
**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 17, 2021

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

Delaware
(State or other jurisdiction
of incorporation)

001-39402
(Commission
File Number)

27-5414423
(IRS Employer
Identification No.)

180 Kimball Way, Suite 200
South San Francisco, California 94080
(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 17, 2021, Annexon, Inc. (“Annexon”) announced certain financial results for the first quarter ended March 31, 2021. A copy of Annexon’s press release, titled “Annexon Biosciences Provides Business Update and Reports First Quarter 2021 Financial Results,” is furnished pursuant to Item 2.02 as Exhibit 99.1 hereto.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit</u>	<u>Description</u>
99.1	Press Release, dated May 17, 2021, titled “Annexon Biosciences Provides Business Update and Reports First Quarter 2021 Financial Results”

The information in this report, including the exhibit hereto, 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 herein and in the accompanying exhibit shall not be incorporated by reference into any filing with the U.S. Securities and Exchange Commission made by Annexon, Inc., 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.

SIGNATURES

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

Dated: May 17, 2021

Annexon, Inc.

By: /s/ Jennifer Lew

Jennifer Lew

Executive Vice President and Chief Financial Officer



Annexon Biosciences Provides Business Update and Reports First Quarter 2021 Financial Results

- ANX005 Huntington’s Disease Phase 2 trial fully enrolled with data anticipated 2H 2021 –
- ANX009 First-in-Human dose-ranging trial completed with data expected summer 2021 –
- Next generation drug candidates, ANX105 and ANX1502, on track to submit INDs by end of 2021 –
- Current cash position sufficient to fund operations through 2023 –

SOUTH SAN FRANCISCO, Calif., May 17, 2021 – Annexon, Inc. (“Annexon”) (Nasdaq: ANNX), a clinical-stage biopharmaceutical company developing a pipeline of novel therapies for patients with classical complement-mediated disorders of the body, brain and eye, today announced first quarter 2021 financial results and business highlights.

Recent Business Highlights

Annexon is advancing a portfolio of innovative C1q inhibitors to stop classical complement-mediated autoimmune and neurodegenerative disease processes at the start in several indications. Recent portfolio highlights include:

- **Completed enrollment in Phase 2 trial of ANX005 in Huntington’s Disease (HD).** The company successfully completed enrollment in a Phase 2 trial evaluating ANX005 in HD patients. ANX005 is an intravenously administered C1q inhibitor in development for autoimmune and neurodegenerative indications. Initial data from this trial is anticipated in the second half of 2021.
- **Completed dose escalation in first-in-human study of ANX009 subcutaneous formulation.** The company successfully completed dosing of ANX009 in a Phase 1 dose-ranging study in healthy volunteers. ANX009 is a subcutaneously administered C1q inhibitor in development for autoimmune indications. Data from this study is anticipated in the summer of 2021.
- **Continued clinical trial progress for lead ANX005 and ANX007 C1q inhibitors.** The company’s Phase 2/3 trial in Guillain-Barré Syndrome and Phase 2 trial in geographic atrophy continue to progress as planned, as well as initiation activities for the company’s Phase 2 trials in warm autoimmune hemolytic anemia and amyotrophic lateral sclerosis.
- **Pipeline expansion.** The company continues to advance two novel classical pathway inhibitors, ANX105 (IV) and ANX1502 (oral small molecule), toward IND submission by the end of 2021 and plans to initiate clinical development in 2022.

“We are pleased with the strong progress on our mission to deliver transformative therapies for patients suffering from complement-driven autoimmune and neurodegenerative diseases,” said Douglas Love, Esq., president and chief executive officer of Annexon. “Annexon remains on track for another exciting year, and looking ahead, is sharply focused on effectively executing our several clinical programs while advancing multiple next generation drug candidates and driving our beachhead strategy to rapidly expand our platform into mechanistically related indications.”

First Quarter 2021 Financial Results

- **Cash and cash equivalents and short-term investments:** Cash and cash equivalents and short-term investments were \$326.7 million as of March 31, 2021.
 - **Research and development (R&D) expenses:** R&D expenses were \$20.7 million for the quarter ended March 31, 2021 compared to \$10.2 million for the quarter ended March 31, 2020.
 - **General and administrative (G&A) expenses:** G&A expenses were \$5.5 million for the quarter ended March 31, 2021 compared to \$2.2 million for the quarter ended March 31, 2020.
 - **Net loss:** Net loss was \$26.0 million for the quarter ended March 31, 2021 compared to \$12.3 million for the quarter ended March 31, 2020.
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About Annexon, Inc.

Annexon is a clinical-stage biopharmaceutical company developing a pipeline of novel therapies for patients with classical complement-mediated disorders of the body, brain and eye. The company's pipeline is based on its platform technology addressing well-researched classical complement-mediated autoimmune and neurodegenerative disease processes, both of which are triggered by aberrant activation of C1q, the initiating molecule of the classical complement pathway. Annexon is deploying a disciplined, biomarker-driven strategy designed to select indications, identify patients and to measure target engagement and response to treatment with its drug candidates. 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," "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: sufficiency of the company's cash to fund operations; continuing advancement of the company's innovative portfolio; timing of data from clinical trials and regulatory submissions; timing of completion of clinical studies and clinical development milestones; the company's ability to deliver on its objectives; and the implementation of the company's business model and strategic plans for its business and product candidates, including potential treatment indications and additional indications that the company may pursue. 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.

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

	Three Months Ended March 31,	
	2021	2020
Operating expenses:		
Research and development (1)	\$ 20,696	\$ 10,217
General and administrative (1)	5,452	2,239
Total operating expenses	<u>26,148</u>	<u>12,456</u>
Loss from operations	(26,148)	(12,456)
Other income, net	142	115
Net loss	(26,006)	(12,341)
Accretion on redeemable convertible preferred stock	—	(279)
Net loss attributable to common stockholders	<u>\$ (26,006)</u>	<u>\$ (12,620)</u>
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (0.68)</u>	<u>\$ (29.10)</u>
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	<u>38,163,062</u>	<u>433,749</u>

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

Research and development	\$ 1,546	\$ 325
General and administrative	\$ 1,416	\$ 338

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

	March 31, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	\$ 206,669	\$ 268,565
Short-term investments	119,985	82,641
Prepaid expenses and other current assets	3,868	2,805
Total current assets	330,522	354,011
Restricted cash	1,166	—
Property and equipment	1,429	1,935
Total assets	<u>\$ 333,117</u>	<u>\$ 355,946</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 4,518	\$ 3,734
Accrued liabilities	5,779	6,497
Deferred rent, current	398	391
Total current liabilities	10,695	10,622
Deferred rent	946	1,046
Total liabilities	11,641	11,668
Stockholders' Equity:		
Common stock	38	38
Additional paid-in capital	513,539	510,309
Accumulated other comprehensive loss	(103)	(77)
Accumulated deficit	(191,998)	(165,992)
Total stockholders' equity	321,476	344,278
Total liabilities and stockholders' equity	<u>\$ 333,117</u>	<u>\$ 355,946</u>