Annexon Reports Third Quarter 2025 Financial Results, Portfolio Progress and Key Anticipated Milestones

November 10, 2025

Late-Stage Neuroinflammation Platform Advancing Global Registrational Programs in Guillain-Barré Syndrome (GBS) and Geographic Atrophy (GA)

Current Tanruprubart GBS Dossier On Track for MAA Filing in January 2026; Potential to Be the First Approved Targeted and Fast-Acting Therapy for the Treatment of GBS; Continued FDA Discussions Regarding Generalizability Package in Support of BLA Filing

Topline ARCHER II Pivotal Data for Vonaprument in Dry AMD with GA on Track for Second Half of 2026; Potential to Be the First Approved Vision Sparing Therapy for the Treatment of Eight Million GA Patients Worldwide

ANX1502 Cold Agglutinin Disease (CAD) Proof of Concept Study Ongoing with Expected 2026 Completion; Potential to Be the Only Oral C1s Inhibitor for the Treatment of Multiple Neuroinflammatory Autoimmune Diseases

Strong Financial Position and Execution Extends Operations into 2027, Through Several Important Milestones, Including Tanruprubart Global GBS Filings, Vonaprument Topline GA Phase 3 Data, and ANX1502 Autoimmune Proof of Concept Data

BRISBANE, Calif., Nov. 10, 2025 (GLOBE NEWSWIRE) -- Annexon, Inc. (Nasdaq: ANNX), a biopharmaceutical company advancing a late-stage clinical platform targeting neuroinflammation across life-changing complement-mediated neuroinflammatory diseases of the body, brain, and eye, today highlighted portfolio progress, announced key anticipated milestones and reported third quarter 2025 financial results.

“We’re pleased with the focused execution of our business strategy across our late-stage neuroinflammation platform, and the strong momentum we’ve built over 2025 heading into a meaningful 2026. Our next-generation complement inhibitor candidates continue to demonstrate the power of stopping neuroinflammation at its source, enabling multiple programs advancing toward key near-term milestones,” said Douglas Love, president and chief executive officer of Annexon. “Our registrational Guillain-Barré Syndrome program is on track for EU Marketing Authorisation Application (MAA) submission in January 2026, positioning it to become the first targeted therapy for GBS, a disease that annually affects 150,000 people worldwide. Dialogue with the FDA is also ongoing regarding the generalizability package supporting the U.S. Biologics License Application (BLA) submission. Furthermore, our registrational Phase 3 trial for vonaprument in GA is on track to deliver topline data in the second half of 2026. The study is designed to confirm the significant vision preservation observed in our Phase 2 trial and benefit the eight million people affected by GA worldwide.”

Mr. Love continued, “Finally, we are building on the early learnings from our ANX1502 program, the first and only clinical stage oral inhibitor of C1s. We’ve observed targeted drug levels in fasted CAD patients, and we continue to dose to deepen our understanding of ANX1502’s profile, anticipating study completion in 2026. With a prioritized capital plan, our runway is extended into 2027 through each of the above anticipated milestones. Overall, Annexon is uniquely positioned to drive near-term value while pursuing additional opportunities to achieve our mission of helping millions of patients suffering from devastating neuroinflammatory diseases.”

Recent Corporate and Clinical Program Updates

Tanruprubart (ANX005) in GBS: Targeted neuroinflammatory inhibitor of C1q and the classical pathway delivered in a single infusion to rapidly halt aggressive neuroinflammation and damage in GBS, an acute, rare, neuromuscular emergency that affects ~150,000 people worldwide each year. There are no FDA-approved therapies for GBS and limited evidence of effectiveness from the current standards of care (SOC) therapy used in GBS.

- Productive regulatory interactions with European Rapporteurs and Pediatric Committee of the European Medicines Agency reaffirm the current tanruprubart GBS data package is on track for MAA filing in January 2026. Collaborative discussions with the FDA on the generalizability package to support the BLA submission are ongoing.
- Large biomarker dataset from the Phase 3 trial reinforces that, distinct from current standard of care therapies, tanruprubart has a rapid impact on the acute inflammatory process across all GBS subtypes, supporting the consistency of its rapid benefit on function and disability across geographies.
- U.S. and European FORWARD open-label study designed to broaden Western experience with tanruprubart, including in pediatric patients, is ongoing with initial pharmacokinetic (PK), pharmacodynamic (PD), biomarker and functional data anticipated in 2026.
- Continued ongoing discussions with pharmaceutical companies on collaboration opportunities to commercialize tanruprubart for GBS in various geographies.
- **Next Milestones: Tanruprubart MAA submission expected in January 2026. Update on FDA BLA submission upon further regulatory dialogue. Initial FORWARD data anticipated in 2026.**

Vonaprument (ANX007) in Dry AMD Patients with GA: Neuroprotective inhibitor of C1q and the classical complement cascade delivered intravitreally for dry AMD with GA, a leading cause of blindness affecting more than eight million people worldwide. There are no approved therapies for GA targeting the preservation of vision.

- Registrational Phase 3 ARCHER II trial, a global, sham-controlled, double-masked trial, completed enrollment early in July

2025 while also exceeding enrollment targets for a total of 659 GA patients. ARCHER II is the first study to evaluate a therapy for dry AMD with GA targeting visual function as the primary endpoint measured by the gold-standard best corrected visual acuity 15-letter loss (BCVA ≥15LL).

- Vonaprument selected by European Medicines Agency (EMA) for the exclusive Product Development Coordinator (PDC) pilot launched in July 2025 to assist Priority Medicine (PRIME) designation holders in navigating regulatory interactions, including expedited scientific advice, MAA submission readiness activities, and ad-hoc queries throughout the development program.
- Recent positive engagements with FDA and EMA support the established vonaprument ARCHER II global regulatory approval path for protection of vision in patients with GA.
- Further analyses of the Phase 2 ARCHER trial reinforce that structural protection of photoreceptors within the center of the retina is critical to visual acuity, consistent with neuroprotective mechanism of vonaprument. In the Phase 2 trial, vonaprument treatment showed 73% reduction in risk of vision loss measured by the gold-standard BCVA ≥15-letter loss endpoint, protection of photoreceptors with greatest impact near the center of the retina, and trends towards greater RPE protection over time and also near the center of the retina.
- **Next Milestone: Topline Phase 3 ARCHER II trial data expected in second half of 2026.**

ANX1502 for Autoimmune Conditions: First-in-kind oral C1s inhibitor, has the potential to offer disruptive advantages of clinically validated upstream classical complement inhibition with the convenience and flexibility of oral administration.

- Currently evaluating an enteric-coated tablet formulation of ANX1502 in an open-label, single arm, POC study in patients with CAD.
- Drug levels at and exceeding pre-defined target in fasted CAD patients observed in the POC trial, and dosing is ongoing to further enhance the understanding of ANX1502's PK/PD profile, including effect on complement and clinical markers of hemolysis.
- POC study completion anticipated in 2026.
- **Next Milestone: ANX1502 program update upon CAD study completion in 2026.**

Third Quarter 2025 Financial Results

- **Cash and operating runway:** Cash and cash equivalents and short-term investments were $188.7 million as of September 30, 2025. Based on focused investments in its lead late-stage programs, Annexon has extended its runway and expects to fund operations and anticipated milestones into late first quarter 2027.
- **Research and development (R&D) expenses:** R&D expenses were $49.7 million for the quarter ended September 30, 2025, compared to $30.1 million for the quarter ended September 30, 2024. The increased R&D expenses are primarily associated with the advancement of the Phase 3 ARCHER II trial of vonaprument in GA and investments toward completion of tanruprubart global filings for GBS.
- **General and administrative (G&A) expenses:** G&A expenses were $7.3 million for the quarter ended September 30, 2025, compared to $9.3 million for the quarter ended September 30, 2024. The decline in G&A expenses reflects ongoing corporate efficiencies and disciplined prioritization of resources.
- **Net loss:** Net loss was $54.9 million or $0.37 per share for the quarter ended September 30, 2025, compared to $34.8 million or $0.25 per share for the quarter ended September 30, 2024.

About Annexon

Annexon Biosciences (Nasdaq: ANNX) is developing the next generation of complement inhibitors to stop neuroinflammation as first-in-kind treatments for millions of people living with serious neuroinflammatory diseases of the body, brain and eye. Our novel scientific approach focuses on C1q, the initiating molecule of classical complement's potent inflammatory pathway that when misdirected can lead to tissue damage and loss in a host of diseases. By targeting C1q, our immunotherapies are designed to stop this neuroinflammatory cascade before it starts. Our pipeline spans three diverse therapeutic areas – autoimmunity, neurodegeneration and ophthalmology – and includes targeted investigational drug candidates designed to address the unmet needs of nearly 10 million people worldwide. Annexon's mission is to deliver game-changing therapies to patients so that they can live their best lives. To learn more visit annexonbio.com.

Forward Looking Statements

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. In some cases, you can identify forward-looking statements by terminology such as "aim," "anticipate," "assume," "believe," "contemplate," "continue," "could," "design," "due," "estimate," "expect," "goal," "intend," "may," "objective," "plan," "positioned," "potential," "predict," "seek," "should," "target," "will," "would" and other similar expressions that are predictions of or indicate future events and future trends, or the negative of these terms or other comparable terminology. All statements other than statements of historical facts contained in this press release are forward-looking statements. These forward-looking statements include, but are not limited to, statements about: the potential therapeutic benefit of ANX005, if approved, compared to existing therapies; anticipated timing and results of regulatory interactions related to ANX005;

the design, objectives and timing of the open-label tanruprubart FORWARD study; the company's ability to gain clarity from the FDA on the generalizability package to support a BLA submission; the company's ability to make an MAA submission for European registration in January 2026 and to achieve regulatory approval for ANX005; the potential therapeutic benefit of ANX007; timing of and results from the Phase 3 ARCHER II trial; ANX007's distinct potential neuroprotective mechanism of action and potential to provide protection from vision loss; the potential for ANX007 to be the first drug approved in Europe and the U.S. for dry AMD with GA; timing of proof-of-concept trial for ANX1502 in cold agglutinin disease and the company's ability to provide an update upon study completion in 2026; the potential for ANX1502 to disrupt the current treatment antibody-mediated autoimmune diseases; the company's ability to commercialize its product candidates, if approved; continued development of ANX007 and ANX1502; anticipated cash runway into late first quarter 2027; the potential benefits from treatment with anti-C1q therapy; and continuing advancement of the company's portfolio. Forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties that could cause actual results and events to differ materially from those anticipated, including, but not limited to, risks and uncertainties related to: the final results from the Phase 3 ARCHER II trial; the company's history of net operating losses; the company's ability to obtain necessary capital to fund its clinical programs; the potential for delays in the company's clinical trials, including if the FDA and comparable foreign regulatory authorities do not accept data from clinical trials for product candidates outside the United States; the early stages of clinical development of the company's product candidates; the effects of public health crises on the company's clinical programs and business operations; the company's ability to obtain regulatory approval of and successfully commercialize its product candidates; any undesirable side effects or other properties of the company's product candidates; the company's reliance on third-party suppliers and manufacturers; the outcomes of any future collaboration agreements; and the company's ability to adequately maintain intellectual property rights for its product candidates. These and other risks are described in greater detail under the section titled "Risk Factors" contained in the company's Annual Report on Form 10-K and Quarterly Reports on Form 10-Q and the company's other filings with the SEC. Any forward-looking statements that the company makes in this press release are made pursuant to the Private Securities Litigation Reform Act of 1995, as amended, and speak only as of the date of this press release. Except as required by law, the company undertakes no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise.

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ANNEXON, INC.
Condensed Consolidated Statements of Operations (Unaudited)
(in thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Operating expenses:				
Research and development (1)	$ 49,700	$ 30,105	$ 142,039	$ 76,094
General and administrative (1)	7,318	9,337	24,110	25,500
Total operating expenses	57,018	39,442	166,149	101,594
Loss from operations	(57,018)	(39,442)	(166,149)	(101,594)
Interest and other income, net	2,096	4,618	7,715	11,984
Net loss	(54,922)	(34,824)	(158,434)	(89,610)
Deemed dividend on modification of common stock warrants	—	—	(1,857)	—
Net loss attributable to common stockholders	$ (54,922)	$ (34,824)	$ (160,291)	$ (89,610)
Net loss per share, basic and diluted	$ (0.37)	$ (0.25)	$ (1.08)	$ (0.68)
Weighted-average shares used in computing net loss per share, basic and diluted	149,123,701	139,933,019	148,521,489	130,945,980
(1) Includes the following stock-based compensation expense:				
Research and development	$ 2,380	$ 2,325	$ 7,897	$ 6,918
General and administrative	$ 1,455	$ 2,284	$ 5,221	$ 7,293

ANNEXON, INC.
Condensed Consolidated Balance Sheets (Unaudited)
(in thousands)

	September 30, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 139,419	$ 49,498
Short-term investments	49,302	262,519
Prepaid expenses and other current assets	4,101	4,444
Total current assets	192,822	316,461
Restricted cash	1,032	1,032
Property and equipment, net	11,152	12,638
Operating lease right-of-use assets	15,587	16,705
Other non-current assets	8,549	3,235
Total assets	$ 229,142	$ 350,071
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 18,219	$ 10,426
Accrued and other current liabilities	22,543	17,568
Operating lease liabilities, current	2,818	2,518
Total current liabilities	43,580	30,512
Operating lease liabilities, non-current	24,120	26,454
Total liabilities	67,700	56,966
Stockholders' equity:		
Common stock	115	109
Additional paid-in capital	1,030,536	1,003,685
Accumulated other comprehensive (loss) income	(76)	10
Accumulated deficit	(869,133)	(710,699)
Total stockholders' equity	161,442	293,105
Total liabilities and stockholders' equity	$ 229,142	$ 350,071