trade. In addition to charitable donations or gifts to family members, friends, trusts or others, this prohibition applies to distributions to limited partners by limited partnerships that are subject to this Insider Trading Policy. Making a gift shall be considered trading in securities for purposes of the Pre-Clearance Procedures and Post-Trade Reporting Procedures in Section II.B. below.

B. Pre-Clearance Procedures

No Insider may trade in our securities, even during an open trading window, unless the trade has been approved by the Compliance Officer in accordance with the procedures described below. Gifts of Company securities are considered a trade in securities for purposes of this Part II.B. In reviewing trading requests, the Compliance Officer may consult with our other members of the executive committee and/or outside legal counsel and will seek approval of their own trades from the Chief Financial Officer.

1. Procedures. No Insider may trade in our securities unless:

- The Insider has notified the Compliance Officer of the amount and nature of the proposed trade(s) using the Stock Transaction Request form attached to this Insider Trading Policy;
- The Insider has certified to the Compliance Officer in writing before the proposed trade(s) that the Insider does not possess material nonpublic information concerning the Company;
- If the Insider is a member of the executive committee or director, the Insider has informed the Compliance Officer, using the Stock Transaction Request form, whether, to the Insider's best knowledge, if the transaction involves a sale by an "affiliate" of the Company or of "restricted securities" (as such terms are defined under Rule 144 under the Securities Act of 1933, as amended ("Rule 144")), whether the transaction meets all of the applicable conditions of Rule 144; and
- The Compliance Officer has approved the trade(s) and has certified their approval in writing (which may be by email).

The Compliance Officer does not assume responsibility for, and approval by the Compliance Officer does not protect the Insider from, the consequences of prohibited insider trading.

2. Additional Information.

Insiders shall provide to the Compliance Officer any documentation the Compliance Officer reasonably requires in furtherance of the foregoing procedures. Any failure to provide such information will be grounds for the Compliance Officer to deny approval of the trade request.

3. No Obligation to Approve Trades.

The foregoing approval procedures do not in any way obligate the Compliance Officer to approve any trade. The Compliance Officer has sole discretion to reject any trading request.

From time to time, an event may occur that is material to the Company and is known by only by a limited number of directors and employees. The Compliance Officer may decline an Insider's request to preclear a proposed trade based on the existence of a material nonpublic development – even if the Insider is not aware of that material nonpublic development. If any Insider engages in a trade before a material nonpublic development is disclosed to the public or resolved, the Insider and the Company might be exposed to a charge of insider trading that could be costly and difficult to refute even if the Insider was

unaware of the development. So long as the event remains material and nonpublic, the Compliance Officer may decide not to approve any transactions in the Company's securities. The Compliance Officer will subsequently notify the Insider once the material nonpublic development is disclosed to the public or resolved. If an Insider requests preclearance of a trade during the pendency of such an event, the Compliance Officer may reject the trading request without disclosing the reason.

4. Completion of Trades.

After receiving written clearance to engage in a trade signed by the Compliance Officer, an Insider must complete the proposed trade within three (3) business days or make a new trading request. Even if an Insider has received clearance, the Insider may not engage in a trade if (i) such clearance has been rescinded by the Compliance Officer, (ii) the Insider has otherwise received notice that the trading window has closed or (iii) the Insider has or acquires material nonpublic information.

5. Post-Trade Reporting.

The details of any transactions in our securities (including transactions effected pursuant to a Rule 10b5-1 Plan) by an Insider (or an Affiliated Person), must be reported to the Compliance Officer by the Insider or their brokerage firm on the same day on which a trade is completed. The report shall include the date of the transaction, quantity of shares, the price, the name of the broker-dealer that effected the transaction and whether the trade was made pursuant to a valid Rule 10b5-1 Plan (as defined below). This reporting requirement may be satisfied by providing (or having the Insider's broker provide) a trade ~~order~~ confirmation to the Compliance Officer if the Compliance Officer receives such information by the required date.

C. Exemptions

1. Pre-Approved Rule 10b5-1 Plan.

Transactions made pursuant to an approved Rule 10b5-1 Plan (as defined below) will not be subject to our trading windows or pre-clearance procedures and Insiders are not required to complete a Stock Transaction Request form for such transactions. Rule 10b5-1 of the Exchange Act provides an affirmative defense from insider trading liability under the federal securities laws for trading plans, arrangements or instructions that meet specified requirements. A trading plan, arrangement or instruction that meets the requirements of the SEC's Rule 10b5-1 (a "Rule 10b5-1 Plan") enables Insiders to trade in Company securities outside of our trading windows, even when in possession of material nonpublic information.

The Company has adopted a Rule 10b5-1 Trading Plan Policy, attached as Annex A to this Insider Trading Policy, that sets forth the requirements for putting in place a Rule 10b5-1 Plan with respect to Company securities.

2. Employee Equity.

Exercise of Stock Options. The trading prohibitions and restrictions set forth in the Trading Procedures do not apply to the exercise for cash of an option to purchase securities of the Company. In addition, the securities acquired upon the exercise of an option to purchase Company securities are subject to all of the requirements of this Insider Trading Policy, including the Trading Procedures. Moreover, the Trading Procedures apply to the use of outstanding Company securities to pay part or all of the exercise price of an option, any net option exercise, any exercise of a stock appreciation right, share withholding and

any sale of shares as part of a broker-assisted cashless exercise of an option or any other market sale for the purpose of generating the cash needed to pay the exercise price of an option.

Tax Withholding on Restricted Stock/Units. The trading prohibitions and restrictions set forth in the Trading Procedures do not apply to the withholding by the Company of shares upon vesting of restricted stock or upon settlement of restricted stock units to satisfy tax withholding requirements if (a) withholding is required by the applicable plan or award agreement or (b) the election to exercise the tax withholding right was made by the Insider in compliance with the Trading Procedures.

3. Transactions in mutual, exchange-traded or index funds.

Transactions in mutual, exchange-traded or index funds that hold Company securities are generally not transactions subject to this Insider Trading Policy. However, you should exercise caution when engaging in transactions in mutual, exchange-traded or index funds that hold Company securities. Transactions in mutual, exchange-traded or index funds may constitute an insider trading violation if you become aware of material non-public information that could materially affect the value of the mutual or index fund as a whole.

D. Waivers

A waiver of any provision of this Insider Trading Policy or the Trading Procedures may be authorized in writing by the Compliance Officer or the Audit Committee of the Board of Directors. All waivers shall be reported to the Board of Directors.

PART III. AMENDMENT

This Insider Trading Policy may be amended from time to time with the approval of the Board of Directors. Following any such amendment, the Compliance Officer shall as soon as reasonably practicable notify and make the amended Insider Trading Policy available to all persons subject to it via email or electronic delivery, corporate intranet posting, and/or other mechanism designed to reach such persons. Any amendment to this Insider Trading Policy shall be effective once such transmission or posting is first made.

PART IV. ACKNOWLEDGEMENT

We will deliver a copy of this Insider Trading Policy to all current employees and directors and consultants and to future employees and directors at the start of their employment or relationship with the Company. Each of these individuals must acknowledge that they have received a copy and agree to comply with the terms of this Insider Trading Policy, and, if applicable, the Trading Procedures contained herein. The attached acknowledgment must be completed and submitted to the Company within ten days of receipt to:

Ellen Lefever
General Counsel
AgomAb Therapeutics NV
Posthoflei 1/6
2600 Antwerpen, Belgium
legal@agomab.com

From time to time, directors and employees and consultants may be required to re-acknowledge and agree to comply with the Insider Trading Policy (including any amendments or modifications).

* * *

Questions regarding this Insider Trading Policy are encouraged and may be directed to the Compliance Officer.

ADOPTED: December 9, 2025
EFFECTIVE: February 6, 2026

EXHIBIT A

STOCK TRANSACTION REQUEST

Pursuant to **AgomAb Therapeutics NV**'s Insider Trading Policy, I hereby notify **AgomAb Therapeutics NV** (the "Company") of my intent to trade the securities of the Company as indicated below:

REQUESTER INFORMATION

Insider's Name: _____

INTENT TO PURCHASE

Number of shares: _____

Intended trade date: _____

Means of acquiring shares:

☐ Acquisition through employee benefit plan (please specify): _____

☐ Purchase through a broker on the open market

☐ Other (please specify): _____

INTENT TO SELL

Number of shares: _____

Intended trade date: _____

Means of selling shares:

☐ Sale through employee benefit plan (please specify): _____

☐ Sale through a broker on the open market

☐ Other (please specify): _____

RULE 144 (Not applicable if transaction requested involves a purchase)

☐ I am not an "affiliate" of the Company and the transaction requested above does not involve the sale of "restricted securities" (as those terms are defined in Rule 144 under the Securities Act of 1933, as amended).

☐ To the best of my knowledge, the transaction requested above will meet all of the applicable conditions of Rule 144.

☐ The transaction requested will be made pursuant to an effective registration statement covering such transaction.

☐ None of the above.

CERTIFICATION

I hereby certify that I am not (1) in possession of any material nonpublic information concerning the Company, as defined in the Company's Insider Trading Policy and (2) purchasing any securities of the Company on margin in contravention of the Company's Trading Procedures. I understand that, if I trade while possessing such information or in violation of such trading restrictions, I may be subject to severe civil and/or criminal penalties and may be subject to discipline by the Company including termination of my employment.

Insider's Signature	Date

APPROVAL

Signature of Compliance Officer (or designee)	Date

**NOTE: Multiple lots must be listed on separate forms or broken out.*

EXHIBIT B

ACKNOWLEDGEMENT

I hereby acknowledge that I have read, that I understand, and that I agree to comply with the Insider Trading Policy of AgomAb Therapeutics NV (the "Company"). I further acknowledge and agree that I am responsible for ensuring compliance with the Insider Trading Policy and the Trading Procedures by all of my "Affiliated Persons." I also understand and agree that I will be subject to sanctions, including termination of employment, that may be imposed by the Company, in its sole discretion, for violation of the Insider Trading Policy, and that the Company may give stop-transfer and other instructions to the Company's transfer agent or any brokerage firm managing the Company's equity incentive plan(s) against the transfer of any Company securities that the Company considers to be in contravention of the Insider Trading Policy.

This acknowledgement constitutes consent for the Company to impose sanctions for violation of the Insider Trading Policy, including the Trading Procedures, and to issue any stop-transfer orders to the Company's transfer agent that the Company, in its sole discretion, deems appropriate to ensure compliance.

I hereby designate the following investment funds and partnerships as entities for which the Trading Procedures shall not apply: _____

_____. I hereby represent to the Company that such entities: (a) engage in the investment of securities in the ordinary course of their respective businesses; (b) have established insider trading controls and procedures in compliance with applicable securities laws; and (c) are aware such securities laws prohibit any person or entity who has material, nonpublic information concerning the Company from purchasing or selling securities of the Company or from communicating such information to any other person under circumstances in which it is reasonably foreseeable that such person is likely to purchase or sell securities.

Date: _____ Signature: _____

Name: _____

Title: _____

Send signed acknowledgement to:

Ellen Lefever
General Counsel
AgomAb Therapeutics NV
Posthoflei 1/6
2600 Antwerpen, Belgium
legal@agomab.com

ANNEX A

Rule 10b5-1 Trading Plan Policy

This Rule 10b5-1 Trading Plan Policy should be read in conjunction with the Company's insider trading policy (the "Insider Trading Policy"). Specifically, Part II, Section C of the Insider Trading Policy provides that transactions made pursuant to an approved Rule 10b5-1 Plan will not be subject to the trading windows or pre-clearance procedures set forth in the Insider Trading Policy. Terms used in this Rule 10b5-1 Trading Plan Policy and not otherwise defined have the meanings set forth in the Insider Trading Policy. Rule 10b5-1(c) under the Exchange Act provides an affirmative defense against allegations of insider trading. This affirmative defense is often referred to as a "safe harbor" from such allegations. The Rule 10b5-1(c) safe harbor is available to the Company's employees, members of the executive committee and directors who make trades pursuant to a trading "plan" that meets the requirements of the rule. A plan that meets the requirements of the Rule 10b5-1(c) safe harbor is referred to herein as a "Trading Plan." Trading Plans may be used for purchases, sales, gifts or other transfers of securities.

The Company allows Insiders to enter into Trading Plans, but only if those plans are pre-approved in writing by our Compliance Officer or their designee(s). The Compliance Officer is assigned the job of approving any Trading Plan as to its form. Most brokerage firms will provide a form Trading Plan that is used for all clients. All Trading Plans adopted after the effective date of this Rule 10b5-1 Trading Plan Policy and any amendment to, modification of, or termination of a Trading Plan adopted after the effective date of this Rule 10b5-1 Trading Plan Policy must comply with Rule 10b5-1 and must meet the following minimum conditions:

1. **Trading Plan Requirements.**

    a. **Plan and Approval.** Each Trading Plan proposed to be entered into by an Insider must be approved in writing by the Compliance Officer prior to its effectiveness. The Trading Plan must be in writing and signed by the Insider. The Trading Plan must include a written representation by the Insider that they are not aware of any material nonpublic information concerning the Company and that they are adopting the Trading Plan in good faith and not as part of a plan or scheme to evade the prohibitions of Section 10(b) and Rule 10b-5 of the Exchange Act. We will keep a copy of each Trading Plan in our files.

    b. **Timing and Term of Plan.** Each Trading Plan used by an Insider must be adopted (a) when the trading window for the Insider is open under our Insider Trading Policy; and (b) when the Insider does not otherwise possess material nonpublic information about the Company. Except with the prior written approval of the Compliance Officer, each Trading Plan entered into by any Insider of the Company must be structured to remain in place for at least one year; provided however, a Trading Plan may be less than one year in duration if the plan solely covers either (a) stock options expiring within one year or (b) selling of a portion of the shares upon vesting of restricted stock units in order to primarily cover estimated applicable tax liability. Except with the prior written approval of the Compliance Officer, each Trading Plan entered into by any Insider must be structured to remain in place no longer than two years after the effective date of such plan.

c. **Timing of Plan Amendment and Modification; Termination of Plans.** Trading Plans may be amended or modified only (a) when the trading window for the Insider is open under our Insider Trading Policy; (b) when the Insider does not possess material nonpublic information about the Company; and (c) with the written approval of the Compliance Officer. Trading Plans may be terminated only (a) when the trading window for the Insider is open under our Insider Trading Policy; (b) when the Insider does not possess material nonpublic information about the Company; and (c) with the written approval of the Compliance Officer.

d. **Delayed Effectiveness of Adoption or Amendment/Modification.** Each Trading Plan used by an Insider must include a "cooling off" period prior to the first trade.

   For members of the Company's executive committee and members of the Company's board of directors, the Trading Plan must provide that the first transaction executed pursuant to the Trading Plan may not occur until the later of (i) the 91st day after adoption, amendment or modification of the plan and (ii) the third business day following the disclosure of the Company's financial results in a Form 6-K or Form 20-F for the period in which the plan was adopted, amended or modified. With respect to the period described in clause (ii), the required cooling off period need not exceed 120 days.

   For Insiders who are not members of the executive committee or directors, the Trading Plan must provide that the first transaction executed pursuant to the Trading Plan may not occur until 31 days following the adoption, amendment or modification of the Trading Plan, as applicable.

e. **Relationships with Plan Broker/Administrator; No Subsequent Influence.** Each Trading Plan used by an Insider must provide that the Insider may not communicate any material nonpublic information about the Company to the broker or other third party administering the plan, or attempt to influence how the broker or such party executes (or exercises its discretion in executing) orders or other transactions under the Trading Plan in any way.

f. **Plan Specifications; Discretion Regarding Transactions Under the Plan.** The Trading Plan must authorize the broker or other third party administering the plan to effect the transactions called for by the plan without any control or influence by you. The Trading Plan must specify the material parameters for the transactions to be effected under the plan. For example, for a plan that will provide for the purchase or sale of shares, the plan must specify the amount of shares to be purchased or sold during specified time periods and the price at which such shares are to be purchased or sold, or the plan may specify or set an objective formula (e.g., share price thresholds) for determining the price and amount of shares to be purchased or sold during specified time periods. The Compliance Officer may require that the specified time periods contained in your Trading Plan during which sales could occur shall not coincide with the specified time periods in similar Trading Plans adopted by other insiders (e.g., to avoid a particular part of a quarter when earnings will be released), or make other arrangements (such as sale volume limitations) to avoid a large number of sales occurring simultaneously or to comply with any required company policy regarding share ownership.

g. **Only One Plan in Effect at Any Time.** Unless otherwise approved by the Compliance Officer in situations where having multiple plans in place at one time is permissible under the provisions of Rule 10b5-1, an Insider may have only one Trading Plan in effect at any time. However, an Insider may adopt a new Trading Plan to replace an existing Trading Plan before the scheduled termination date of such existing Trading Plan so long as the new Trading Plan does not become effective prior to the completion of or expiration of transactions under the existing Trading Plan, in all cases consistent with Rule 10b5-1, and the new Trading Plan must comply with the cooling off period and other requirements of this Policy. In addition, an Insider may have in place an additional Trading Plan in connection with sell-to-cover transactions as necessary to satisfy tax withholding obligations incident to the vesting of a compensatory award from the Company such as restricted stock, restricted stock units or stock appreciation rights and where the Insider does not control the timing of such sales.

h. **Limitations on Single Trade Plans.** During any 12-month period, an Insider may only enter into one Trading Plan that is designed to effect the purchase or sale or other transfer of the total amount of the Company's securities covered by the Trading Plan in a single transaction; provided, however, an Insider may have in place an additional non-concurrent single-trade Trading Plan during this same 12-month period in connection with sell-to-cover transactions as necessary to satisfy tax withholding obligations incident to the vesting of a compensatory award from the Company such as restricted stock, restricted stock units or stock appreciation rights and where the Insider does not control the timing of such sales.

i. **Suspensions.** Each Trading Plan used by an Insider must provide for suspension of transactions under such plan if legal, regulatory or contractual restrictions are imposed on the Insider, or other events occur, that would prohibit transactions under such plan.

j. **Compliance with Rule 144.** Each Trading Plan used by an Insider must provide for specific procedures to comply with Rule 144 under the Securities Act of 1933, as amended, including the filing of Form 144.

k. **Broker Obligation to Provide Notice of Trades.** For members of the Company's executive committee and members of the Company's board of directors, each Trading Plan must provide that the broker will provide notice of any transactions under the Trading Plan to the Insider and the Company no later than the close of business on the day of the transaction.

l. **Required Footnote Disclosure.** Insiders must footnote all trades disclosed on Form 144.

Exhibit 12.1

Certification by the Principal Executive Officer
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Tim Knotnerus, certify that:

1. I have reviewed this annual report on Form 20-F of AgomAb Therapeutics NV (the "Company");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Company as of, and for, the periods presented in this report;

4. The Company's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the Company and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Evaluated the effectiveness of the Company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(c) Disclosed in this report any change in the Company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting; and

5. The Company's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Company's auditors and the audit committee of the Company's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Company's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the Company's internal control over financial reporting.

Date: April 23, 2026

By: /s/ Tim Knotnerus
Name: Tim Knotnerus
Title: *Chief Executive Officer*
(Principal Executive Officer)

Exhibit 12.2

Certification by the Principal Financial Officer
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Pierre Kemula, certify that:

1. I have reviewed this annual report on Form 20-F of AgomAb Therapeutics NV (the "Company");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Company as of, and for, the periods presented in this report;

4. The Company's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the Company and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Evaluated the effectiveness of the Company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(c) Disclosed in this report any change in the Company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting; and

5. The Company's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Company's auditors and the audit committee of the Company's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Company's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the Company's internal control over financial reporting.

Date: April 23, 2026

By: /s/ Pierre Kemula
Name: Pierre Kemula
Title: *Chief Financial Officer*
(Principal Financial Officer)

Exhibit 13.1

Certification Pursuant to 18 U.S.C. Section 1350,
as Adopted Pursuant to Section 906 Of The Sarbanes-Oxley Act of 2002

Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, Tim Knotnerus, the Chief Executive Officer, and Pierre Kemula, the Chief Financial Officer, of AgomAb Therapeutics NV (the "Company"), hereby certify, that, to their knowledge:

(1) The Annual Report on Form 20-F for the year ended December 31, 2025 (the "Report") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: April 23, 2026

By: /s/ Tim Knotnerus
Name: Tim Knotnerus
Title: *Chief Executive Officer*
(Principal Executive Officer)

By: /s/ Pierre Kemula
Name: Pierre Kemula
Title: *Chief Financial Officer*
(Principal Financial Officer)

Exhibit 15.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statement on Form S-8 (No. 333-294220) of AgomAb Therapeutics NV of our report dated April 23, 2026 relating to the financial statements, which appears in this Form 20-F.

PwC Bedrijfsrevisoren BV / Reviseurs d'Entreprises SRL
Represented by

/s/ Didier Delanoye
Statutory auditor

Diegem, Belgium
April 23, 2026

AGOMAB THERAPEUTICS NV

COMPENSATION RECOVERY POLICY

AgomAb Therapeutics NV, a Belgian corporation (the "Company"), has adopted a Compensation Recovery Policy (this "Policy") as described below.

1. Overview

The Policy sets forth the circumstances and procedures under which the Company shall recover Erroneously Awarded Compensation from Covered Persons (as defined below) in accordance with rules issued by the United States Securities and Exchange Commission (the "SEC") under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and the Nasdaq Stock Market. Capitalized terms used and not otherwise defined herein shall have the meanings given in Section 3 below.

2. Compensation Recovery Requirement

In the event the Company is required to prepare a Financial Restatement, the Company shall recover reasonably promptly all Erroneously Awarded Compensation with respect to such Financial Restatement.

3. Definitions

a. "Applicable Recovery Period" means the three completed fiscal years immediately preceding the Restatement Date for a Financial Restatement. In addition, in the event the Company has changed its fiscal year: (i) any transition period of less than nine months occurring within or immediately following such three completed fiscal years shall also be part of such Applicable Recovery Period and (ii) any transition period of nine to 12 months will be deemed to be a completed fiscal year.

b. "Applicable Rules" means any rules or regulations adopted by the Exchange pursuant to Rule 10D-1 under the Exchange Act and any applicable rules or regulations adopted by the SEC pursuant to Section 10D of the Exchange Act.

c. "Board" means the Board of Directors of the Company.

d. "Committee" means the Remuneration, Nomination and Corporate Governance Committee of the Board or, in the absence of such committee, a majority of independent directors serving on the Board.

e. "Covered Person" means any members of the executive committee and any other person designated by the Board or the Committee as being subject to this Policy. A person's status as a Covered Person with respect to Erroneously Awarded Compensation shall be determined as of the time of receipt of such Erroneously Awarded Compensation regardless of the person's current role or status with the Company (e.g., if a person began service as an Executive Officer after the beginning of an Applicable Recovery Period, that person would not be considered a Covered Person with respect to Erroneously Awarded Compensation received before the person began service as an Executive Officer, but would be considered a Covered Person with respect to Erroneously Awarded Compensation received after the

person began service as an Executive Officer where such person served as an Executive Officer at any time during the performance period for such Erroneously Awarded Compensation).

f. "Effective Date" means February 6, 2026.

g. "Erroneously Awarded Compensation" means the amount of any Incentive-Based Compensation received by a Covered Person on or after the Effective Date and during the Applicable Recovery Period that exceeds the amount that otherwise would have been received by the Covered Person had such compensation been determined based on the restated amounts in a Financial Restatement, computed without regard to any taxes paid. Calculation of Erroneously Awarded Compensation with respect to Incentive-Based Compensation based on stock price or total shareholder return, where the amount of Erroneously Awarded Compensation is not subject to mathematical recalculation directly from the information in a Financial Restatement, shall be based on a reasonable estimate of the effect of the Financial Restatement on the stock price or total shareholder return upon which the Incentive-Based Compensation was received, and the Company shall maintain documentation of the determination of such reasonable estimate and provide such documentation to the Exchange in accordance with the Applicable Rules. Incentive-Based Compensation is deemed received, earned or vested when the Financial Reporting Measure is attained, not when the actual payment, grant or vesting occurs.

h. "Exchange" means the Nasdaq Stock Market LLC.

i. A "Executive Officer" means any person who served the Company in any of the following roles at any time during the performance period applicable to Incentive-Based Compensation and received Incentive-Based Compensation after beginning service in any such role (regardless of whether such Incentive-Based Compensation was received during or after such person's service in such role): the president, principal executive officer, principal financial officer, principal accounting officer (or if there is no such accounting officer the controller), any vice president in charge of a principal business unit, division or function (such as sales, administration or finance), any other officer who performs a policy making function or any other person who performs similar policy making functions for the Company. Executive officers of parents or subsidiaries of the Company may be deemed executive officers of the Company if they perform such policy making functions for the Company.

j. "Financial Reporting Measures" mean measures that are determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, any measures that are derived wholly or in part from such measures (including, for example, a non-GAAP financial measure), and stock price and total shareholder return.

k. "Incentive-Based Compensation" means any compensation provided, directly or indirectly, by the Company or any of its subsidiaries that is granted, earned or vested based, in whole or in part, upon the attainment of a Financial Reporting Measure and any other equity-based compensation provided by the Company or any of its subsidiaries, including, without limitation, stock options, restricted stock awards, restricted stock units and stock

appreciation rights. For avoidance of doubt, Incentive-Based Compensation is "received" for purposes of this Policy in fiscal period during which the Financial Reporting Measure specified in the Incentive-Based Compensation award is attained, even if the payment or grant of such Incentive-Based Compensation occurs after the end of that period.

l. A "Financial Restatement" means a restatement of previously issued financial statements of the Company due to the material noncompliance of the Company with any financial reporting requirement under the securities laws, including any required restatement to correct an error in previously-issued financial statements that is material to the previously-issued financial statements or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period.

m. "Restatement Date" means, with respect to a Financial Restatement, the earlier to occur of: (i) the date the Board concludes, or reasonably should have concluded, that the Company is required to prepare the Financial Restatement or (ii) the date a court, regulator or other legally authorized body directs the Company to prepare the Financial Restatement.

4. Exception to Compensation Recovery Requirement

The Company may elect not to recover Erroneously Awarded Compensation pursuant to this Policy if the Committee determines that recovery would be impracticable, and one or more of the following conditions, together with any further requirements set forth in the Applicable Rules, are met: (i) the direct expense paid to a third party, including outside legal counsel, to assist in enforcing this Policy would exceed the amount to be recovered, and the Company has made a reasonable attempt to recover such Erroneously Awarded Compensation; (ii) recovery would cause the Company to violate a law of Belgium that was adopted prior to November 28, 2022, and the Company obtains an opinion of Belgian counsel that recovery would result in a violation of such country's law and provides the opinion to the Exchange; or (iii) recovery would likely cause an otherwise tax-qualified retirement plan to fail to be so qualified under applicable regulations.

5. Tax Considerations

To the extent that, pursuant to this Policy, the Company is entitled to recover any Erroneously Awarded Compensation that is received by a Covered Person, the gross amount received (i.e., the amount the Covered Person received, or was entitled to receive, before any deductions for tax withholding or other payments) shall be returned by the Covered Person.

6. Method of Compensation Recovery

The Committee shall determine, in its sole discretion, the method for recovering Erroneously Awarded Compensation hereunder, which may include, without limitation, any one or more of the following:

a. requiring reimbursement of cash Incentive-Based Compensation previously paid;

b. seeking recovery of any gain realized on the vesting, exercise, settlement, sale, transfer or other disposition of any equity-based awards;

c. cancelling or rescinding some or all outstanding vested or unvested equity-based awards;

d. adjusting or withholding from unpaid compensation or other set-off, to the extent permissible under applicable laws;

e. cancelling or offsetting against planned future grants of equity-based awards; and/or

f. any other method permitted by applicable law or contract.

The Committee need not utilize the same method of recovery from all Covered Persons or with respect to all types of Erroneously Awarded Compensation.

A Covered Person will be deemed to have satisfied such person's obligation to return Erroneously Awarded Compensation to the Company if such Erroneously Awarded Compensation is returned in the exact same form in which it was received; provided that equity withheld to satisfy tax obligations will be deemed to have been received in cash in an amount equal to the tax withholding payment made.

In the event the Company is required to recover Erroneously Awarded Compensation from a Covered Person who is no longer an employee, the Company is entitled to seek such recovery in order to comply with applicable law, regardless of the terms of any release of claims or separation agreement such individual may have signed.

7. Policy Interpretation

This Policy shall be interpreted in a manner that is consistent with the Applicable Rules and any other applicable law. The Committee shall take into consideration any applicable interpretations and guidance of the SEC in interpreting this Policy, including, for example, in determining whether a financial restatement qualifies as a Financial Restatement hereunder. To the extent the Applicable Rules require recovery of Incentive-Based Compensation in additional circumstances besides those specified above, nothing in this Policy shall be deemed to limit or restrict the right or obligation of the Company to recover Incentive-Based Compensation to the fullest extent required by the Applicable Rules.

8. Policy Administration

This Policy shall be administered by the Committee; provided, however, that the Board shall have exclusive authority to authorize the Company to prepare a Financial Restatement. In doing so, the Board may rely on a recommendation of the Audit Committee of the Board. The Committee shall have such powers and authorities related to the administration of this Policy as are consistent with the governing documents of the Company and applicable law. The Committee shall have full power and authority to take, or direct the taking of, all actions and to make all determinations required or provided for under this Policy and shall have full power and authority to take, or direct the taking of, all such other actions and make all such other determinations not inconsistent with the specific terms and provisions of this Policy that the Committee deems to be necessary or appropriate to the administration of this Policy. The interpretation and construction by the Committee of any provision of this Policy and all determinations made by the Committee under this policy shall be final, binding and conclusive.

9. Compensation Recovery Repayments not Subject to Indemnification

Notwithstanding anything to the contrary set forth in any agreement with, or the organizational documents of, the Company or any of its subsidiaries, Covered Persons are not entitled to indemnification for Erroneously Awarded Compensation or for any losses arising out of or in any way related to Erroneously Awarded Compensation recovered under this Policy.

10. No Impairment of Other Remedies

Nothing contained in this Policy, and no recoupment or recovery as contemplated herein, shall limit any claims, damages or other legal remedies the Company or any of its affiliates may have against a Covered Person arising out of or resulting from any actions or omissions by the Covered Person. This Policy does not preclude the Company from taking any other action to enforce a Covered Person's obligations to the Company, including, without limitation, termination of employment and/or institution of civil proceedings. This Policy is in addition to the requirements of Section 304 of the Sarbanes-Oxley Act of 2002 ("SOX 304") that are applicable to the Company's Chief Executive Officer and Chief Financial Officer and to any other compensation recoupment policy and/or similar provisions in any employment, equity plan, equity award, or other individual agreement, to which the Company is a party or which the Company has adopted or may adopt and maintain from time to time; provided, however, that compensation recouped pursuant to this Policy shall not be duplicative of compensation recouped pursuant to SOX 304 or any such compensation recoupment policy and/or similar provisions in any such employment, equity plan, equity award, or other individual agreement except as may be required by law.

11. Recovery Requirement Shall not Constitute "Good Reason" Under Employment or Other Compensation Agreements

Any action by the Company to recoup or any recoupment of Erroneously Awarded Compensation under this Policy from a Covered Person shall not be deemed (i) "good reason" for such Covered Person's resignation or to serve as a basis for a claim of constructive termination under any employment or severance agreement with the Company or under the terms of any benefits or compensation arrangement applicable to such Covered Person, or (ii) to constitute a breach of a contract or other arrangement to which such Covered Person is party.

12. Amendment; Termination

The Committee may amend this Policy in its discretion, including as it deems necessary to comply with the regulations adopted by the SEC under Rule 10D-1 and the rules of any national securities exchange or national securities association on which the Company's securities are listed. The Committee may terminate this Policy at any time. Notwithstanding anything herein to the contrary, no amendment or termination of this Policy shall be effective if that amendment or termination would cause the Company to violate any federal securities laws, SEC rules or the rules of any national securities exchange or national securities association on which the Company's securities are listed.

13. Successors

This Policy shall be binding and enforceable against all Covered Executives and their successors, beneficiaries, heirs, executors, administrators, or other legal representatives.

Adopted: December 9, 2025

Effective: February 6, 2026

* * *

ACKNOWLEDGMENT

(to be signed by all Covered Persons)

I, the undersigned, agree and acknowledge that I am fully bound by, and subject to, all of the terms and conditions of the AgomAb Therapeutics NV Compensation Recovery Policy (as may be amended, restated, supplemented or otherwise modified from time to time, the "Policy") and that I have been provided a copy of the Policy. In the event of any inconsistency between the Policy and the terms of any employment or similar agreement to which I am a party, or the terms of any compensation plan, program or agreement under which any compensation has been granted, awarded, earned or paid, the terms of the Policy shall govern. If the Committee determines that any amounts granted, awarded, earned or paid to me must be forfeited or reimbursed to the Company, I will promptly take any action necessary to effectuate such forfeiture and/or reimbursement.

Name: