agenus

NEWS RELEASE

Agenus Reports 2025 Results; BOT+BAL Advances to Phase 3 and Early Access Programs Expand Globally with Initial Revenues Recognized

2026-03-16

- Early access programs expand globally: 200+ physician inquiries across 30+ countries; $4.2M in initial program revenue recognized
- CRC leads BOT+BAL clinical development: 42% two-year overall survival and ~21-month median overall survival in heavily pretreated microsatellite stable (MSS) metastatic CRC (mCRC) patients
- BATTMAN Phase 3 registrational trial underway: First global next-generation CTLA-4/PD-1 combination registrational trial in refractory MSS mCRC
- France expands reimbursed AAC access: Metastatic ovarian cancer and sarcoma added alongside MSS mCRC
- Zydus collaboration strengthens balance sheet and manufacturing capacity: Strategic capital and dedicated U.S. biologics production secured to support BOT+BAL development for commercialization

LEXINGTON, Mass.--(BUSINESS WIRE)-- **Agenus Inc**. (Nasdaq: AGEN) today reported financial results for the fourth quarter and full year ended December 31, 2025, highlighting progress for the botensilimab (BOT) plus balstilimab (BAL) immunotherapy program across patient access, clinical execution, and commercial readiness. BOT+BAL is a next-generation CTLA-4/PD-1 immunotherapy combination which activates both innate and adaptive immunity and has demonstrated immunotherapy benefit in tumors historically resistant to checkpoint inhibition.

The BOT+BAL program entered global Phase 3 evaluation in refractory microsatellite-stable (MSS) metastatic colorectal cancer (mCRC), expanded through regulatory-authorized early access pathways in multiple countries and recognized initial revenue associated with treatment supplied through these programs while preparing for potential future regulatory submissions in the United States and Europe.

"BOT+BAL is beginning to stand out for the reasons that matter most; patients with few options are actively seeking

access, physicians are gaining experience with the regimen, and the clinical foundation continues to strengthen," said Garo H. Armen, PhD, Chairman and CEO of Agenus. "When real-world interest and clinical relevance start to align, conviction builds. We believe BOT+BAL has the potential to become an important new immunotherapy franchise in CRC and across other difficult-to-treat cancers."

Key Business Highlights

Early Access Programs Expand Patient Reach and Build Physician Experience

In parallel with clinical development, Agenus has begun providing BOT+BAL through regulatory-authorized early access pathways in certain countries. These programs are designed to enable treatment for patients with serious diseases who have exhausted approved therapies while allowing physicians to gain experience with the investigational combination in real-world clinical settings.

France AAC Early Access Program:

France's national Autorisation d'Accès Compassionnel (AAC) program provides hospital-based access to BOT+BAL for eligible patients with certain refractory cancers, with treatment reimbursed through the national health system. BOT+BAL was first authorized through the national AAC protocol in MSS mCRC with non-liver metastases (NLM) in September 2025 and was expanded to include platinum-resistant ovarian cancer (PROC) and soft-tissue sarcomas (STS) in January 2026. The expansion broadens reimbursed access across multiple difficult-to-treat tumors and adds to the clinical experience with BOT+BAL in France.

Global Paid Named-Patient Programs (NPP):

Outside France, BOT+BAL may be available in select countries through paid named-patient programs where permitted by local regulations and initiated at the request of treating physicians. Depending on local requirements, access may involve out-of-pocket payment and/or special insurance arrangements.

Initial BOT+BAL Revenues from Paid Early Access Programs

Across both access programs, Agenus has received over 200 inquiries from more than 30 countries. In the year ended December 31, 2025, Agenus recognized approximately $4.2 million in net revenue from the AAC and paid NPP programs, after consideration of estimated government rebates. Reimbursed treatment in France and paid named-patient activity in other markets are providing additional clinical experience and data ahead of potential approvals in major regions.

Clinical Data Reinforce BOT+BAL Potential

Clinical data generated in 2025 and early 2026 continued to support the development of BOT+BAL as a differentiated, next-generation CTLA-4/PD-1 immunotherapy combination for cancers historically resistant to checkpoint inhibition. The clinical dataset, now spanning more than 1,200 patients across nine tumor types, is most mature in CRC while continuing to expand across other immunologically “cold” tumors. Additional updates from ongoing company and investigator sponsored trials, including Phase 2 neoadjuvant CRC trials, are expected in 2026.

Key highlights from 2H 2025 and early 2026 include:

- MSS metastatic colorectal cancer (ESMO-GI 2025):
  42% two-year overall survival (OS) and median overall survival of approximately 21 months in patients with heavily pretreated MSS mCRC without active liver metastases treated with BOT+BAL; previously reported data from available standard of care therapies demonstrated a median OS of 10-14 months.
- Pan-tumor activity (ESMO 2025):
  In more than 400 heavily pretreated patients (median 3 prior lines of treatment) across more than nine tumor types, BOT+BAL demonstrated approximately 39% two-year OS, including activity in metastatic colorectal, ovarian, sarcoma, PD(L)-1 refractory NSCLC, and hepatocellular cancers.
- AACR-IO biomarker analysis (AACR-IO 2026):
  Integrated analysis of systemic inflammation and tumor immune features identified biologically distinct patient subgroups with differential survival outcomes and outperformed conventional biomarkers such as PD-L1 and tumor mutational burden.

These data support the differentiated immune-modulating mechanism of the BOT+BAL combination and reinforce its potential across immunologically “cold” tumors.

Phase 3 BATTMAN MSS mCRC Registrational Trial Initiated

The BATTMAN (CCTG CO.33, NCT07152821) trial is the first global Phase 3 study evaluating the next-generation CTLA-4-based immunotherapy combination in patients with refractory MSS/mismatch repair proficient (pMMR) mCRC who have exhausted other available options. MSS CRC represents approximately 95% of mCRC cases and has historically shown limited benefit from immunotherapy.

The international cooperative-group study is led by the Canadian Cancer Trials Group (CCTG), with participation from leading academic networks including CCTG, GI Cancer Trials in Australia, and France's PRODIGE consortium.

The study is expected to enroll approximately 830 patients across more than 100 sites in Canada, France, Australia

and New Zealand through leading cooperative group networks and is designed to support potential regulatory filings in the United States, Europe, Canada and other geographies.

Zydus Collaboration Strengthens Manufacturing, U.S. Infrastructure and Balance Sheet

In January 2026, Agenus closed its previously announced strategic collaboration with Zydus Lifesciences, providing strategic capital and dedicated biologics manufacturing capacity to support clinical development, authorized access programs and future commercial supply of BOT+BAL. Zydus paid $91 million of upfront capital at the close of the transaction, less certain adjustments. These adjustments include reimbursable expenses, other required closing payments, including approximately $5.8 million of transaction expenses and $7.5 million placed into a twelve-month escrow.

In March 2026, a $20 million contingent payment was triggered based on initial BOT+BAL work orders.

The collaboration strengthens Agenus' balance sheet while securing dedicated U.S. manufacturing infrastructure for the next stage of clinical, regulatory and commercial expansion.

Financial Results

Fourth Quarter and Full Year 2025

Metric	Fourth Quarter 2025	Full Year 2025
Pre-commercial product revenue	$3.2 million	$4.2 million
Other revenue, including non-cash royalty revenue	$31.1 million	$110.0 million
Operating income (loss)	$14.4 million	$(20.2) million
Net loss	$(10.6) million	$(3.1) million

Pre-commercial product revenue represents initial contributions associated with treatment of investigational BOT+BAL supplied through early access programs, including France's AAC program which commenced in the fourth quarter 2025.

2026 Strategic Priorities

- Expand patient access through French ACC and global NPP early access pathways
- Advance regulatory filings in the U.S. and the EU
- Advance enrollment in the Phase 3 BATTMAN trial
- Complete additional clinical and translational data in neoadjuvant CRC and other tumor types

- Strengthen balance sheet and commercial readiness

Webcast and Conference Call Information

As part of Agenus' newly launched webcast series, the Company will host a Stakeholder Briefing Webcast to review corporate activities. 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 GI Cancer Trials in Australia and PRODIGE (France), which comprises Unicancer, GERCOR, and FFCD. The trial will include more than 100 sites in Canada, France, Australia, and New Zealand.

Agenus' Commitment to Patient Access

Until marketing authorization is granted, BOT+BAL is accessible only through clinical trials including the planned Phase 3 BATTMAN trial in refractory MSS colorectal cancer and authorized early access mechanisms where permitted and available under each country's regulatory framework.

For eligible French patients treated in hospital under AAC meeting the pre-defined criteria, BOT+BAL is fully reimbursed by France's national health system (Assurance Maladie). Reimbursement is structured as a single, upfront, course-based reimbursement per patient that covers the patient's full course of therapy according to the national AAC protocol, rather than on a per-dose basis. Once a patient is authorized and treatment is initiated

under the protocol, full course of treatment and all subsequent administrations are supplied without additional product charges. In line with AAC requirements, the maximum indemnity applicable to BOT+BAL is declared to the relevant French authorities.

Outside France, access may be available in select countries through paid named-patient programs, which may involve out-of-pocket payment and/or special insurance arrangements depending on local regulations and individual coverage decisions.

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.

Investors

917-362-1370 | **investor@agenusbio.com**

Media

781-674-4422 | **communications@agenusbio.com**

Source: Agenus Inc.