UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 OR 15(d)
of the Securities Exchange Act of 1934
Date of Report (Date of earliest event reported): May 13, 2024

ANNEXON, INC.
(Exact name of registrant as specified in its charter)

Delaware	001-39402	27-5414423
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

1400 Sierra Point Parkway, Bldg C, Suite 200
Brisbane, California 94005
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (650) 822-5500
Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	**ANNX**	**The Nasdaq Stock Market**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02. Results of Operations and Financial Condition.

On May 13, 2024, Annexon, Inc. (the "Company") announced certain financial results for the first quarter ended March 31, 2024. A copy of the Company's press release, titled "Annexon Reports First Quarter 2024 Financial Results and Key Anticipated Milestones," is furnished pursuant to Item 2.02 as Exhibit 99.1 hereto.

The information in Item 2.02 of this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section or Section 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information contained in Item 2.02 of this Current Report on Form 8-K, including Exhibit 99.1, shall not be incorporated by reference into any filing with the U.S. Securities and Exchange Commission made by the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing, except as expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit	Description
99.1	Press Release, dated May 13, 2024, titled "Annexon Reports First Quarter 2024 Financial Results and Key Anticipated Milestones"
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: May 13, 2024

Annexon, Inc.

By: /s/ Jennifer Lew

Jennifer Lew

Executive Vice President and Chief Financial Officer

Exhibit 99.1

Annexon Reports First Quarter 2024 Financial Results and Key Anticipated Milestones

Multiple Value-creating Catalysts Across the Annexon Portfolio Throughout 2024

Pivotal Phase 3 Data for ANX005 in Guillain-Barré Syndrome (GBS) Expected in Second Quarter 2024; Potential to be the First Targeted Treatment for GBS

New Phase 2 Data Showing Neuroprotection of Vision and Vision-Associated Structures by ANX007 in Geographic Atrophy (GA) Presented at ARVO 2024; Initiation of Pivotal Phase 3 ANX007 ARCHER II Trial in GA Expected in mid-2024

Clinical Proof of Concept (POC) Data for ANX1502, an Oral Classical Pathway Inhibitor for Chronic Autoimmune Conditions, on Track for Second Half of 2024

Robust Balance Sheet with Cash, Cash Equivalents, and Short-term Investments of Approximately $264.9 Million as of March 31, 2024, and Anticipated Runway into mid-2026

BRISBANE, Calif., May 13, 2024 – 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 first quarter 2024 financial results.

“We are pleased with the increasingly robust opportunities across our flagship programs to drive significant value, including the late-stage potential of ANX005 to be the first targeted treatment for GBS with upcoming pivotal Phase 3 data, the potential of ANX007 to change the GA treatment landscape following first-in-class vision and anatomical neuroprotection data from the Phase 2 ARCHER study, and an upcoming proof-of-concept trial with the first and only oral compound targeting classical complement mediated diseases,” said Douglas Love, president and chief executive officer of Annexon. “2024 is an exciting and potentially transformative year for Annexon, with multiple value-creating catalysts culminating from a decade of research in developing treatments designed to stop harmful classical complement pathway inflammation where it starts.”

Mr. Love continued, “Our foundational research and deep knowledge of the classical complement pathway has identified several diseases and patient populations uniquely impacted by classical complement activity and translated these learnings into the development of multiple drug candidates and formulations tailored for diseases of the body, brain and eye. With our strong cash position and the compelling functional data generated across our pipeline to date, we are well-positioned to achieve our mission of bringing our first-in-kind therapies to millions of patients and families impacted by devastating classical complement diseases.”

Recent Clinical Program Updates

Flagship Programs

ANX005 in GBS: First-in-class monoclonal antibody designed to block C1q and the entire classical complement pathway in both the body and the brain.

- Hosted an R&D Day on GBS that covered its serious unmet need, Annexon’s novel targeted approach and the significant market opportunity for GBS in March 2024.
- Ongoing randomized, double-blind, placebo-controlled, multi-center Phase 3 clinical trial (N=241) designed to evaluate the efficacy, safety, pharmacokinetics, and pharmacodynamics of ANX005 in patients with GBS.
- Initiated a real-world evidence (RWE) comparability study with global experts in GBS using the International Guillain-Barré Syndrome Outcomes Study (IGOS), with initial RWE data expected by first half of 2025 to support a planned Biologics License Application (BLA) submission. IGOS is a global, prospective, observational, multicenter cohort study that has enrolled 2,000 patients who were followed for one to three years.

ANX007 in GA: First-in-class, non-pegylated antigen-binding fragment (Fab) designed to block C1q and activation of the classical complement cascade locally in the eye with an intravitreal formulation.

- Presented new neuroprotective analyses supporting the effect of ANX007 in GA at the Association for Research in Vision and Ophthalmology (ARVO) 2024 Annual Meeting
    - Key Additional Phase 2 Analyses from ARCHER Study Show ANX007 Treatment:

        - Provided broad-based protection against vision loss, including dose dependent and time-dependent protection in BCVA ≥15-letter loss including patients with foveal-center and non-foveal-center involved GA.
        - First known demonstration for statistically significant protection of Low Light Visual Acuity (LLVA), a sensitive assessment of photoreceptor function in low light conditions.
        - Statistically significant reduction of photoreceptor loss as measured by assessment of the Ellipsoid Zone (EZ) layer via Optical Coherence Tomography (OCT), a key anatomical measure of the cells responsible for light detection and visual acuity.
        - Meaningful slowing of lesion growth measured by retinal pigment epithelium (RPE) loss near the fovea, the region of the retina most important for visual acuity.
    - New preclinical data demonstrating that C1q blockade protected photoreceptor synapses, cells and retinal function in a model of photoreceptor damage, supporting a neuroprotective mechanism for ANX007 in preserving photoreceptor structures and visual function in GA.

ANX1502 for Autoimmune Conditions: First-in-class oral small molecule inhibitor of the classical complement pathway designed to target chronic autoimmune diseases.

- Ongoing bridging trial evaluating comparability of tablet and liquid suspension formulations.
- ANX1502 has the potential to offer the advantages of selective upstream classical complement inhibition with the convenience and dosing flexibility of oral administration.
- Upon completion of proof-of-concept (POC) trial in Cold Agglutinin Disease (CAD) in the second half of 2024, anticipate advancing ANX1502 into multiple mid-to-late-stage clinical trials in antibody-mediated autoimmune diseases.

Key 2024 Anticipated Milestones for Flagship Programs

- **ANX005 in GBS:** Topline data from the pivotal, randomized, placebo-controlled Phase 3 trial expected in the second quarter of 2024. Initial data from RWE comparability protocol with IGOS expected in first half 2025 to support a planned BLA submission.
- **ANX007 in GA:** Global pivotal Phase 3 ARCHER II trial vs. sham control expected to initiate in mid-2024. Pivotal Phase 3 head-to-head ARROW trial vs. SYFOVRE® (pegcetacoplan injection) planned to initiate in the second half of 2024. Expect to host an R&D Day on GA and therapeutic potential of ANX007 in mid-2024.
- **ANX1502 in CAD:** POC trial evaluating the pharmacodynamics and efficacy of an oral tablet formulation in CAD anticipated to provide initial data in the second half of 2024.

First Quarter 2024 Financial Results

- **Cash and operating runway:** Cash and cash equivalents and short-term investments were $264.9 million as of March 31, 2024. Annexon continues to expect its cash, cash equivalents and marketable securities as of March 31, 2024, to be sufficient to fund the company's planned operating expenses into mid-2026.
- **Research and development (R&D) expenses:** R&D expenses were $21.0 million for the quarter ended March 31, 2024, reflecting the advancement of the Company's priority programs, including GBS, GA and ANX1502, compared to $32.3 million for the quarter ended March 31, 2023.
- **General and administrative (G&A) expenses:** G&A expenses were $7.6 million for the quarter ended March 31, 2024, compared to $8.9 million for the quarter ended March 31, 2023.
- **Net loss:** Net loss was $25.2 million or $0.21 per share for the quarter ended March 31, 2024, compared to $38.7 million or $0.52 per share for the quarter ended March 31, 2023.

About Annexon

Annexon Biosciences (Nasdaq: ANNX) is 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. Annexon's novel scientific approach targets upstream C1q to block the classical complement inflammatory cascade before it starts, and its therapeutic candidates are designed to provide meaningful benefits across multiple autoimmune, neurodegenerative and ophthalmic diseases. With proof-of concept data in Guillain-Barré syndrome, Huntington's disease and geographic atrophy, Annexon is rigorously advancing its mid-to late-stage clinical trials to bring new potential treatments to patients as quickly as possible. 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 timing of completion of Phase 3 trial of ANX005 in patients with GBS; 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 therapeutic benefit of ANX007; timing of initiation of the ARCHER II and ARROW trials; ANX007’s distinct potential neuroprotective mechanism of action and potential to provide protection from vision loss; timing of proof-of-concept data for ANX1502; continued development of ANX007 and ANX1502; anticipated cash runway into mid-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 March 31,	
	2024	**2023**
Operating expenses:		
Research and development (1)	$ 20,963	$ 32,345
General and administrative (1)	7,609	8,897
Total operating expenses	28,572	41,242
Loss from operations	(28,572)	(41,242)
Interest and other income, net	3,396	2,566
Net loss	$ (25,176)	$ (38,676)
Net loss per share, basic and diluted	$ (0.21)	$ (0.52)
Weighted-average shares used in computing net loss per share, basic and diluted	122,673,202	73,855,642

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

Research and development	$ 2,282	$ 2,251
General and administrative	$ 2,378	$ 2,356

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

	March 31, 2024 (unaudited)	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 151,941	$ 225,110
Short-term investments	113,007	34,606
Prepaid expenses and other current assets	5,792	4,144
Total current assets	270,740	263,860
Restricted cash	1,032	1,032
Property and equipment, net	14,235	14,773
Operating lease right-of-use assets	17,701	18,009
Other non-current assets	361	—
Total assets	$ 304,069	$ 297,674
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 3,972	$ 5,487
Accrued liabilities	6,857	10,235
Operating lease liabilities, current	2,254	2,165
Other current liabilities	50	41
Total current liabilities	13,133	17,928
Operating lease liabilities, non-current	28,531	29,190
Total liabilities	41,664	47,118
Stockholders’ equity:		
Common stock	90	78
Additional paid-in capital	860,092	823,029
Accumulated other comprehensive loss	(102)	(52)
Accumulated deficit	(597,675)	(572,499)
Total stockholders' equity	262,405	250,556
Total liabilities and stockholders’ equity	$ 304,069	$ 297,674