

Agenus Reports Q3 2025 Results Showcasing Clinical and Regulatory Advances

2025-11-10

- France grants reimbursed access with patients having commenced treatment
- Two-year BOT/BAL survival presented at ESMO spanning more than five cancers in over 400 patients
- Phase 3 on track to commence in fourth quarter 2025

LEXINGTON, Mass.--(BUSINESS WIRE)-- **Agenus Inc.** (Nasdaq: AGEN) today reported quarterly results for the period ended September 30, 2025, and provided a business update. Highlights include government-funded, reimbursed compassionate access (AAC) in France for botensilimab plus balstilimab (BOT/BAL), new survival data presented at ESMO and ESMO-GI across more than 400 patients spanning more than five refractory cancers, and initiation of the global Phase 3 BATTMAN trial.

Access & Regulatory

- France authorizes reimbursed AAC for BOT/BAL. In September, France's medicines agency (ANSM) authorized reimbursed compassionate access (Accès Compassionnel, AAC) for BOT/BAL in refractory MSS mCRC without active liver metastases—the first government-funded access for this population and the first reimbursed access provided for BOT/BAL by a regulatory agency. [link](#)

Clinical Highlights

BOT/BAL has demonstrated durable, long-term survival in patients with advanced solid tumors, reinforcing its potential to expand the reach of immunotherapy to those historically unresponsive to treatment.

- MSS metastatic colorectal cancer (ESMO-GI 2025): In 123 heavily pretreated MSS mCRC patients without active liver metastases, BOT/BAL achieved 42% two-year overall survival(OS) and 20.9-month median OS. Median OS

benchmarks in this third-line-plus setting is 8-14ⁱ months with current standards of care. [link](#)

- Pan-tumor cohort (ESMO 2025): Updated Phase 1b results in >400 patients demonstrated 39% two-year OS across more than five refractory cancers, including colorectal, ovarian, sarcoma, lung, and hepatocellular tumors. Important to note that responses were seen after prior checkpoint inhibitor failure; immune-related AEs were treatable and reversible. [link](#)

Phase 3 Program

- Global registrational trial initiated. The BATTMAN (CCTG CO.33) Phase 3 trial conducted with the Canadian Cancer Trials Group and supported by AGITG (Australasia), and PRODIGE (France)—is launching in Q4 2025 across 100+ sites in Canada, France, Australia, and New Zealand to evaluate BOT/BAL versus best supportive care in refractory, unresectable MSS/pMMR colorectal cancer. [link](#)

Q3 2025 Financial Highlights

- Zydus transactions: In October, Agenus and Zydus agreed to a \$10 million bridge facility ahead of the anticipated \$91 million upon closing of the transaction which also includes an equity investment at \$7.50 per share.
- MiNK deconsolidation: In July 2025, Agenus' ownership of MiNK fell below 50%, resulting in deconsolidation in Q3 2025. This generated approximately \$100.9 million gain, resulting in net income for the three-month and nine-month period ended September 30, 2025.

Key Financial Metrics	Financial Highlights (in thousands, except per share data) (unaudited)		
	Q3 2025	YTD 2025	YTD 2024
Revenue, including non-cash royalties	\$ 30.2	\$ 80.0	\$ 76.6
Operating loss	(4.5)	(34.6)	(94.6)
Net income (loss)	63.9	7.5	(185.5)
Net income (loss) per share attributable common stockholders			
Basic	\$ 2.00	\$ 0.37	\$ (8.65)
Diluted	1.94	0.37	(8.65)
Cash used in operations	\$ 14.7	\$ 60.6	\$ 129.7

Upcoming Catalysts

- BATTMAN patient enrollment to commence before year-end 2025
- BOT/BAL paid access programs: government reimbursed in France and self-pay in several European countries as well as other regions – patients currently under treatment in both pathways.
- Investigator-initiated trials: Neoadjuvant and frontline data updates expected 1H 2026

- France AAC: Will generate real world evidence

Webcast and Conference Call Information

As part of Agenus' newly launched webcast series, the Company will host a Stakeholder Briefing Webcast in late November, featuring internal and external experts. Additional details will be announced prior to the event.

About Agenus

Agenus is a leading immuno-oncology company targeting cancer with a comprehensive pipeline of immunological agents. The company was founded in 1994 with a mission to expand patient populations benefiting from cancer immunotherapy through combination approaches, using a broad repertoire of antibody therapeutics, adoptive cell therapies (through MiNK Therapeutics) and adjuvants. Agenus has robust end-to-end development capabilities, across commercial and clinical cGMP manufacturing facilities, research and discovery, and a global clinical operations footprint. Agenus is headquartered in Lexington, MA. For more information, visit www.agenusbio.com or @agenus_bio. Information that may be important to investors will be routinely posted on our website and social media channels.

About BATTMAN CO.33 Phase 3 Trial

Agenus, in collaboration with the Canadian Cancer Trials Group (CCTG), is initiating a global Phase 3 trial evaluating the immunotherapy combination of botensilimab (BOT) and balstilimab (BAL) versus best supportive care (BSC) in patients with refractory, unresectable microsatellite stable (MSS)/mismatch repair proficient (pMMR) colorectal cancer. This registrational study will be conducted as an international cooperative group trial, led by CCTG and supported by academic networks including AGITG (Australasian Gastro-Intestinal Trials Group) and PRODIGE (France), which comprises Unicancer, GERCOR, and FFCD. The trial will launch in Q4 2025 across more than 100 sites in Canada, France, Australia, and New Zealand.

Agenus' Commitment to Patient Access

Agenus is dedicated to making investigational medicines available to patients with cancer at the appropriate time and in the correct manner. For more information, visit <https://agenusbio.com/access-to-investigational-medicines-policy>

About Botensilimab (BOT)

Botensilimab (BOT) is a human Fc enhanced multifunctional anti-CTLA-4 antibody designed to boost both innate and adaptive anti-tumor immune responses. Its novel design leverages mechanisms of action to extend

immunotherapy benefits to “cold” tumors which generally respond poorly to standard of care or are refractory to conventional PD-1/CTLA-4 therapies and investigational therapies. Botensilimab augments immune responses across a wide range of tumor types by priming and activating T cells, downregulating intratumoral regulatory T cells, activating myeloid cells and inducing long-term memory responses.

Approximately 1,200 patients have been treated with botensilimab and/or balstilimab in phase 1 and phase 2 clinical trials. Botensilimab alone, or in combination with Agenus’ investigational PD-1 antibody, balstilimab, has shown clinical responses across nine metastatic, late-line cancers. For more information about botensilimab trials, visit www.clinicaltrials.gov.

About Balstilimab (BAL)

Balstilimab is a novel, fully human monoclonal immunoglobulin G4 (IgG4) designed to block PD-1 (programmed cell death protein 1) from interacting with its ligands PD-L1 and PD-L2. It has been evaluated in more than 900 patients to date and has demonstrated clinical activity and a favorable tolerability profile in several tumor types.

Forward-Looking Statements

This press release contains forward-looking statements that are made pursuant to the safe harbor provisions of the federal securities laws, including statements regarding its botensilimab and balstilimab programs, expected regulatory timelines and filings, and any other statements containing the words “may,” “believes,” “expects,” “anticipates,” “hopes,” “intends,” “plans,” “forecasts,” “estimates,” “will,” “establish,” “potential,” “superiority,” “best in class,” and similar expressions are intended to identify forward-looking statements. These forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially. These risks and uncertainties include, among others, the factors described under the Risk Factors section of our most recent Annual Report on Form 10-K for 2024, and subsequent Quarterly Reports on Form 10-Q filed with the Securities and Exchange Commission. Agenus cautions investors not to place considerable reliance on the forward-looking statements contained in this release. These statements speak only as of the date of this press release, and Agenus undertakes no obligation to update or revise the statements, other than to the extent required by law. All forward-looking statements are expressly qualified in their entirety by this cautionary statement.

[†]Fruquintinib, regorafenib or trifluridine and tipiracil; cross-trial comparisons are descriptive; differences in eligibility, assessments, and data cutoffs may confound comparisons. BAL, balstilimab; BOT, botensilimab; mo, months; FDA, US Food and Drug Administration; MSS CRC, microsatellite stable metastatic colorectal cancer; Q4, quarter 4; SOC, standard of care.

1. Schlechter BM, et al. Poster presented at the ESMO Gastrointestinal Cancers Congress. Barcelona, Spain. 2025. Poster #8P. 2. Cohen R, et al. Eur J Cancer. 2024;207:114160. 3. Tabernero J, et al. Poster presented at the ASCO Annual Meeting. Chicago, IL, USA. 2024. Abstract #3584. 4. Garcia-

Carbonero R, et al. Poster presented at the ASCO Annual Meeting. Chicago, IL, USA. 2024. Poster 520P.

Investors

917-362-1370 | investor@agenusbio.com

Media

781-674-4422 | communications@agenusbio.com

Source: Agenus Inc.