Annexon Reports First Quarter 2026 Financial Results, Portfolio Progress and Key Anticipated Milestones

May 7, 2026

Topline Pivotal Phase 3 Data for Vonaprument for the Treatment of Geographic Atrophy (GA) Expected Q4 2026, with Potential to Redefine Vision Preservation in GA

Tanruprubart EU Marketing Authorization Application (MAA) Under Review as the Potentially First Targeted Therapy for Guillain-Barré Syndrome (GBS); Biologics License Application (BLA) Submission with U.S./European FORWARD Data Expected in 2026

Proof-of-Concept (POC) Data for ANX1502, a First-in-Kind Oral C1 Inhibitor for Autoimmune Disease, Expected in 2026

Strong Balance Sheet with Cash, Cash Equivalents and Short-Term Investments of Approximately $225 Million as of March 31, 2026, and Anticipated Runway into Second Half 2027

BRISBANE, Calif., May 07, 2026 (GLOBE NEWSWIRE) -- Annexon, Inc. (Nasdaq: ANNX), a biopharmaceutical company advancing the next generation platform of targeted immunotherapies aimed at neuroinflammatory diseases that impact nearly 10 million people worldwide, today highlighted portfolio progress, announced key anticipated milestones, and reported first quarter 2026 financial results.

“As we execute toward major milestones in 2026, we are sharply focused on our strategic priorities across the organization,” said Douglas Love, president and chief executive officer of Annexon. “In GA, where no vision-preserving therapies are available for the approximately 8 million people impacted worldwide, we’re eagerly anticipating topline pivotal data from our ARCHER II Phase 3 trial in the fourth quarter of the year. ARCHER II is designed to reproduce the ARCHER Phase 2 data where vonaprument demonstrated the preservation of photoreceptor neurons and vision on multiple measures.

In GBS, a debilitating rare disease and leading cause of acute neuromuscular paralysis that can strike anyone, any time and anywhere, our EU MAA for tanruprubart is under review for approval as the potentially first targeted therapy for the treatment of GBS. Enrollment continues in our U.S./EU FORWARD study, which is designed to broaden experience across western geographies to support our planned BLA submission in 2026. Finally, our POC study for ANX1502, a first-in-kind oral inhibitor designed to treat a host of neuromuscular diseases, is ongoing with data anticipated in 2026.

With a bold mission to address neuroinflammatory diseases for millions worldwide, and a strong balance sheet powering us through several upcoming catalysts, we are more energized than ever by the potential and the building momentum of our highly differentiated complement platform.”

2026 Strategic Priorities and Key Milestones

Vonaprument: Potential to be the first targeted vision-preserving therapy for GA, a leading cause of blindness affecting more than 8 million patients worldwide.

- ARCHER II is an ongoing global, pivotal, Phase 3 sham-controlled, double-masked trial of vonaprument in 659 patients with GA, a disease driven by early photoreceptor degeneration leading to vision loss. Enrollment was completed in July 2025. The primary endpoint is the proportion of patients with confirmed best corrected visual acuity 15-letter loss at two consecutive visits, measured at month 15.
- Global registration path has been established with U.S. and European regulators for ARCHER II; vonaprument is the only program to receive PRIME designation from the European Medicines Agency (EMA) and FastTrack Designation from the U.S. Food and Drug Administration for GA.
- Additional information on vonaprument pivotal GA program from the March 2026 Investor Day event can be accessed here:
    - C1q blockade with vonaprument targets the key driver of vision loss in GA by protecting photoreceptor neurons to preserve visual acuity. In contrast, C3/C5 inhibition blocks clearance of dysfunctional cells at the lesion edge, slowing lesion growth without preserving vision.
    - Phase 2 ARCHER findings demonstrated vonaprument consistently preserved visual function and ellipsoid zone retinal structure, reinforcing the therapeutic potential of protecting photoreceptor health early in disease progression.
    - Phase 3 ARCHER II trial mirrors the Phase 2 patient selection profile, enriching for higher-risk patients by including patients with foveal involvement and excluding those with poor baseline vision, where 15-letter loss is less frequent.
- **Next Milestone: Topline Phase 3 ARCHER II trial data expected in fourth quarter of 2026.**

Tanruprubart: Potential to be the first targeted and fast-acting therapy for GBS, a leading cause of neuromuscular paralysis impacting 150,000 people annually worldwide.

- MAA under review with EMA supported by robust data package demonstrating rapid benefit on function and disability in

placebo-controlled studies and Real-World Evidence study demonstrating favorable outcomes versus current treatments, intravenous immunoglobulin and plasma exchange.

- Ongoing FORWARD study in the U.S. and Europe designed to expand Western experience with tanruprubart, including in pediatric patients. The study will evaluate initial pharmacokinetics (PK), pharmacodynamics (PD), early impact on function and biomarkers, and safety data to support generalizability of tanruprubart's rapid benefit across geographies and broad intended label for the treatment of GBS.

- **Next Milestone: BLA submission with initial U.S./European data from FORWARD trial anticipated in 2026.**

ANX1502 for Autoimmune Conditions: First-in-kind oral small molecule inhibiting activated C1s, with convenient and flexible dosing.

- Ongoing POC study evaluating PK/PD in relation to food intake, and reduction in complement and bilirubin markers as a measure of hemolysis in patients with cold agglutinin disease (CAD).
- **Next Milestone: Update on POC trial in CAD anticipated in 2026.**

First Quarter 2026 Financial Results

- **Cash and operating runway:** Cash, cash equivalents and short-term investments were $225.0 million as of March 31, 2026. Based on focused investments in its lead late-stage programs, Annexon expects to fund operations and anticipated milestones into the second half of 2027.
- **Research and development (R&D) expenses:** R&D expenses were $35.8 million for the quarter ended March 31, 2026, compared to $48.2 million for the quarter ended March 31, 2025. The change in R&D expenses is primarily associated with the Phase 3 ARCHER II trial of vonaprument in GA, global regulatory filings of tanruprubart for GBS and contract manufacturing expenses of our product candidates.
- **General and administrative (G&A) expenses:** G&A expenses were $10.3 million for the quarter ended March 31, 2026, compared to $9.2 million for the quarter ended March 31, 2025. The change in G&A expenses reflects ongoing corporate consulting and professional services costs.
- **Net loss:** Net loss attributable to common stockholders was $44.1 million or $0.23 per share for the quarter ended March 31, 2026, compared to $54.4 million or $0.37 per share for the quarter ended March 31, 2025.

About Annexon

Annexon Biosciences (Nasdaq: ANNX) is advancing the next generation platform of targeted immunotherapies for nearly 10 million people worldwide living with serious neuroinflammatory diseases. Our founding scientific approach focuses on C1q, the initiating molecule of a potent inflammatory pathway that when misdirected can lead to tissue damage and loss of function in a host of diseases. Our targeted therapies are designed to stop classical complement-driven neuroinflammation at its source to provide meaningful functional benefit and alter the course of disease. 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 for the company's two late stage registrational programs to improve the lives of millions of patients; timing of and topline data from the pivotal Phase 3 ARCHER II trial; the potential of vonaprument to be the first targeted vision-preserving therapy for GA; the potential of tanruprubart to be the first targeted and fast-acting therapy for GBS; timing of a BLA submission with supportive initial U.S./European data from FORWARD trial; timing of POC trial data for ANX1502 in CAD; anticipated cash runway into the second half of 2027; 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 most recent Annual Report on Form 10-K and Quarterly Reports on Form 10-Q and the company's other filings with the Securities and Exchange Commission. 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 March 31,	
	2026	**2025**
Operating expenses:		
Research and development (1)	$ 35,786	$ 48,179
General and administrative (1)	10,267	9,226
Total operating expenses	46,053	57,405
Loss from operations	(46,053)	(57,405)
Interest and other income, net	1,911	3,049
Net loss	(44,142)	$ (54,356)
Net loss per share, basic and diluted	$ (0.23)	$ (0.37)
Weighted-average shares used in computing net loss per share, basic and diluted	194,186,001	148,108,809

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

Research and development	$ 2,368	$ 2,829
General and administrative	$ 1,788	$ 2,249

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

	March 31, 2026	**December 31, 2025**
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 175,208	$ 162,051
Short-term investments	49,817	76,294
Prepaid expenses and other current assets	3,241	3,846
Total current assets	228,266	242,191
Restricted cash	1,032	1,032
Property and equipment, net	10,107	10,617
Operating lease right-of-use assets	14,767	15,185
Other non-current assets	8,716	8,546
Total assets	$ 262,888	$ 277,571
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 17,529	$ 14,931
Accrued and other current liabilities	15,392	24,791
Operating lease liabilities, current	3,016	2,908
Total current liabilities	35,937	42,630
Operating lease liabilities, non-current	22,418	23,293
Total liabilities	58,355	65,923
Stockholders' equity:		
Common stock	162	149

Additional paid-in capital	1,165,983	1,128,917
Accumulated other comprehensive loss	(81)	(29)
Accumulated deficit	(961,531)	(917,389)
Total stockholders' equity	204,533	211,648
Total liabilities and stockholders' equity	$ 262,888	$ 277,571