
**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): November 16, 2020

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

Delaware
(State or other jurisdiction
of incorporation)

001-39402
(Commission
File No.)

27-5414423
(IRS Employer
Identification No.)

180 Kimball Way, Suite 200
South San Francisco, California
(Address of principal executive offices)
94080
(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 (see General Instruction A.2. below):

- 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 November 16, 2020, Annexon, Inc. (“Annexon”) announced certain financial results for the third quarter ended September 30, 2020. A copy of Annexon’s press release, titled “Annexon Biosciences Reports Third Quarter 2020 Financial Results and Recent Business Highlights,” 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	<u>Press Release, dated November 16, 2020, titled “Annexon Biosciences Reports Third Quarter 2020 Financial Results and Recent Business Highlights”</u>

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 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.

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: November 16, 2020

Annexon, Inc.

By: /s/ Jennifer Lew

Jennifer Lew

Executive Vice President and Chief Financial Officer

Annexon Biosciences Reports Third Quarter 2020 Financial Results and Recent Business Highlights

- Cash balance of \$370.7 million as of September 30, 2020 bolstered by July IPO –
- Recently expanded ANX005 clinical program into neurodegeneration, with initiation of Phase 2 in Huntington’s Disease –
- Fully enrolled Phase 1b DDI trial in Guillain-Barré Syndrome –

SOUTH SAN FRANCISCO, Calif., November 16, 2020 – 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 brain, body and eye, today announced third quarter 2020 financial results and recent business highlights.

“We continue to make strong progress across our classical complement platform, including expanded development of ANX005 in Huntington’s Disease, and advancement of our subcutaneous formulation, ANX009, into the clinic,” said Douglas Love, Esq., president and chief executive officer of Annexon. “Our unique focus on C1q allows us to address a diverse set of classical complement-mediated autoimmune and neurodegenerative diseases, and we’re well capitalized to conduct several promising near- and mid-term Phase 2 clinical trials in these devastating diseases.”

Program Highlights

- **Initiated Phase 2 trial evaluating ANX005 in Huntington’s Disease (HD).** Initiated patient dosing in a Phase 2 trial designed to assess safety, tolerability, and biomarkers of target engagement and impact on neurodegeneration
- **Initiated Phase 1 first-in-human trial of ANX009.** Initiated subcutaneous dosing of healthy volunteers with Annexon’s third clinical-stage drug candidate in a Phase 1 trial designed to assess safety, tolerability, pharmacokinetics and pharmacodynamics of single and multiple ascending doses
- **Completed enrollment of Guillain-Barré Syndrome (GBS) Drug-Drug Interaction (DDI) trial.** Fully enrolled global Phase 1b DDI trial assessing safety and potential pharmacokinetic effect of ANX005 co-administered with IVIg in GBS patients. Data are anticipated in early 2021

Anticipated Upcoming Milestones

- **ANX005, a clinical-stage investigational monoclonal antibody intended to treat patients with complement-mediated disorders**
 - Phase 2 trial in patients with HD is ongoing with initial data anticipated in 2H 2021
 - Phase 2/3 trial in patients with GBS is planned to initiate in early 2021 with data anticipated in 2023
 - Phase 2 trial in patients with amyotrophic lateral sclerosis (ALS) is planned to initiate in early 2021 with initial data anticipated in 2H 2021
 - Phase 2 trial in patients with warm autoimmune hemolytic anemia (wAIHA) is planned to initiate in early 2021 with initial data anticipated in 1H 2022
- **ANX007, a clinical-stage investigational monoclonal antibody Fab for the treatment of patients with complement-mediated neurodegenerative ophthalmic diseases**
 - Phase 2 trial in patients with geographic atrophy (GA) is planned to initiate in early 2021 with data anticipated in 2023
- **ANX009, a clinical-stage investigational, subcutaneous formulation of an antigen-binding fragment (Fab) intended to treat systemic antibody-mediated autoimmune diseases**
 - Phase 1 first-in-human trial is ongoing with data anticipated in 1H 2021

Third Quarter 2020 Financial Results

- **Cash and cash equivalents:** Cash and cash equivalents were \$370.7 million as of September 30, 2020 compared to \$43.9 million as of December 31, 2019. In July 2020, Annexon completed an upsized IPO of 14,750,000 shares of its common stock, including the exercise of the underwriters’ option to purchase an additional 2,139,403 shares of common stock, resulting in net proceeds of \$262.4 million, after deducting underwriting commissions and offering expenses
 - **Research and development (R&D) expenses:** R&D expenses were \$11.8 million for the quarter ended September 30, 2020 compared to \$7.1 million for the quarter ended September 30, 2019
 - **General and administrative (G&A) expenses:** G&A expenses were \$3.8 million for the quarter ended September 30, 2020 compared to \$2.0 million for the quarter ended September 30, 2019
 - **Net loss:** Net loss was \$15.6 million for the quarter ended September 30, 2020 compared to \$10.2 million for the quarter ended September 30, 2019. Net loss attributable to common stockholders was \$22.0 million or \$0.77 per share for the quarter ended September 30, 2020 compared to \$10.5 million or \$24.14 per share for the quarter ended September 30, 2019
-

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 brain, body 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 development strategy designed to establish that its product candidates are engaging the target at a well-tolerated therapeutic dose in the intended tissue compartments. 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," "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: advancement of the company's clinical and preclinical programs; the company's capital position and ability to conduct promising near- and mid-term Phase 2 clinical trials; timing and commencement of future nonclinical studies and clinical trials and research and development programs; and the implementation of the company's business model and strategic plans for its business and product candidates, including additional indications which 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 Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2020 filed with the Securities and Exchange Commission (SEC) on November 16, 2020 pursuant to Rule 424(b) under the Securities Act 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:

Sylvia Wheeler

swheeler@wheelhousesa.com

Alexandra Santos

asantos@wheelhousesa.com**Media Contact:**

Caroline Rufo, Ph.D.

cruf@macbiocom.com

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,	
	2020	2019	2020	2019
Operating expenses:				
Research and development (1)	\$ 11,775	\$ 7,089	\$ 31,279	\$ 17,729
General and administrative (1)	3,810	1,981	8,999	5,660
Total operating expenses	<u>15,585</u>	<u>9,070</u>	<u>40,278</u>	<u>23,389</u>
Loss from operations	(15,585)	(9,070)	(40,278)	(23,389)
Loss on remeasurement of redeemable convertible preferred stock liability	—	(1,340)	—	(5,670)
Other (expense) income, net	(52)	224	64	821
Net loss before taxes	(15,637)	(10,186)	(40,214)	(28,238)
Provision for income taxes	1	2	5	3
Net loss	(15,638)	(10,188)	(40,219)	(28,241)
Accretion on redeemable convertible preferred stock	(145)	(281)	(705)	(815)
Deemed dividend – beneficial conversion feature on redeemable convertible preferred stock	(6,219)	—	(6,219)	—
Net loss attributable to common stockholders	<u>\$ (22,002)</u>	<u>\$ (10,469)</u>	<u>\$ (47,143)</u>	<u>\$ (29,056)</u>
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (0.77)</u>	<u>\$ (24.14)</u>	<u>\$ (4.79)</u>	<u>\$ (67.04)</u>
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	<u>28,465,156</u>	<u>433,749</u>	<u>9,845,754</u>	<u>433,406</u>

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

Research and development	624	159	1,284	391
General and administrative	847	451	1,613	1,122

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

	September 30, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	\$ 370,686	\$ 43,931
Prepaid expenses and other current assets	2,889	1,475
Total current assets	<u>373,575</u>	<u>45,406</u>
Property and equipment, net	2,039	2,138
Other long-term assets	—	2,354
Total assets	<u>\$ 375,614</u>	<u>\$ 49,898</u>
Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	\$ 3,954	\$ 2,371
Accrued liabilities	4,649	2,194
Deferred rent, current	385	366
Total current liabilities	<u>8,988</u>	<u>4,931</u>
Deferred rent	1,147	1,437
Total liabilities	<u>10,135</u>	<u>6,368</u>
Redeemable convertible preferred stock	—	143,984
Stockholders' Equity (Deficit):		
Preferred stock	—	—
Common stock	38	4
Additional paid-in capital	508,318	2,202
Accumulated other comprehensive loss	(78)	(80)
Accumulated deficit	<u>(142,799)</u>	<u>(102,580)</u>
Total stockholders' equity (deficit)	<u>365,479</u>	<u>(100,454)</u>
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	<u>\$ 375,614</u>	<u>\$ 49,898</u>