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

August 14, 2025

Tanruprubart (formerly ANX005) for GBS Advancing Through Regulatory Interactions; MAA Submission in Europe Anticipated in First Quarter of 2026; Ongoing Discussions with FDA Regarding Generalizability Package to Support a BLA

Accelerated Completion of Enrollment for Global Phase 3 ARCHER II Trial of Vonaprument (formerly ANX007) for Dry AMD with GA; Selected for EMA PRIME Product Development Candidate Pilot; Topline ARCHER II Data Expected in Second Half of 2026

ANX1502 First-in-Kind Oral C1s Inhibitor Exposure Exceeded Target Concentration in Fasted Patients; Evaluation in Relation to Food Intake Ongoing in Proof-of-Concept CAD Study, Update Expected by Year-end 2025

$227 Million in Cash Supports Operations into the Fourth Quarter of 2026 Through Vonaprument Topline Phase 3 Data in GA

BRISBANE, Calif., Aug. 14, 2025 (GLOBE NEWSWIRE) -- Annexon, Inc. (Nasdaq: ANNX), a biopharmaceutical company advancing a late-stage clinical platform of novel therapies for people living with devastating classical complement-mediated neuroinflammatory diseases of the body, brain, and eye, today highlighted portfolio progress, announced key anticipated milestones and reported second quarter 2025 financial results.

"We are well positioned to achieve our mission of helping millions of people with devastating complement-mediated diseases live their best lives by the consistent validation generated by our innovative C1 platform across multiple potential best-in-class therapeutics," said Douglas Love, president and chief executive officer of Annexon. "In Guillain-Barré Syndrome (GBS), approximately 90% of tanruprubart-treated patients improved by week 1 and more than twice as many patients achieved a normal state of health at week 26 vs. placebo in our Phase 3 study. As a result, we are actively engaged in global regulatory interactions to bring tanruprubart to patients worldwide, which includes preparing to submit our Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) in the first quarter of 2026. In parallel, we are also working with the Food and Drug Administration (FDA) to gain clarity on the generalizability package to support a Biologics License Application (BLA) submission."

Mr. Love continued, "We are also increasingly excited by the positive momentum of vonaprument for dry age-related macular degeneration (AMD) with geographic atrophy (GA), exemplified by the accelerated enrollment of our Phase 3 ARCHER II trial coupled with the established global registration path to provide a potentially new vision preserving treatment for the eight million people with GA worldwide. We are on pace to deliver topline pivotal data in the second half of 2026. For our oral C1s inhibitor ANX1502, we are optimistic as the exposure demonstrated thus far has exceeded our target threshold in patients without concomitant food intake. We are confirming these findings in fasted patients to achieve proof-of-concept (POC) for this first-in-kind oral program, and we anticipate providing an update later this year. Finally, we remain disciplined with our financial and operational execution, and are capitalized into the fourth quarter of 2026 through our pivotal Phase 3 data in GA."

Recent Corporate and Clinical Program Updates

Tanruprubart (ANX005) in GBS: Targeted immunotherapy 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.

- Ongoing regulatory interactions to support advancement of tanruprubart towards potential worldwide registration.
    - MAA submission for registration in Europe expected in the first quarter of 2026.
    - Ongoing discussion with the FDA on the generalizability package to support a BLA submission, with update expected upon further regulatory clarity.
- In parallel, continuing ongoing discussions with pharmaceutical companies regarding collaborating on the commercialization of tanruprubart for GBS in various geographies.
- Tanruprubart helped patients get better sooner and more completely versus SOC with a comprehensive and unprecedented data set that continues to build across five GBS studies:
    - Completed placebo-controlled POC and pivotal Phase 3 studies conducted in Southeast Asia with high disease prevalence and ability to run gold standard placebo-controlled studies.
    - Completed generalizability package including a Real-World Evidence study matching the Phase 3 patients to immunoglobulin (IVIg) or plasma exchange-treated Western patients from a 2,000 patient GBS prospective, observational study, and comparing outcomes versus SOC where tanruprubart demonstrated favorable outcomes versus SOC on all assessed clinical measures.
    - Completed drug-drug interaction safety study with tanruprubart on top of IVIg that included E.U. and Southeast Asian patients.
    - Ongoing FORWARD study in U.S. and Europe designed to broaden Western experience with tanruprubart by measuring pharmacokinetics (PK), pharmacodynamics (PD), early efficacy in week 1, and safety in up to 30

subjects including pediatric patients.

- Positive outcomes with tanruprubart treatment in the Phase 3 trial were highlighted as part of oral and poster presentations at the 2025 Peripheral Nerve Society (PNS) Annual Meeting.
- **Next Milestone: Tanruprubart MAA submission expected in first quarter of 2026, and update on FDA BLA submission timing upon further regulatory clarity on the generalizability package.**

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 worldwide. There are no approved therapies for GA targeting the preservation of vision.

- Accelerated enrollment of 659 patients completed for ARCHER II, a global, pivotal, sham-controlled, double-masked Phase 3 trial.
- Global registration path established with U.S. and European regulators supports potential of vonaprument to be the first treatment approved in both Europe and the U.S. for protection of vision in patients who have dry AMD with GA, assuming positive Phase 3 results.
- Vonaprument selected by EMA for the exclusive Product Development Coordinator (PDC) pilot launched in July 2025 to help Priority Medicine (PRIME) designation holders efficiently navigate regulatory interactions, including expedited scientific advice, MAA submission readiness activities, and ad-hoc queries throughout the development program.
- Bolstered ophthalmology expertise with appointment of Lloyd Clark, M.D., as senior vice president, ophthalmology strategy and innovation. Dr. Clark brings more than 25 years of experience as a practicing retina specialist with deep expertise in drug development, portfolio strategy and bringing novel therapies to market.
- Phase 2 ARCHER data showing significant preservation of vision and central retinal photoreceptors necessary for visual acuity presented at the 2025 Association for Research in Vision and Ophthalmology (ARVO) Annual Meeting and at the 2025 Retina World Congress.
- **Next Milestone: Topline Phase 3 ARCHER II trial data expected in second half of 2026.**

ANX1502 for Autoimmune Conditions: First-in-kind oral small molecule inhibiting the activated form of C1s, an enzyme carried by C1q to initiate the classical cascade, has the potential to offer the advantages of selective upstream classical complement inhibition with the convenience and flexibility of oral administration.

- Exposure exceeded target concentrations in fasted patients treated to date in ongoing, open-label, single arm, POC study evaluating enteric-coated tablets of ANX1502 in patients with cold agglutinin disease (CAD).
- Evaluation of PK/PD in relation to food intake, and reduction in complement and bilirubin markers as a measure of hemolysis, are ongoing.
- PK/PD learnings from CAD patients anticipated to inform application of ANX1502 in broad array of other autoimmune diseases, leveraging oral delivery to potentially disrupt biologics-treated indications.
- **Next Milestone: Update on POC trial in CAD anticipated by year-end 2025.**

Second Quarter 2025 Financial Results

- **Cash and operating runway:** Cash and cash equivalents and short-term investments were $227.0 million as of June 30, 2025. Annexon continues to expect its cash, cash equivalents and short-term investments as of June 30, 2025, to be sufficient to fund the company's planned operating expenses and late-stage milestones for its lead programs into the fourth quarter of 2026.
- **Research and development (R&D) expenses:** R&D expenses were $44.2 million for the quarter ended June 30, 2025, reflecting the advancement of the Company's priority programs, including GBS, GA and ANX1502, compared to $25.0 million for the quarter ended June 30, 2024.
- **General and administrative (G&A) expenses:** G&A expenses were $7.6 million for the quarter ended June 30, 2025, compared to $8.6 million for the quarter ended June 30, 2024.
- **Net loss:** Net loss was $49.2 million or $0.34 per share for the quarter ended June 30, 2025, compared to $29.6 million or $0.23 per share for the quarter ended June 30, 2024.

About Annexon

Annexon Biosciences (Nasdaq: ANNX) is developing therapeutics that stop classical complement-driven 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 the first quarter of 2026 and to achieve regulatory approval for ANX005; the company's discussions with pharmaceutical companies regarding collaborating on the commercialization of tanruprubart for GBS in various geographies; 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; the potential benefits of participating in the EMA's PDC Pilot for PRIME designation holders; timing of proof-of-concept trial for ANX1502 in cold agglutin disease and the company's ability to provide an update by year-end of 2025; 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 the fourth quarter of 2026; 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 June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Operating expenses:				
Research and development (1)	$ 44,160	$ 25,026	$ 92,339	$ 45,989
General and administrative (1)	7,566	8,554	16,792	16,163
Total operating expenses	51,726	33,580	109,131	62,152
Loss from operations	(51,726)	(33,580)	(109,131)	(62,152)
Interest and other income, net	2,570	3,970	5,619	7,366
Net loss	(49,156)	(29,610)	(103,512)	(54,786)
Deemed dividend on modification of common stock warrants	(1,857)	—	(1,857)	—
Net loss attributable to common stockholders	$ (51,013)	$ (29,610)	$ (105,369)	$ (54,786)
Net loss per share, basic and diluted	$ (0.34)	$ (0.23)	$ (0.71)	$ (0.43)
Weighted-average shares used in computing net loss per share, basic and diluted	148,320,803	130,132,960	148,215,392	126,403,081

(1) Includes the following stock-based compensation expense:

Research and development	$ 2,688	$ 2,311	$ 5,517	$ 4,593
General and administrative	$ 1,517	$ 2,631	$ 3,766	$ 5,009

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

	June 30, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 132,288	$ 49,498
Short-term investments	94,729	262,519
Prepaid expenses and other current assets	3,603	4,444
Total current assets	230,620	316,461
Restricted cash	1,032	1,032
Property and equipment, net	11,650	12,638
Operating lease right-of-use assets	15,974	16,705
Other non-current assets	5,297	3,235
Total assets	$ 264,573	$ 350,071
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 11,515	$ 10,426
Accrued and other current liabilities	26,411	17,568
Operating lease liabilities, current	2,716	2,518
Total current liabilities	40,642	30,512
Operating lease liabilities, non-current	24,914	26,454
Total liabilities	65,556	56,966
Stockholders' equity:		
Common stock	110	109
Additional paid-in capital	1,013,211	1,003,685
Accumulated other comprehensive (loss) income	(93)	10
Accumulated deficit	(814,211)	(710,699)
Total stockholders' equity	199,017	293,105
Total liabilities and stockholders' equity	$ 264,573	$ 350,071