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): March 6, 2023

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 March 6, 2023, Annexon, Inc. (the "Company") announced certain financial results for the fourth quarter and the year ended December 31, 2022. A copy of the Company's press release, titled "Annexon Reports Fourth Quarter and Year-End 2022 Financial Results and Reiterates 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 March 6, 2023, titled "Annexon Reports Fourth Quarter and Year-End 2022 Financial Results and Reiterates 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: March 6, 2023

Annexon, Inc.

By: /s/ Jennifer Lew

Jennifer Lew

Executive Vice President and Chief Financial Officer

Annexon Reports Fourth Quarter and Year-End 2022 Financial Results and Reiterates Anticipated Milestones

Initial Clinical Data from Phase 2 Trial of ANX007 in Patients with Geographic Atrophy On-track for Mid-2023

Oral Small Molecule ANX1502, for Autoimmune Indications, Advances into Multi-Ascending Dose Trial

Well-capitalized with Operating Runway into 2025, Including through Multiple Mid-stage and Pivotal Clinical Trial Readouts Anticipated in 2023 and 2024

BRISBANE, Calif., March 6, 2023 – Annexon, Inc. (Nasdaq: ANNX), a clinical-stage biopharmaceutical company developing a new class of complement medicines for patients with classical complement-mediated autoimmune, neurodegenerative and ophthalmic disorders, today outlined anticipated upcoming milestones across its portfolio of complement therapies and reported fourth quarter and full year 2022 financial results.

“2022 was a year of focused execution at Annexon, establishing a strong foundation on which to drive near- and long-term value across our deep portfolio of complement therapeutics,” said Douglas Love, president and CEO of Annexon. “We expect this year to be even stronger for Annexon, as we execute the pivotal and late-stage development of our four flagship programs across all three of our therapeutic franchises – autoimmune, ophthalmology and neurodegeneration. We’re prioritizing our focus and resources on well-supported, value creating programs, including our Phase 2 program for geographic atrophy with data anticipated mid-year, using our first-in-class up- and down-stream complement approach, and our potentially paradigm-shifting oral small molecule, ANX1502, for autoimmune indications. Overall, Annexon is well-positioned to continue executing our goals with a passionate and talented team, a strong balance sheet and multi-year runway, and a steady cadence of anticipated clinical catalysts over the next six to 18 months – all designed to deliver game-changing medicines to patients.”

Recent Pipeline Progress

- **Dosing Initiated in Phase 1 Multiple-Ascending Dose (MAD) Trial of ANX1502:** Annexon has initiated dosing in its Phase 1 MAD trial of ANX1502 in healthy volunteers. The study is designed to evaluate the safety and tolerability of twice-daily dosing of ANX1502 for two weeks. To date, ANX1502 has been generally well-tolerated in the ongoing single-ascending dose (SAD) trial with no dose-limiting safety signals observed. The company also plans to expand development of ANX1502 into additional autoimmune indications with strong scientific rationale, including multifocal motor neuropathy (MMN), in early 2024.

Key 2023-2024 Anticipated Milestones

Flagship Programs

- Autoimmune: Complete expanded enrollment in the ongoing pivotal Phase 3 trial of ANX005 in patients with Guillain-Barré syndrome (GBS) in 2023 with pivotal data anticipated in the first half of 2024
- Autoimmune: Complete the ongoing SAD trial of ANX1502 and identify the maximum tolerated dose; execute the ongoing MAD trial in healthy volunteers; and initiate a proof-of-concept study in patients with cold agglutinin disease (CAD) in 2023
- Ophthalmology: Complete the ongoing Phase 2 trial of ANX007 in patients with geographic atrophy (GA) and report initial data in mid-2023 followed by additional data by the end of 2023 after the conclusion of the six-month off-treatment period
- Neurodegeneration: Initiate a randomized, double-blind, placebo-controlled Phase 2/3 trial for ANX005 in patients with Huntington’s disease (HD) in 2023

Additional Complement Programs

- Autoimmune: Report data from the Phase 1b signal-finding trial of ANX009, which applies a precision medicine approach and is enrolling patients with lupus nephritis (LN) who have high baseline complement activity, in the first half of 2023

- Neurodegeneration: Report full data from the Phase 2a signal-finding trial in patients with amyotrophic lateral sclerosis (ALS) in 2023
- Next-generation development: Report initial data from the SAD study of ANX105 in healthy volunteers in 2023

Fourth Quarter and Full Year 2022 Financial Results

- **Cash and operating runway:** Cash and cash equivalents and short-term investments were $242.7 million as of December 31, 2022. Annexon continues to expect its cash, cash equivalents and marketable securities as of December 31, 2022, to be sufficient to fund the company's current operating plan into 2025.
- **Research and development (R&D) expenses:** R&D expenses were $28.5 million for the quarter ended December 31, 2022, and $112.5 million for the year ended December 31, 2022, compared to $27.2 million for the quarter ended December 31, 2021, and $100.0 million for the year ended December 31, 2021.
- **General and administrative (G&A) expenses:** G&A expenses were $8.2 million for the quarter ended December 31, 2022, and $33.1 million for the year ended December 31, 2022, compared to $10.2 million for the quarter ended December 31, 2021, and $30.6 million for the year ended December 31, 2021.
- **Net loss:** Net loss was $34.4 million for the quarter ended December 31, 2022, and $141.9 million for the year ended December 31, 2022, compared to $37.4 million for the quarter ended December 31, 2021, and $130.3 million for the year ended December 31, 2021.

About Annexon

Annexon (Nasdaq: ANNX) is a clinical-stage biopharmaceutical company seeking to bring game-changing medicines to patients with classical complement-mediated diseases of the body, brain and eye. The classical complement cascade is a seminal pathway within the immune system that anchors and drives a host of autoimmune, neurodegenerative and ophthalmic diseases. Annexon is advancing a new class of complement medicines targeting the early classical cascade and all downstream pathway components that contribute to disease, while selectively preserving the beneficial immune functions of other complement pathways. Annexon is rigorously developing a pipeline of diversified product candidates across multiple mid- to late-stage clinical trials, with clinical data anticipated throughout 2023 and beyond.

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," "suggest," "target," "on track," "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: anticipated milestones; cash operating runway; the potential benefits from treatment with anti-C1q therapy; timing of data reports; and continuing advancement of the company's broad 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 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 COVID-19 or other 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.

Investor Contact:

Chelcie Lister
THRUST Strategic Communications
chelcie@thrustsc.com

Media Contact:

Sheryl Seapy
Real Chemistry
949-903-4750
sseapy@realchemistry.com

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

	Three Months Ended December 31,		Year Ended December 31,	
	2022	2021	2022	2021
	(unaudited)	(unaudited)		
Operating expenses:				
Research and development (1)	$ 28,535	$ 27,217	$ 112,501	$ 100,066
General and administrative (1)	8,160	10,241	33,098	30,647
Total operating expenses	36,695	37,458	145,599	130,713
Loss from operations	(36,695)	(37,458)	(145,599)	(130,713)
Interest and other income (expense), net	2,312	87	3,652	390
Net loss	(34,383)	(37,371)	(141,947)	(130,323)
Net loss attributable to common stockholders	$ (34,383)	$ (37,371)	$ (141,947)	$ (130,323)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.48)	$ (0.97)	$ (2.60)	$ (3.40)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	72,368,539	38,479,221	54,673,572	38,316,273

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

Research and development	$ 2,365	$ 2,280	$ 8,874	$ 8,610
General and administrative	$ 2,468	$ 2,075	$ 9,642	$ 7,652

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

	December 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 140,020	$ 74,843
Short-term investments	102,637	167,872
Prepaid expenses and other current assets	5,441	4,978
Total current assets	248,098	247,693
Restricted cash	1,032	1,166
Property and equipment, net	16,838	17,848
Operating lease right-of-use assets	19,128	20,333
Total assets	$ 285,096	$ 287,040
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 7,416	$ 11,153
Accrued liabilities	13,448	9,250
Operating lease liabilities, current	1,316	1,202
Other current liabilities	180	139
Total current liabilities	22,360	21,744
Operating lease liabilities, non-current	31,542	33,387
Total liabilities	53,902	55,131
Stockholders’ equity:		
Common stock	48	39
Additional paid-in capital	669,780	528,365
Accumulated other comprehensive loss	(372)	(180)
Accumulated deficit	(438,262)	(296,315)
Total stockholders' equity	231,194	231,909
Total liabilities and stockholders’ equity	$ 285,096	$ 287,040