

**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): September 8, 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:

| <u>Title of each class</u> | <u>Trading Symbol(s)</u> | <u>Name of each exchange on which registered</u> |
|--|------------------------------|--|
| 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 September 8, 2020, Annexon, Inc. (“Annexon”) announced certain financial results for the second quarter ended June 30, 2020. A copy of Annexon’s press release, titled “Annexon Biosciences Reports Second Quarter 2020 Financial Results and Recent 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 | Press Release, dated September 8, 2020, titled “Annexon Biosciences Reports Second Quarter 2020 Financial Results and Recent Highlights” |

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: September 8, 2020

Annexon, Inc.

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

Annexon Biosciences Reports Second Quarter 2020 Financial Results and Recent Highlights

– Completed \$263M IPO in July, and private financing in late June –

– Company plans to initiate four new clinical trials by year-end, including in three expanded indications for ANX005 and first-in-human trial of ANX009 –

– Phase 2 trials of ANX005 in GBS and ANX007 in GA remain on track for 2021 -

South San Francisco, CA – September 8, 2020 (GLOBE NEWSWIRE) – 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 second quarter 2020 financial results and recent highlights.

“This is an exciting time in Annexon’s history as we advance our pioneering platform to treat a wide array of classical complement-mediated diseases,” said Douglas Love, Esq., president and chief executive officer of Annexon. “We continue to make notable progress advancing our deep pipeline, and remain intensely focused on the execution of our near-term strategic and development plans. In that regard, we remain on track to initiate several clinical trials in diverse diseases over the balance of 2020 and early 2021.”

Recent Highlights

- 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 \$262.7 million, after deducting underwriting commissions and offering expenses.
- In July 2020, Michael Overdorf was appointed chief business officer to oversee corporate development and commercial strategy efforts for the company. Mr. Overdorf brings nearly 20 years of industry experience to Annexon. Prior to joining, he spent 19 years at Eli Lilly and Company in various executive leadership roles, most recently in Corporate Business Development.
- In June 2020, prior to its IPO, Annexon successfully completed a private crossover financing, with net proceeds of \$96.8 million.

Anticipated Upcoming Milestones

- ANX005, a clinical-stage investigational monoclonal antibody intended to treat patients with complement-mediated disorders, is currently being evaluated to treat Guillain-Barre Syndrome (GBS), warm autoimmune hemolytic anemia (wAIHA), Huntington’s Disease (HD) and ALS. Phase 2a trials in patients with HD and ALS and a Phase 2 trial in patients with wAIHA are planned for 2H 2020. A Phase 2/3 trial in patients with GBS is expected to begin in early 2021.
- ANX009, an investigational, subcutaneous formulation of an antigen-binding fragment (Fab), is being evaluated to treat systemic antibody-mediated autoimmune diseases. A Phase 1 first-in-human trial is expected to begin in 2020.
- ANX007, a clinical-stage investigational monoclonal antibody Fab for the treatment of patients with complement-mediated neurodegenerative ophthalmic diseases, is being evaluated to treat geographic atrophy. A Phase 2 trial is expected to begin in 2021.

Second Quarter 2020 Financial Results:

- **Cash and cash equivalents:** Cash and cash equivalents were \$124.8 million as of June 30, 2020 compared to \$43.9 million as of December 31, 2019.
- **Research and development (R&D) expenses:** R&D expenses were \$9.3 million for the quarter ended June 30, 2020 compared to \$6.0 million for the quarter ended June 30, 2019.
- **General and administrative (G&A) expenses:** G&A expenses were \$2.9 million for the quarter ended June 30, 2020 compared to \$2.2 million for the quarter ended June 30, 2019.
- **Net loss:** Net loss attributable to common stockholders was \$12.5 million or \$28.87 per share for the quarter ended June 30, 2020 compared to \$9.7 million or \$22.30 per share for the quarter ended June 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 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. The company's first product candidate, ANX005, is a full-length monoclonal antibody formulated for intravenous administration in autoimmune and neurodegenerative disorders. The company's second product candidate, ANX007, is a monoclonal antibody Fab formulated for intravitreal administration for the treatment of neurodegenerative ophthalmic disorders. Annexon is advancing its current programs while evaluating additional orphan and large market indications. 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 patient tissue. 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 (Securities Act), 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; 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 prospectus filed with the Securities and Exchange Commission (SEC) on July 24, 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.

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

| | Three Months Ended | | Six Months Ended | |
|---|--------------------|-------------------|--------------------|--------------------|
| | June 30, | | June 30, | |
| | 2020 | 2019 | 2020 | 2019 |
| Operating expenses: | | | | |
| Research and development (1) | \$ 9,287 | \$ 5,987 | \$ 19,504 | \$ 10,640 |
| General and administrative (1) | 2,950 | 2,230 | 5,189 | 3,679 |
| Total operating expenses | <u>12,237</u> | <u>8,217</u> | <u>24,693</u> | <u>14,319</u> |
| Loss from operations | (12,237) | (8,217) | (24,693) | (14,319) |
| Loss on remeasurement of redeemable convertible preferred stock liability | — | (1,560) | — | (4,330) |
| Other income, net | 1 | 376 | 116 | 597 |
| Net loss before taxes | (12,236) | (9,401) | (24,577) | (18,052) |
| Provision for income taxes | 4 | — | 4 | 1 |
| Net loss | (12,240) | (9,401) | (24,581) | (18,053) |
| Accretion on redeemable convertible preferred stock | 281 | 272 | 560 | 534 |
| Net loss attributable to common stockholders | <u>\$ (12,521)</u> | <u>\$ (9,673)</u> | <u>\$ (25,141)</u> | <u>\$ (18,587)</u> |
| Net loss per share attributable to common stockholders, basic and diluted | <u>\$ (28.87)</u> | <u>\$ (22.30)</u> | <u>\$ (57.96)</u> | <u>\$ (42.90)</u> |
| Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted | <u>433,749</u> | <u>433,749</u> | <u>433,749</u> | <u>433,232</u> |

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

| | | | | |
|----------------------------|-----|-----|-----|-----|
| Research and development | 335 | 135 | 660 | 232 |
| General and administrative | 428 | 302 | 766 | 671 |

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

| | <u>June 30,</u> <u>2020</u> | <u>December 31,</u> <u>2019</u> |
|--|--------------------------------|------------------------------------|
| Assets | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 124,761 | \$ 43,931 |
| Prepaid expenses and other current assets | 907 | 1,475 |
| Total current assets | <u>125,668</u> | <u>45,406</u> |
| Property and equipment, net | 2,048 | 2,138 |
| Other long-term assets | 3,371 | 2,354 |
| Total assets | <u>\$ 131,087</u> | <u>\$ 49,898</u> |
| Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Deficit | | |
| Current liabilities: | | |
| Accounts payable | \$ 3,064 | \$ 2,371 |
| Accrued liabilities | 9,218 | 2,194 |
| Deferred rent, current | 378 | 366 |
| Total current liabilities | <u>12,660</u> | <u>4,931</u> |
| Deferred rent | 1,247 | 1,437 |
| Total liabilities | <u>13,907</u> | <u>6,368</u> |
| Redeemable convertible preferred stock | 235,054 | 143,984 |
| Stockholders' Deficit: | | |
| Common stock | 4 | 4 |
| Additional paid-in capital | 9,365 | 2,202 |
| Accumulated other comprehensive loss | (82) | (80) |
| Accumulated deficit | <u>(127,161)</u> | <u>(102,580)</u> |
| Total stockholders' deficit | <u>(117,874)</u> | <u>(100,454)</u> |
| Total liabilities, redeemable convertible preferred stock and stockholders' deficit | <u>\$ 131,087</u> | <u>\$ 49,898</u> |