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 9, 2022

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 9, 2022, Annexon, Inc. (the "Company") announced certain financial results for the first quarter ended March 31, 2022. A copy of the Company's press release, titled "Annexon Biosciences Highlights Portfolio Progress and Key Anticipated Milestones, and Reports First Quarter 2022 Financial Results," 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 9, 2022, titled "Annexon Biosciences Highlights Portfolio Progress and Key Anticipated Milestones, and Reports First Quarter 2022 Financial Results"
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 9, 2022

Annexon, Inc.

By: /s/ Jennifer Lew
Jennifer Lew
Executive Vice President and Chief Financial Officer

Annexon Biosciences Highlights Portfolio Progress and Key Anticipated Milestones, and Reports First Quarter 2022 Financial Results

Pioneering Upstream Complement-Targeted Platform with Broad Portfolio of Five Differentiated Product Candidates

Anticipating Eight Clinical Catalysts Across Robust Pipeline throughout 2022 and 2023

BRISBANE, Calif., May 9, 2022 - 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 announced progress across its broad pipeline of product candidates and reported first quarter 2022 financial results.

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's unique platform targets C1q, the initiator of the pathway that localizes on disease tissue and triggers complement's harmful inflammation and tissue-damaging activity. The company's product candidates are designed to block the early classical cascade and all downstream pathway components that contribute to disease, while selectively preserving the beneficial immune functions of other complement pathways.

"I am very proud of the strong execution by the Annexon team in advancing our classical complement platform across multiple indications driven by aberrant complement activity. In doing so, we're actively building on the learnings and momentum from the first two clinical datasets generated with our lead product candidate, ANX005, which showed rapid improvement in clinical measures in two historically challenging diseases – Guillain-Barré Syndrome and Huntington's disease," said Douglas Love, Esq., president and chief executive officer of Annexon. "After years of research and development across our platform, and with eight clinical datasets anticipated throughout 2022 and 2023, we're reaching a significant inflection point in proving our founding thesis: stopping the classical complement cascade *at its start* has the potential to provide more complete protection against inappropriate complement activity, and thereby provide important benefit to patients. We're excited by the promise of our pioneering upstream complement platform, and we are well-positioned to create meaningful near-term value for patients, our supporters and for the business."

Portfolio Highlights and Key Anticipated Milestones

Annexon is rigorously advancing five drug candidates, each with distinct routes of administration and dosing schedules, and a *fit-for-purpose* design to selectively inhibit the classical complement pathway in specific compartments of the body, brain or eye.

- **ANX005:** ANX005 is an investigational, full-length monoclonal antibody (mAb) formulated for intravenous (IV) administration that is designed to *fully* inhibit C1q and the entire classical complement pathway in the body and across the blood brain barrier. ANX005 is being evaluated in **Guillain-Barré Syndrome** (GBS), an autoimmune condition where maximum suppression of C1q and the classical cascade may act early in the disease course to rapidly prevent nerve damage and irreversible neurological disability. ANX005 is also being studied in the autoimmune disease **warm autoimmune hemolytic anemia** (wAIHA), a program that has been informed by learnings from the GBS program, as well as in neurodegenerative disorders, **Huntington's disease** (HD) and **amyotrophic lateral sclerosis** (ALS), where maximum inhibition of aberrant classical complement activity is intended to preserve synapse loss and function to slow or halt disease progression.

  To date, ANX005 has been evaluated in more than 170 patients with autoimmune and neurodegenerative diseases and was generally well-tolerated, demonstrated full target engagement in the periphery and central nervous system, and in two distinct indications – GBS and HD – showed rapid and meaningful improvement in clinical measures.

  Key ANX005 Updates and Anticipated Milestones

  - Phase 2 trial in patients with HD has completed the six-month treatment period and three-month follow-up period, with data anticipated in the second quarter of 2022
  - Phase 2 trial in patients with wAIHA was initiated, with initial data anticipated in the second half of 2022
  - Phase 2/3 trial in patients with GBS is underway, with data anticipated in 2023
  - Phase 2 trial in patients with ALS is underway, with data anticipated in 2023

- **ANX007:** ANX007 is an investigational antibody antigen-binding-fragment (Fab) formulated for intravitreal administration that is designed to inhibit C1q *locally in the eye* for patients with complement-mediated neurodegenerative ophthalmic disorders. To date, ANX007 has been administered to more than 200 patients, has been generally well-tolerated, and has demonstrated full target engagement in the aqueous humor. ANX007 is currently being evaluated in a global Phase 2 clinical trial in patients with **geographic atrophy (GA)**, the leading cause of permanent blindness resulting from damaged and dying retinal cells. Annexon's approach aims to leverage the blocking of C1q at the start of the pathway to provide more complete protection against excess classical complement activity, a potentially key driver of disease.

  Key ANX007 Updates and Anticipated Milestones

  - Phase 2 ARCHER trial fully enrolled ahead of schedule with a total of 270 patients; initial data is anticipated in the first half of 2023, with full data expected after the conclusion of the six-month off-treatment period

- **ANX009:** ANX009 is an investigational subcutaneous formulation of a Fab that is designed to inhibit C1q selectively *in the vascular space*. In a Phase 1 trial, ANX009 was evaluated in 24 healthy volunteers, was well-tolerated and showed complete and sustained C1q inhibition in the vascular space. ANX009 is being evaluated in a Phase 1b trial in patients with **lupus nephritis (LN)**, a disease in which enhanced C1q deposition is known to uniquely amplify kidney inflammation and damage. The Phase 1b trial is being conducted in patients with biomarkers of excess complement activity.

  Key ANX009 Anticipated Milestones

  - Initial data from Phase 1b trial in patients with LN is anticipated in the second half of 2022

- **ANX105:** ANX105 is a next-generation investigational mAb formulated for IV administration with enhanced dosing properties designed for treatment of chronic autoimmune and neurodegenerative diseases.

  Key ANX105 Updates and Anticipated Milestones

  - First-in-human trial of ANX105 was initiated in the second quarter of 2022, following clearance of the clinical trial application (CTA) by Dutch regulatory authorities, with data expected in 2023

- **ANX1502:** ANX1502 is an investigational oral small molecule inhibitor of the classical complement cascade designed for the treatment of autoimmune diseases. ANX1502 has the potential to be a game-changing first-in-class small molecule classical complement inhibitor for a broad and deep set of autoimmune conditions.

  Key ANX1502 Updates and Anticipated Milestones

  - Preclinical activities for ANX1502 have been completed, enabling a planned CTA submission in the Netherlands
  - Initiation of the first-in-human trial of ANX1502 is anticipated in the second half of 2022, with data expected in 2023

First Quarter 2022 Financial Results

- **Cash and operating runway:** Cash and cash equivalents and short-term investments were $206.7 million as of March 31, 2022. Annexon continues to expect that its current cash position is sufficient to fund its operating plans into 2024.
- **Research and development (R&D) expenses:** R&D expenses were $27.0 million for the quarter ended March 31, 2022, compared to $20.7 million for the quarter ended March 31, 2021.
- **General and administrative (G&A) expenses:** G&A expenses were $8.4 million for the quarter ended March 31, 2022, compared to $5.5 million for the quarter ended March 31, 2021.
- **Net loss:** Net loss was $35.4 million or $0.92 per share for the quarter ended March 31, 2022, compared to $26.1 million or $0.68 per share for the quarter ended March 31, 2021.

About Annexon

Annexon (Nasdaq: ANNX) is a clinical-stage biopharmaceutical company that aims 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 2022 and 2023. For more information, visit www.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,” “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 trial initiation and design; and continuing advancement of the company’s innovative 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)
(unaudited)

	Three Months Ended March 31,	
	2022	2021 (As restated)
Operating expenses:		
Research and development (1)	$ 26,998	$ 20,696
General and administrative (1)	8,428	5,506
Total operating expenses	35,426	26,202
Loss from operations	(35,426)	(26,202)
Interest and other income (expense), net	53	142
Net loss	(35,373)	(26,060)
Net loss attributable to common stockholders	$ (35,373)	$ (26,060)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.92)	$ (0.68)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	38,563,384	38,163,062

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

Research and development	$ 1,959	$ 1,546
General and administrative	$ 2,293	$ 1,416

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

	March 31, 2022 (Unaudited)	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 112,828	$ 74,843
Short-term investments	93,831	167,872
Prepaid expenses and other current assets	4,595	4,978
Total current assets	211,254	247,693
Restricted cash	1,166	1,166
Property and equipment, net	17,805	17,848
Operating lease right-of-use assets	20,103	20,333
Other non-current assets	241	—
Total assets	$ 250,569	$ 287,040
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 9,378	$ 11,153
Accrued liabilities	6,211	9,250
Operating lease liabilities, current	1,275	1,202
Other current liabilities	189	139
Total current liabilities	17,053	21,744
Operating lease liabilities, non-current	32,902	33,387
Total liabilities	49,955	55,131
Stockholders’ equity:		
Common stock	39	39
Additional paid-in capital	532,636	528,365
Accumulated other comprehensive loss	(373)	(180)
Accumulated deficit	(331,688)	(296,315)
Total stockholders' equity	200,614	231,909
Total liabilities and stockholders’ equity	$ 250,569	$ 287,040