# Annexon Reports Third Quarter 2024 Portfolio and Financial Results, and Key Anticipated Milestones

November 14, 2024

*Topline Real-World Evidence (RWE) Comparability and Outcomes Data for ANX005 in Guillain-Barré Syndrome (GBS) Expected by Year-End 2024; Biologics License Application (BLA) Submission Targeted for First Half 2025*

*Ongoing Enrollment in Phase 3 ARCHER II Trial for ANX007 in Geographic Atrophy (GA); Topline Data Expected Second Half 2026*

*Proof-of-Concept Study with First-in-Kind Oral C1s Inhibitor ANX1502 Transitioned to an Enhanced Tablet Formulation; Data in Cold Agglutinin Disease (CAD) Expected in First Quarter 2025*

*Bolstered Commercial, Medical Affairs and Health Economics Senior Leadership in Preparation for Potential ANX005 Commercialization*

*Robust Balance Sheet with Cash, Cash Equivalents, and Short-term Investments of Approximately $340 Million as of September 30, 2024, and Anticipated Runway into Second Half 2026*

BRISBANE, Calif., Nov. 14, 2024 (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 and reported third quarter 2024 financial results.

“We are executing toward a strong finish for the year to propel us into the start of an impactful 2025. The RWE data for our ANX005 GBS program expected by year end 2024 will be an important part of our first BLA submission as a company and a significant step toward providing GBS patients with a targeted and approved therapy. ARCHER II, our Phase 3 trial in GA, is actively enrolling and designed to provide the first significant data for protection of vision in a pivotal GA trial. Finally, we’re anticipating data from our first-in-kind oral C1s program, ANX1502, with an improved tablet formulation in patients with CAD in the first quarter of 2025,” said Douglas Love, president and chief executive officer of Annexon.

Mr. Love continued, “Our portfolio of programs has provided consistent support for our approach to target C1q, a key upstream driver of neuroinflammatory diseases of the body, brain and eye, and we’re encouraged by the outlook for our programs. With a strong balance sheet and runway into the second half of 2026, we are laser-focused to deliver on our near-term goals and achieve our mission of helping millions of patients live their best lives.”

**Recent Corporate and Clinical Program Updates**

**Strengthened senior leadership team in commercial, medical affairs and health economics to advance global late-stage neuroinflammatory-targeted portfolio:** Appointments include Shikhar Agarwal, M.B.A. as senior vice president, head of commercial, Sunil B. Mehta, Pharm.D as senior vice president of medical affairs and Myoung Kim, PhD, M.A., M.B.A. as vice president of health economics and outcomes research.

*Flagship Programs*

**ANX005 in Guillain-Barré syndrome (GBS):** First-in-kind monoclonal antibody designed to block C1q and the entire classical complement pathway in both the body and the brain has the potential to be the first targeted therapy for GBS, if approved.

- Positive topline Phase 3 data demonstrated statistically significant effects of ANX005 treatment on multiple measures of GBS, including on the primary endpoint GBS-disability scale (GBS-DS)
    - Demonstrated higher likelihood of being in a better state of health as early as week 1, and observed through 26-weeks on the GBS-DS
    - Early, robust and durable treatment effects expedited recovery and led to patients walking and off ventilation for those requiring it approximately one month earlier
    - Single infusion of ANX005 was generally well-tolerated with a safety profile similar to placebo and balanced across groups
    - Patients with baseline characteristics similar to those of patients in North America and Europe had greater responses to ANX005 over placebo than were observed in the overall population of the study
- Ongoing RWE study conducted by global experts in GBS using the International Guillain-Barré Syndrome Outcomes Study (IGOS)
    - Study will produce a cohort of patients from our GBS Phase 3 trial matched to patients in the IGOS registry based on key prognostic factors to support BLA submission
    - Study will compare outcomes of patients treated with ANX005 vs. patients treated with IVIg or plasma exchange assessed on the GBS-DS primary and other outcome measures, including impact on muscle strength

**ANX007 in Geographic Atrophy (GA):** First-in-kind, non-pegylated antigen-binding fragment (Fab) designed to block C1q and the classical complement cascade locally in the eye is the only investigational medicine to date to show significant protection against ≥15-letter loss (vision

protection) on the endpoint of best corrected visual acuity (BCVA) in GA.

- Ongoing global registrational Phase 3 ARCHER II trial, a well-powered, randomized, double masked, sham-controlled trial that will include a robust safety database expected to enroll approximately ~630 patients
- Regulatory alignment with the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) on the primary outcome measure for the Phase 3 program, BCVA protection against ≥15-letter loss
- New Phase 2 ARCHER data on the protection of vision and vision-related retinal structure presented at the 2024 American Society of Retina Specialists Annual Scientific meeting, at the Retina Society's 57 th annual scientific meeting, at the 24th annual Euretina Congress, at the American Academy of Ophthalmology (AAO) 2024 annual meeting and at the Eyecelerator conference at AAO. Highlighted data with ANX007 treatment included:
    - Significant vision protection in both standard and low light conditions, and protection of photoreceptor integrity in the central fovea, the region of the retina most important for activities such as reading, driving and recognizing faces
    - Enhanced protection of vision in healthier eyes and greater preservation of central photoreceptor cells in patients with less advanced GA, as measured by the photoreceptor ellipsoid zone (EZ) in the central fovea

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

- Completed bridging study in healthy volunteers from a liquid suspension formulation to a twice daily tablet with safety and pharmacokinetic profile similar or better than previous studies
- Created an enteric-coated tablet formulation to enhance the patient experience and provide improved tolerability, for use in the proof-of-concept (POC) study in CAD
- Ongoing open label single arm study in CAD patients will evaluate enteric-coated tablet formulation of ANX1502 administered twice daily for up to 4 weeks. The study will characterize the pharmacodynamics of ANX1502 on objective and established markers of complement activation and disease-related hemolysis
    - POC study is designed to enable advancement in multiple antibody-mediated autoimmune indications, including those with clinical validation and where approved treatments require weekly or every other week infusions

**Key Anticipated Milestones for Flagship Programs**

- **ANX005 in GBS:** Initial topline data from RWE comparability protocol with IGOS expected by year-end 2024 to support a planned BLA submission in the first half of 2025
- **ANX007 in GA:** Phase 3 ARCHER II trial topline data expected in the second half of 2026. Plans for an injection-controlled study, ARROW, to assess the prevention of ≥15-letter loss of BCVA, are being assessed
- **ANX1502 in CAD:** Initial data from POC trial evaluating the pharmacodynamics of an oral tablet formulation in CAD expected in the first quarter of 2025

**Third Quarter 2024 Financial Results**

- **Cash and operating runway:** Cash, cash equivalents and short-term investments were $340.1 million as of September 30, 2024. Annexon continues to expect its cash, cash equivalents and short-term investments as of September 30, 2024, to be sufficient to fund the company's planned operating expenses into the second half of 2026
- **Research and development (R&D) expenses:** R&D expenses were $30.1 million for the quarter ended September 30, 2024, reflecting the advancement of the Company's priority programs, including GBS, GA and ANX1502, compared to $27.9 million for the quarter ended September 30, 2023
- **General and administrative (G&A) expenses:** G&A expenses were $9.3 million for the quarter ended September 30, 2024, compared to $6.9 million for the quarter ended September 30, 2023
- **Net loss:** Net loss was $34.8 million or $0.25 per share for the quarter ended September 30, 2024, compared to $32.5 million or $0.43 per share for the quarter ended September 30, 2023

**About Annexon**

Annexon Biosciences (Nasdaq: ANNX) is harnessing classical complement-driven neuroinflammation to advance potentially 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. By targeting C1q, our immunotherapies are designed to stop neuroinflammatory diseases where they start. Our pipeline spans three diverse therapeutic areas – autoimmune, neurodegenerative and ophthalmic diseases – and includes targeted investigational drug candidates designed to address the unmet needs of over 8 million people worldwide. Annexon's mission is to deliver game-changing therapies to patients so that they can live their best lives. When they thrive, we thrive. 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 of the completion of a RWE comparability study and BLA submission for ANX005; the potential for the RWE comparability study to show that ANX005 treatment is comparable or better than treatment with IVIg/plasma exchange; the company’s ability to achieve regulatory approval for ANX005; the potential therapeutic benefit of ANX007; timing of the ARCHER II trial and initiation of ARROW trial; ANX007’s distinct potential neuroprotective mechanism of action and potential to provide protection from vision loss; timing of proof-of-concept data for ANX1502; the company’s ability to commercialize its product candidates, if approved; continued development of ANX007 and ANX1502; anticipated cash runway into the second half 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 ongoing off-treatment follow-up portion of the ARCHER trial and final results from the ARCHER trial; the company’s history of net operating losses; the company’s ability to obtain necessary capital to fund its clinical programs; 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**
**(in thousands, except share and per share amounts)**
**(unaudited)**

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | **2024** | **2023** | **2024** | **2023** |
| Operating expenses: | | | | |
| Research and development (1) | $ 30,105 | $ 27,893 | $ 76,094 | $ 90,489 |
| General and administrative (1) | 9,337 | 6,888 | 25,500 | 23,225 |
| Total operating expenses | 39,442 | 34,781 | 101,594 | 113,714 |
| Loss from operations | (39,442) | (34,781) | (101,594) | (113,714) |
| Interest and other income, net | 4,618 | 2,299 | 11,984 | 7,368 |
| Net loss | $ (34,824) | $ (32,482) | $ (89,610) | $ (106,346) |
| Net loss per share, basic and diluted | $ (0.25) | $ (0.43) | $ (0.68) | $ (1.42) |
| Weighted-average shares used in computing net loss per share, basic and diluted | 139,933,019 | 75,342,495 | 130,945,980 | 74,815,274 |

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

| | | | | |
|---|---|---|---|---|
| Research and development | $ 2,325 | $ 2,243 | $ 6,918 | $ 6,801 |
| General and administrative | $ 2,284 | $ 2,306 | $ 7,293 | $ 7,015 |

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

| | September 30, 2024 | December 31, 2023 |
|---|---|---|
| | (unaudited) | |
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 79,540 | $ 225,110 |
| Short-term investments | 260,576 | 34,606 |
| Prepaid expenses and other current assets | 4,176 | 4,144 |
| Total current assets | 344,292 | 263,860 |
| Restricted cash | 1,032 | 1,032 |
| Property and equipment, net | 13,169 | 14,773 |
| Operating lease right-of-use assets | 17,050 | 18,009 |
| Other non-current assets | 3,233 | — |
| Total assets | $ 378,776 | $ 297,674 |
| **Liabilities and Stockholders' Equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 6,748 | $ 5,487 |
| Accrued and other current liabilities | 10,861 | 10,276 |
| Operating lease liabilities, current | 2,437 | 2,165 |
| Total current liabilities | 20,046 | 17,928 |
| Operating lease liabilities, non-current | 27,170 | 29,190 |
| Total liabilities | 47,216 | 47,118 |
| Stockholders' equity: | | |
| Common stock | 106 | 78 |
| Additional paid-in capital | 993,486 | 823,029 |
| Accumulated other comprehensive loss | 77 | (52) |
| Accumulated deficit | (662,109) | (572,499) |
| Total stockholders' equity | 331,560 | 250,556 |
| Total liabilities and stockholders' equity | $ 378,776 | $ 297,674 |