Agomab Reports Half Year 2026 Financial Results and Confirms 2026 Outlook

August 6, 2026

-- Regulatory alignment with U.S. Food and Drug Administration (FDA) on key elements of NOV-ERA Phase 2b study design with Ontunisertib in Fibrostenosing Crohn's Disease (FSCD), including Novel Primary Endpoint of Endoscopic Passability --

-- Topline Data from Open-Label Long-term Extension Study (OLE) Part of STENOVA Study with Ontunisertib in FSCD and from Phase 1b Idiopathic Pulmonary Fibrosis (IPF) Study Cohort with AGMB-447 Expected in Coming Months --

-- On Track to Initiate NOV-ERA Phase 2b Study in FSCD with Ontunisertib and Phase 2 Study in with AGMB-447 in IPF in Second Half of 2026 --

-- Cash and Cash Investments at June 30, 2026 of €252 Million, including $208 Million in Gross Proceeds from Initial Public Offering (IPO), Expected to Support Cash Runway into First Half of 2029 --

Antwerp, Belgium, August 6, 2026 – Agomab Therapeutics NV (Nasdaq: AGMB) ("Agomab"), a clinical-stage biopharmaceutical company focused on fibro-inflammation, today reported financial results for the half year period ended June 30, 2026, and confirmed its outlook for the second half of 2026.

"In the first half of 2026, we continued to execute on our clinical and operational strategy, and we are on track with the clinical read-outs and trial initiations of ontunisertib and AGMB-447 expected later this year," said Tim Knotnerus, Chief Executive Officer of Agomab. "Our recent engagement with the FDA provides important support for our development strategy with ontunisertib, and we believe the NOV-ERA Phase 2b study will be a crucial next step in evaluating ontunisertib's potential as a differentiated therapy to address the high unmet medical need in FSCD. As we head into a catalyst-rich second half of 2026, we especially look forward to the OLE results with ontunisertib and first IPF data with AGMB-447."

Pierre Kemula, Chief Financial Officer of Agomab, added, "The first half of 2026 marked a defining moment for Agomab, with our Nasdaq IPO raising $208 million in gross proceeds, extending the cash runway into the first half of 2029. We are well-resourced to drive our clinical programs forward with both focus and discipline. As we look ahead to important milestones across our fibro-inflammatory disease portfolio, we are well positioned to deliver meaningful value for patients and shareholders alike."

First Half 2026 Program Highlights and Anticipated Milestones

- *Ontunisertib (AGMB-129), a gut-restricted small molecule inhibitor of ALK5 for the treatment of FSCD*
    - We announced the design of the NOV-ERA study, a randomized, double-blind, placebo-controlled, dose-ranging, multicenter Phase 2b trial designed to evaluate the efficacy and safety of ontunisertib in adults with symptomatic FSCD. We have aligned with the FDA on the NOV-ERA design, including the study's primary efficacy endpoint of endoscopic passability at Week 24 as assessed by the SES-CD narrowing score, as well as several secondary efficacy endpoints relevant to patients with FSCD.
    - The protocol has been submitted to the FDA and has cleared central Institutional Review Board (IRB) approval in the U.S. In addition, the study has received approval by Health Canada and the Medicines and Healthcare products Regulatory Agency (MHRA) in the UK. The Company has also submitted Clinical Trial Applications (CTAs) in multiple countries globally, including in the European Union and Asia Pacific territories. We plan to initiate the NOV-ERA study following receipt of applicable regulatory and ethics approvals and expect to dose the first participants in the second half of 2026.
    - We are progressing the OLE part of the STENOVA study (Part B) with ontunisertib in FSCD patients, with topline results expected in the coming months. The 48-week data may provide important insights into extended treatment with ontunisertib in FSCD patients.
    - As of February 2026, the Data Safety and Monitoring Board has not raised any safety issue and has recommended for the OLE study to continue as per the protocol with 200mg BID ontunisertib for up to 60 weeks.
    - The results of the 12-week placebo-controlled double-blind part of the STENOVA Phase 2a study with ontunisertib in FSCD (Part A) were presented as a late-breaker at the 21st Congress of ECCO (ECCO'26) in Stockholm, Sweden in February 2026. The late-breaking presentation was also featured by *Nature Reviews Gastroenterology & Hepatology* as one of the highlights of ECCO'26.
- *AGMB-447, an inhaled small molecule inhibitor of ALK5 in development for the treatment of IPF*
    - In January 2026, we announced positive interim results of the Phase 1 study of AGMB-447 in 108 healthy participants. The data pointed to a generally favorable safety, tolerability and pharmacokinetic profile of AGMB-447, with robust target engagement of ALK5 observed in the lungs of healthy participants.

- We have enrolled 10 participants in the IPF cohort of the Phase 1b study with AGMB-447. In this cohort, participants receive multiple doses of AGMB-447 or placebo over 14 days. We expect to report topline results from the IPF patient cohort in the coming months.
- We are on track to initiate a Phase 2 trial with AGMB-447 in IPF in the second half of the year.
- We were granted a patent covering the composition of matter of AGMB-447 by the United States Patent and Trademark Office (USPTO), solidifying the foundational intellectual property for AGMB-447 in the U.S.

Half Year 2026 Financial Results (consolidated)

- **Cash Position**: Cash, cash equivalents and short-term cash investments totaled €252.0 million as of June 30, 2026. In February 2026, we completed our IPO, in which we raised gross proceeds of approximately $208 million, including the proceeds from the underwriters' partial exercise of their overallotment option, before deducting underwriting discounts and commissions and other offering expenses. We expect that our existing cash 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.

- **R&D Expenses:** Research and development (R&D) expenses were €23.0 million for the six months ended June 30, 2026, as compared with €22.0 million for the six months ended June 30, 2025.

- **G&A Expenses:** General and administrative (G&A) expenses were €12.2 million for the six months ended June 30, 2026, as compared with €6.7 million for the six months ended June 30,2025. The increase of €5.5 million for the period mainly relates to one-off expenses incurred for the IPO.

- **Net Loss:** Net loss was €31.0 million for the six months ended June 30, 2026, compared to €26.9 million for the six months ended June 30, 2025.

Ontunisertib and AGMB-447 are investigational drugs and not approved by any regulatory authority. Their efficacy and safety have not been established.

Financial performance

Condensed consolidated statement of profit and loss (unaudited)

	for the six months ended June 30,	
(in thousands of €)	**2026**	**2025**
Research and development expenses	(22,967)	(22,022)
General and administrative expenses	(12,171)	(6,682)
Total operating expenses	**(35,138)**	**(28,704)**
Other operating income	1,079	1,312
Operating loss	**(34,059)**	**(27,393)**
Changes in fair value of financial liabilities	(438)	(256)
Financial expenses	(215)	(75)
Financial income	3,741	855
Loss before taxes	**(30,971)**	**(26,868)**
Income tax (expenses)/income	—	—
Loss for the period	**(30,971)**	**(26,868)**
Weighted average number of common shares outstanding	40,763,420	541,126
Basic and diluted loss per share (in €)	(0.80)	(63.86)

Condensed consolidated statement of comprehensive income or loss (unaudited)

	for the six months ended June 30,	
(in thousands of €)	**2026**	**2025**

Loss for the period	(30,971)	(26,868)
Items that may be reclassified to profit or loss		
Foreign currency translation differences	*66*	*(36)*
Items that will not be reclassified to profit or loss		
Remeasurements of post-employment benefit obligations	*3*	*1*
Other comprehensive income or loss for the period, net of tax	69	(35)
Total comprehensive income or loss for the period	**(30,902)**	**(26,903)**

Condensed consolidated statement of financial position (unaudited)

(in thousands of €)	**As of June 30, 2026**	**As of December 31, 2025**
Assets		
Non-current assets		
Intangible assets	20,110	20,110
Goodwill	8,612	8,612
Property, plant and equipment	443	503
Right-of-use assets	962	1,083
Other financial assets	13	11
Other non-current assets	2,302	2,150
Total non-current assets	**32,442**	**32,469**
Current assets		
Other current assets	6,504	4,723
Current financial investments	30,389	30,096
Cash and cash equivalents	221,588	86,418
Total current assets	**258,481**	**121,237**
Total assets	**290,923**	**153,706**
Equity		
Share capital	304,618	223,072
Share premium reserve	172,948	76,634
Retained earnings	(212,617)	(181,714)
Share-based payment reserves	14,784	13,877
Other reserves	(14,357)	(967)
Equity attributable to the owners of the parent	**265,376**	**130,902**
Total equity	**265,376**	**130,902**
Liabilities		
Non-current liabilities		
Non-current lease liabilities	910	1,005
Non-current contingent consideration	3,437	3,210
Non-current deferred income	1,129	—
Total non-current liabilities	**5,476**	**4,215**
Current liabilities		
Current lease liabilities	229	249
Anti-dilutive warrants	—	—
Current contingent consideration	6,737	6,526
Trade and other payables	11,843	10,266
Deferred income and accrued charges	1,262	1,548
Total current liabilities	**20,071**	**18,589**
Total liabilities	**25,547**	**22,804**
Total equity and liabilities	**290,923**	**153,706**

Condensed consolidated statement of cash flows (unaudited)

(In thousands €)	for the six months ended June 30, 2026	2025
Net income/(loss) for the period	**(30,971)**	**(26,868)**
Adjustments for non-cash items:		
Fair value (gain) loss on financial assets	(293)	
Fair value gain (loss) on financial liabilities	438	256
Depreciation & amortization	173	195
Share-based payment expenses	2,467	2,597
Net foreign exchange losses (gains)	(2,219)	(53)
Interest expenses	33	37
Interest income	(1,048)	(764)
Operating cash flows before movements in working capital	**(31,420)**	**(24,600)**
Movements in working capital:		
Decrease/(increase) in other current assets	(1,780)	(1,994)
Decrease/(increase) in other non-current assets	(152)	(138)
Increase/(decrease) in trade and other payables	1,576	(115)
Increase/(decrease) in current deferred income	(286)	1,156
Increase/(decrease) in non-current deferred income	1,129	—
Interest paid	(32)	(5)
Interest received	1,048	764
Net cash flow from /(used in) operating activities	**(29,917)**	**(24,932)**
Payment of contingent consideration from previous acquisition	—	(3,000)
Net cash flow from /(used in) investing activities		**(3,000)**
Repayment of lease liabilities	(149)	(148)
Proceeds from capital increase, net of issuance costs	163,899	—
Transaction costs paid	(1,056)	—
Exchange gains from currency conversion on proceeds from capital increase	2,329	—
Proceeds from exercise of stock options	64	—
Net cash flow from /(used in) financing activities	**165,087**	**(148)**
Net increase/(decrease) in cash and cash equivalents	**135,170**	**(28,080)**
Cash and cash equivalents at beginning of the period	86,418	171,459
Effect of foreign exchange rate changes		—
Cash and cash equivalents at end of the period	221,588	143,379

About ontunisertib

Ontunisertib (AGMB-129) is an oral small molecule GI-restricted inhibitor of ALK5 (or TGF-β RI) currently in clinical development for the treatment of Fibrostenosing Crohn's Disease (FSCD). TGF-β is a major driver of fibrosis. Ontunisertib is specifically designed to inhibit ALK5/TGF-β in the GI-tract. Rapid first-pass metabolism in the liver prevents clinically relevant systemic exposure, potentially delivering an improved safety profile over systemically available inhibitors in this class. Ontunisertib has received U.S. FDA Fast Track Designation.

About Fibrostenosing Crohn's Disease

Crohn's disease is a chronic progressive disease of the gastrointestinal tract. It is estimated that approximately 46% of patients with Crohn's disease have fibrosis of the gastrointestinal tract, resulting in stricture formation and intestinal obstructions, most frequently in the terminal ileum. These strictures can cause obstructive symptoms leading to dietary change, malnutrition and surgery. Despite the large unmet medical need, there are no approved pharmacological therapies for FSCD.

About Agomab

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.

Cautionary Note Regarding Forward-Looking Statements

This press release includes certain disclosures that contain "forward-looking statements," including, without limitation, statements regarding our expected cash runway, including that we anticipate our cash and cash investments and IPO proceeds will extend our runway into the first half of 2029, our focus on the discovery and development of our pipeline of novel product candidates for fibro-inflammatory disorders, the design of planned Phase 2 clinical trials with ontunisertib for FSCD and AGMB-447 for IPF, our expectation to initiate our Phase 2b Study of ontunisertib in FSCD and our Phase 2 study of AGMB-447 in IPF in the second half of 2026, our interactions with regulatory authorities as well as statements regarding future data readouts, including our expectation to release topline data from the OLE part of the STENOVA study and of the Phase 1b IPF Study Cohort with AGMB-447 in the coming months. Forward-looking statements are based on Agomab's current expectations and are subject to inherent uncertainties, risks and assumptions that are difficult to predict. Factors that could cause actual results to differ include, but are not limited to, risks and uncertainties related to the results of our clinical trials; expectations regarding the inherent uncertainties associated with the development of novel drug therapies; preclinical and clinical trial and product development activities and regulatory approval requirements for product candidates; the impact of governmental laws and regulations on our business; disruptions caused by our reliance on third party suppliers and service providers; the risk that our expectations and management's guidance regarding our cash position and other financial estimates may be incorrect; and risks related to geopolitical conflicts and macro-economic events. These and other risks and uncertainties are described more fully in our filings and reports with the SEC, including in our most recent annual report on Form 20-F filed with the SEC and our subsequent filings and reports filed with the SEC. Forward-looking statements contained in this announcement are made as of this date, and Agomab undertakes no duty to update such information except as required under applicable law. Readers should not rely upon the information in this announcement as current or accurate after its publication date.

Contacts
Investors

Sofie Van Gijsel
VP of Investor Relations
E-Mail: sofie.vangijsel@agomab.com
Phone: +1 781 296 1143

Media

Gretchen Schweitzer
Trophic Communications
E-Mail: agomab@trophic.eu
Phone: +49 172 861 8540