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NEWS RELEASE

Agenus Reports Third Quarter 2026 Results, Highlighted by First Marketing Authorizations for BOT+BAL and Global Investigator Support for Phase 3 ROBBIN Study

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- ROBBIN Phase 3 on track for first patient enrolled in Q1 2027; strong global investigator engagement advances preparations across the Americas, Europe and Asia
- Peer-reviewed NEST and UNICORN manuscripts report approximately 30% pathologic complete responses with short-course BOT+BAL in MSS colon cancer; no observed recurrences at median follow-up of 23.5–32.2 months in NEST and 19.2 months in UNICORN
- First marketing authorizations for BOT+BAL granted in Armenia
- $17.0 million in year-to-date pre-commercial product revenue from global patient access programs
- Positive operating income for third consecutive quarter; $86.9 million in cash, cash equivalents and short-term investments, with milestone-aligned financing supporting ROBBIN's development and corporate operations through 2031

LEXINGTON, Mass.--(BUSINESS WIRE)-- **Agenus Inc.** (Nasdaq: AGEN), a leader in immuno-oncology innovation, today reported financial results for the third quarter ended September 30, 2026, and highlighted progress preparing its global randomized Phase 3 ROBBIN trial of botensilimab (BOT), a multifunctional, Fc-enhanced anti-CTLA-4 antibody, plus balstilimab (BAL), an anti-PD-1 antibody, before surgery in patients with high-risk Stage II and Stage III microsatellite-stable (MSS) colon cancer.

The clinical foundation for ROBBIN has strengthened through two independent, peer-reviewed Phase 2 studies of short-course BOT+BAL before surgery. NEST, published in **Clinical Cancer Research** in August, and the multicenter UNICORN study, published in **Nature Medicine** on November 2, 2026, each reported pathologic complete

responses in approximately 30% of patients with MSS colon cancer treated with neoadjuvant BOT+BAL. Neither study reported colon cancer recurrences in the BOT+BAL cohorts at the respective data cutoffs, with median follow-up of 32.2 and 23.5 months across NEST-1 and NEST-2 and 19.2 months in the UNICORN MSS cohort. The depth of response and encouraging follow-up strengthen our confidence in advancing BOT+BAL in the curative-intent setting, where ROBBIN will test whether treatment before surgery can prevent recurrence and increase the potential for cure.

Long-term outcomes in advanced, metastatic cancer add another dimension to the BOT+BAL evidence. In the Phase 1b C-800-01 program that enrolled more than 400 patients with advanced, metastatic solid tumors, extended follow-up of 123 heavily pretreated patients with MSS metastatic colorectal cancer without active liver metastases demonstrated 33% three-year overall survival, presented at ESMO GI 2026 in July and subsequently published in **Clinical Cancer Research.** The heavily pretreated recurrent ovarian cancer cohort, in which patients had received a median of four prior therapies and nearly three-quarters had platinum-resistant or refractory disease, demonstrated 48% estimated overall survival at three years, unchanged from the two-year estimate, as presented at International Gynecologic Cancer Society (IGCS) 2026 Meeting. The durability observed in refractory disease strengthens the rationale for investigating BOT+BAL before surgery, when the primary tumor and tumor-draining lymph nodes remain intact and may provide an opportunity to generate a broader immune response.

“We have moved beyond planning ROBBIN to mobilizing investigators and activating sites around the world in preparation for patient enrollment,” said Garo H. Armen, Ph.D., Chairman and Chief Executive Officer of Agenus. “The strong investigator engagement in Madrid and São Paulo, together with the peer-reviewed NEST and UNICORN publications, strengthens our confidence in the potential of BOT+BAL to change outcomes for patients with MSS colon cancer. We have a clear registrational path and financing aligned with key development milestones anticipated in 2027. Our priority is to bring BOT+BAL earlier in the treatment of cancer, before surgery and other systemic therapies, with the goal of preventing recurrence and increasing the potential for cure.”

Armen continued, “At the same time, patients with advanced cancer need better options today. We continue to see growing international demand for BOT+BAL through France’s AAC program and physician-initiated named-patient programs. Armenia’s decision to grant the first marketing authorizations for BOT and BAL anywhere in the world marks an important step in bringing treatment options to patients with advanced disease who need it today.”

Third Quarter and Recent Business Highlights

Global investigator support advances ROBBIN Phase 3 readiness

Investigator and site meetings in Madrid alongside ESMO and in São Paulo brought together teams preparing to enroll ROBBIN across North America, Europe, South America and Asia. Site qualification and startup activities are

advancing toward first patient dosing anticipated in the first quarter of 2027. ROBBIN, the global, randomized registrational Phase 3 trial is designed with feedback from the FDA to enroll approximately 850 patients and will evaluate event-free survival as its primary endpoint, with an interim pathologic response assessment of the first 100 patients enrolled anticipated in Q4 of 2027.

MSS disease accounts for approximately 85% of early-stage colorectal cancers.[1,2] Despite important immunotherapy advances in mismatch repair-deficient disease (dMMR), patients with MSS colon cancer continue to rely principally on surgery followed by chemotherapy or observation, with no new curative-intent therapies approved for this population in more than two decades. ROBBIN addresses an estimated 38,000 newly diagnosed U.S. patients each year, representing an estimated annual U.S. total addressable market exceeding $7 billion.

Independent Neoadjuvant Evidence Strengthens the Curative-Intent Rationale

Two independent, peer-reviewed Phase 2 studies strengthen the rationale for short-course BOT+BAL before surgery in MSS colon cancer. NEST, published in Clinical Cancer Research, reported a 32% pathologic complete response rate in MSS tumors, with no observed colorectal cancer recurrences at median follow-up of 32.2 months in NEST-1 and 23.5 months in NEST-2. UNICORN, published in Nature Medicine, reported a 29% pathologic complete response rate and 36% major pathologic response rate in its MSS BOT+BAL cohort, with no observed recurrences at 19.2 months of median follow-up. Although BOT alone produced some tumor regression in MSS disease, the deeper major and complete pathologic responses occurred with the BOT+BAL combination. Together with NEST's longer follow-up, the multicenter UNICORN findings provide independent clinical and biological evidence strengthening the curative-intent rationale for ROBBIN. Importantly, neoadjuvant BOT+BAL did not delay planned surgery in NEST, and 98% of patients in UNICORN underwent surgery on schedule, with no new safety concerns identified.

Additional neoadjuvant evidence from the investigator-initiated NEOASIS study in the mismatch repair-deficient (dMMR) colon cancer cohort was presented at ESMO 2026. Following six weeks of BOT+BAL, 72% of 18 patients achieved a pathologic complete response and 83% achieved a major pathologic response. Although dMMR is a distinct molecular population from the MSS patients targeted by ROBBIN, the results add to the clinical experience with short-course treatment before surgery.

Financing aligned with development milestones

The oversubscribed July private placement provided approximately $85 million in upfront gross proceeds, with milestone-aligned warrants that could provide up to approximately $255 million in additional gross proceeds if fully exercised. Based on the current operating plan, the upfront proceeds are expected to support ROBBIN initiation, regulatory activities and operations through the third quarter of 2027. Assuming full exercise of the warrants, the

financing is expected to support the planned ROBBIN program and company operations through year-end 2031.

Armenia grants first worldwide marketing authorizations for BOT+BAL

Shortly after quarter-end, Armenia's Ministry of Health granted marketing authorizations for Botvymo® (botensilimab) and Evamplix® (balstilimab), each for use in combination with the other in adult patients with microsatellite stable (MSS) metastatic colorectal cancer without active liver metastases who have previously received available standard therapies. These are the first marketing authorizations for either medicine anywhere in the world. The authorizations followed a rigorous review of the registration dossier and were supported by clinical evidence from the fully enrolled Phase 1b C-800-01 MSS metastatic colorectal cancer cohort and the randomized Phase 2 C-800-25 study, both reported in peer-reviewed publications. The milestone establishes an approved treatment pathway for eligible patients with advanced disease and provides a foundation for Agenus to pursue potential additional marketing authorizations in other Eurasian Economic Union member countries.

Growing international interest in authorized patient-access programs

Physician and patient interest in BOT+BAL continues to grow across authorized access pathways. In France, the national Autorisation d'Accès Compassionnel (AAC) program provides fully reimbursed, hospital-based access to eligible patients with MSS metastatic colorectal cancer without active liver metastases, platinum-resistant or platinum-refractory ovarian cancer, and certain advanced soft-tissue sarcomas. Physician-initiated paid named-patient programs provide additional access across select countries in Europe and South and Central America, where permitted by local regulations. Patients from outside these countries, including the United States, have also traveled to markets where authorized access is available to receive treatment.

Pre-commercial BOT+BAL product revenue from these programs was $6.0 million in the third quarter of 2026, compared with $6.4 million in the second quarter, and $17.0 million for the first nine months of 2026. These are non-promotional access programs, and recognized revenue can vary with country-specific pricing, reimbursement, taxation, distribution arrangements and timing; it does not necessarily move in proportion to physician inquiries or patient treatment activity.

Third Quarter 2026 Financial Results

Revenue. Total revenue for the third quarter of 2026 was $31.5 million, compared with $30.2 million for the third quarter of 2025, and included $6.0 million of pre-commercial BOT+BAL product revenue, compared with $6.4 million in the second quarter of 2026, and $25.5 million of non-cash royalty revenue, compared with $28.1 million in the second quarter. Total revenue for the first nine months of 2026 was $99.7 million, compared with $80.0 million for the same period in 2025, and included $17.0 million of product revenue and $82.7 million of non-cash royalty

revenue. Non-cash royalty revenue relates to royalty interests Agenus previously monetized and does not generate cash for the company.

Operating income and net income. Operating income was $11.4 million for the third quarter, the third consecutive quarter of positive operating income, compared with an operating loss of $4.6 million in the third quarter of 2025. Net income was $2.8 million for the quarter and $41.4 million for the first nine months of 2026.

Cash and financing. Cash, cash equivalents and short-term investments were $86.9 million at September 30, 2026, compared with $18.7 million at June 30, 2026. The oversubscribed private placement completed in July provided approximately $85 million in upfront gross proceeds and includes milestone-aligned warrants that provide up to approximately $255 million in additional gross proceeds if fully exercised. Based on the current operating plan, the upfront proceeds are expected to support ROBBIN initiation, regulatory activities and operations through the third quarter of 2027. Assuming full exercise of the warrants, the financing is expected to support the planned ROBBIN program and company operations through year-end 2031.

Financial Summary

($ in millions)

Metric	Q1 2026	Q2 2026	Q3 2026	YTD Q3 2026	Q3 2025	YTD Q3 2025
Pre-commercial product revenue	$4.6	$6.4	$6.0	$17.0	—	—
Non-cash royalty revenue	29.1	28.1	25.5	82.7	29.1	77.5
Service and other revenue	—	—	—	—	1.1	2.5
Total revenue	$33.7	$34.5	$31.5	$99.7	$30.2	$80.0
Operating income (loss)	$15.1	$11.3	$11.4	$37.8	$(4.6)	$(34.6)
Net income (loss)	$39.2	$(0.6)	$2.8	$41.4	$63.9	$7.5
Cash, cash equivalents and short-term investments	$35.0	$18.7	$86.9	$86.9	$3.5	$3.5

Upcoming Milestones

- November 2026: BOT+BAL long-term survivor characteristics and translational research presentations at SITC 2026
- Q1 2027: ROBBIN Phase 3 initiation and first patient enrollment
- Q2 2027: Anticipated 60 patients enrolled in ROBBIN (Series A Warrants milestone)
- Second half of 2027: Anticipated interim pathologic response assessment from ROBBIN (Series B Warrants milestone)
- 2027: Additional clinical publications and updates as available, and potential additional regulatory

submissions

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 Botensilimab (BOT)

Botensilimab (BOT) is a human multifunctional, Fc-enhanced 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. BOT augments immune responses across a wide range of tumor types by priming and activating T cells, reducing intratumoral regulatory T cells, activating myeloid cells and inducing durable memory responses.

BOT+ balstilimab (BAL) has been studied in over 1,500 patients across more than nine tumor types, spanning late-line refractory disease and early-stage neoadjuvant settings. The combination is being developed to expand immunotherapy benefit to more patients, including those with microsatellite stable (MSS) disease and tumors considered immunologically “cold” or resistant to existing immunotherapies. Agenus’ Phase 3 ROBBIN study is designed to evaluate BOT+BAL given before surgery in earlier-stage colon cancer. 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.

Botvymo and Evamplix Armenia Approval and Indication

Botvymo® (botensilimab) and Evamplix® (balstilimab) are separately authorized in Armenia, each for use in

combination with the other, for the treatment of adult patients with microsatellite stable (MSS) metastatic colorectal cancer without active liver metastases who have previously received available standard therapies. The Armenian marketing authorizations are conditional and valid for one year, with renewal based on annual clinical updates provided to the regulator. Their use in other indications and in other countries remains investigational.

Agenus' Commitment to Patient Access

Agenus is committed to expanding patient access to BOT+BAL through regulatory approvals, clinical trials and authorized early-access pathways. Following the first marketing authorizations for Botvymo® (botensilimab) and Evamplix® (balstilimab) in Armenia for eligible adults with previously treated microsatellite-stable (MSS) metastatic colorectal cancer without active liver metastases, BOT+BAL remains investigational outside Armenia and is not approved by the U.S. Food and Drug Administration (FDA).

In France, the national Autorisation d'Accès Compassionnel (AAC) program provides fully reimbursed, hospital-based access to BOT+BAL for eligible patients with MSS metastatic colorectal cancer without active liver metastases, platinum-resistant or platinum-refractory ovarian cancer, and certain advanced soft-tissue sarcomas. In a growing number of other countries, BOT+BAL is available through physician-initiated named-patient programs under local regulations. BAP Pharma serves as Agenus' global partner for the French AAC pathway and named-patient access programs.

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 Agenus' botensilimab and balstilimab programs, access programs, clinical development plans and ROBBIN milestones, expected regulatory timelines and filings, the conditional Armenian marketing authorizations and their renewal, liquidity, anticipated cash runway, the Company's need for additional capital, the exercise of the Series A and Series B warrants, and any other statements containing the words "may," "believes," "expects," "anticipates," "hopes," "intends," "plans," "forecasts," "estimates," "will," "potential," and similar expressions 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 Agenus' most recent Annual Report on Form 10-K for 2025 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 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.

References

1. Buchler T. Front Oncol. 2022;12:888181. 2. Guven DC, et al. Oncologist. 2024;29(5):e580–e600.

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