
**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): August 12, 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 August 16, 2021, Annexon, Inc. (the “Company”) announced certain financial results for the second quarter ended June 30, 2021. A copy of the Company’s press release, titled “Annexon Biosciences Reports Second Quarter 2021 Financial Results and Provides Mid-Year Business Update,” 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 (the “SEC”) 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 5.02. Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

(d) On August 12, 2021, the Board of Directors (the “Board”) of the Company appointed William D. Waddill to the Board and as chairperson of the Board’s Audit Committee (the “Audit Committee”), effectively immediately. Mr. Waddill will serve as a Class II director with a term expiring at the 2022 annual meeting of stockholders and until his successor has been elected and qualified.

Pursuant to the Company’s non-employee director compensation program, as a non-employee director, Mr. Waddill will receive (i) a \$35,000 annual retainer for his service on the Board, prorated for the remainder of 2021, (ii) a \$15,000 annual retainer for his service as chairperson of the Audit Committee, prorated for the remainder of 2021, (iii) an automatic initial grant of a stock option to purchase 20,000 shares of Common Stock under the Company’s 2020 Incentive Award Plan and (iv) on the date of each annual stockholder meeting, an automatic grant of a stock option to purchase 10,000 shares of Common Stock under the Company’s 2020 Incentive Award Plan. The foregoing description is qualified in its entirety by reference to the text of the Company’s non-employee director compensation program, the form of which was filed as Exhibit 10.12 to the Company’s Registration Statement on Form S-1 filed with the SEC on July 20, 2020.

In addition, Mr. Waddill will enter into the Company’s standard indemnification and advancement agreement for directors and executive officers, the form of which was filed as Exhibit 10.12 to the Company’s Registration Statement on Form S-1 filed with the SEC on July 2, 2020.

Item 9.01. Financial Statements and Exhibits.**(d) Exhibits.**

<u>Exhibit</u>	<u>Description</u>
99.1	Press Release, dated August 16, 2021, titled “Annexon Biosciences Reports Second Quarter 2021 Financial Results and Provides Mid-Year Business Update”
104.1	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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: August 16, 2021

Annexon, Inc.

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



Annexon Biosciences Reports Second Quarter 2021 Financial Results and Provides Mid-Year Business Update

– Recently expanded Autoimmune franchise with advancement of third clinical candidate, ANX009, and strategically expanded into additional autoantibody-driven diseases –

– Continued progress in Neurodegeneration franchise with initial Phase 2 data results from ANX005 in Huntington’s disease expected in Q4 2021 and initiation of Phase 2 ANX005 trial in Amyotrophic Lateral Sclerosis –
– Appointed William D. Waddill to the Board of Directors –

SOUTH SAN FRANCISCO, Calif., August 16, 2021 – Annexon, Inc. (“Annexon”) (Nasdaq: ANNX), Annexon, a clinical-stage biopharmaceutical company developing a class of new complement medicines for patients with classical complement-mediated autoimmune and neurodegenerative disorders of the body, brain and eye, today announced second quarter 2021 financial results and provided a mid-year business update.

“We continue to make strong and consistent progress on our mission to deliver transformative therapies for patients suffering from classical complement-driven autoimmune and neurodegenerative diseases. With three clinical-stage drug candidates advancing in seven clinical trials, we remain laser-focused on developing game-changing therapies for patients in need while generating significant value for our shareholders,” said Douglas Love, Esq., president and chief executive officer of Annexon. “We also continue to expand our corporate capabilities and are pleased to announce the appointment of Will Waddill to our Board of Directors. Will has extensive experience in biotech and finance, and will provide an invaluable perspective as we enter our next phase of growth and value creation.”

Therapeutic Franchise Highlights and Updates

Annexon is advancing a portfolio of innovative C1 inhibitors to stop classical complement-mediated diseases at the start of the pathway in three therapeutic franchise areas: Autoimmune, Neurodegeneration and Ophthalmology.

Autoimmune Franchise

Annexon is pursuing a range of carefully selected neuromuscular, hematologic and nephritic antibody-mediated autoimmune indications where excess classical complement activity is a key driver of disease. During its July 28th C1q R&D series presentation, Annexon showcased the rationale and potential of its anti-C1 approach in autoimmune disease.

Recent highlights and updates in the Autoimmune franchise include:

- **Progressed enrollment in the Phase 2/3 trial of ANX005 in Guillain-Barré Syndrome (GBS), which remains on track for completion in 2023.** Data from the completed drug-drug interaction study and Phase 1b trial were recently presented at the 2021 Peripheral Nerve Society Annual Meeting, demonstrating tolerability and full C1q target engagement of ANX005 in combination with IVIg and reduction of cerebrospinal fluid (CSF) complement activity following ANX005 treatment in GBS patients.
 - **Advanced precision medicine approach to treat patients with a complement signature in the Phase 2 trial of ANX005 in warm autoimmune hemolytic anemia (wAIHA).** In the ongoing Phase 0 (patient selection) component of the trial, several wAIHA patients have demonstrated a classical complement signature, making them potentially eligible for enrollment into the Phase 2 component of the trial. ANX005 was shown to fully inhibit complement activation of wAIHA antibodies in these patient sera. Data from the Phase 0 portion of the Phase 2 trial is expected to be submitted to a peer reviewed forum in 2021.
 - **Strategic expansion of ANX005 into a Phase 2 program in Multifocal Motor Neuropathy (MMN), a neuromuscular disorder mechanistically related to GBS.** Initiation of the Phase 2 study is anticipated in early 2022.
 - **Reported Phase 1 first-in-human (FIH) data for ANX009 subcutaneous product candidate, Annexon’s third clinical stage drug candidate, which is being developed for the treatment of antibody-mediated autoimmune diseases of blood and vascular tissues.** ANX009 was shown to be well tolerated with complete and sustained C1q inhibition, supporting twice weekly subcutaneous administration. Data from the FIH study is expected to be submitted to a peer reviewed forum in 2021.
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- **Advanced ANX009 into a Phase 1b study in Lupus Nephritis (LN), a nephritic disease characterized by autoantibody-driven activation of C1q and the classical complement pathway.** Endogenous pathogenic anti-C1q antibodies (PACAs) have been shown to correlate with classical complement activation and disease activity. Initiation of the Phase 1b study is anticipated in early 2022 and will deploy Annexon's precision medicine approach targeting patients with excess classical complement and PACA activity. Complement and PACA data in LN patient samples is expected to be submitted to a peer reviewed forum in 2021.

Neurodegeneration Franchise

Annexon is pioneering an approach to stop complement-mediated neurodegeneration at the start, leveraging its original discoveries of the role of C1q as a major driver of synaptic loss and neurodegeneration. Blocking C1q potentially protects against functioning synapse loss and may provide functional benefit. Annexon is utilizing biomarkers of neuronal damage to measure impact on disease.

Recent highlights and updates in the Neurodegeneration franchise include:

- **Completed enrollment in Phase 2 trial of ANX005 in Huntington's Disease (HD) and expects to report initial data in Q4 2021.**
- **Initiated patient dosing in Phase 2 trial of ANX005 in Amyotrophic Lateral Sclerosis (ALS) and now expects to report data in 2022 due to slower initial enrollment.**
- **Completed preclinical study of ANX005 in SOD1 model of ALS, which demonstrated preserved neuromuscular function and reduced neuronal damage as measured by Neurofilament Light Chain (NfL).** Data from the SOD1 preclinical study represent the third instance of NfL reduction by ANX005, following the Phase 1b trial in GBS patients and R6/2 preclinical model of HD. Results from the ALS preclinical study are expected to be submitted to a peer-reviewed forum in 2021.

Ophthalmology Franchise

Annexon is utilizing intravitreal administration of ANX007 to inhibit C1q, which is implicated in neurodegeneration in the retina. Selectively targeting C1q at the start of the classical pathway versus downstream approaches may enhance efficacy and safety for patients in ophthalmic disorders, including Geographic Atrophy (GA).

Recent highlights and updates in the Ophthalmology franchise include:

- **Progressed enrollment in the Phase 2 trial of ANX007 in GA, which remains on track for completion in 2023.**
 - **ANX007 data demonstrating full target engagement of C1q in the outer layers of the retina in preclinical models is expected to be submitted to a peer-reviewed forum in 2021.**
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Corporate Update

- **In August 2021, Annexon appointed Will Waddill to its Board of Directors.** Mr. Waddill brings decades of financial and operational expertise in the biotechnology industry and a distinguished track record of leadership in industry organizations, including the Association of Bioscience Financial Officers (ABFO) and the Biotechnology Industry Organization (BIO). Mr. Waddill currently serves on the boards of Protagonist Therapeutics and Arrowhead Pharmaceuticals. Most recently, he served as Senior Vice President, CFO, of Calithera Bioscience from 2014 to 2016 and previously held senior finance leadership roles at OncoMed Pharmaceuticals and Ilypsa.

Second Quarter 2021 Financial Results

- **Cash and cash equivalents and short-term investments:** Cash and cash equivalents and short-term investments were \$302.4 million as of June 30, 2021.
- **Research and development (R&D) expenses:** R&D expenses were \$24.6 million for the quarter ended June 30, 2021, and \$45.3 million for the six months ended June 30, 2021, compared to \$9.3 million for the quarter ended June 30, 2020, and \$19.5 million for the six months ended June 30, 2020.
- **General and administrative (G&A) expenses:** G&A expenses were \$6.8 million for the quarter ended June 30, 2021, and \$12.3 million for the six months ended June 30, 2021, compared to \$3.0 million for the quarter ended June 30, 2020, and \$5.2 million for the six months ended June 30, 2020.
- **Net loss:** Net loss was \$31.3 million for the quarter ended June 30, 2021, and \$57.4 million for the six months ended June 30, 2021, compared to \$12.2 million for the quarter ended June 31, 2020, and \$24.6 million for the six months ended June 30, 2020. Net loss attributable to common stockholders was \$31.3 million or \$0.82 per share for the quarter ended June 30, 2021, and \$57.4 million or \$1.50 per share for the six months ended June 30, 2021, compared to \$12.5 million or \$28.87 per share for the quarter ended June 30, 2020, and \$25.1 million or \$57.96 per share for the six months ended June 30, 2020.

About Annexon, Inc.

Annexon is a clinical-stage biopharmaceutical company developing a class of new complement medicines for patients with classical complement-mediated disorders of the body, brain and eye. The company's pipeline is based on its platform technology addressing a broad spectrum of well-researched classical complement-mediated autoimmune and neurodegenerative diseases triggered by aberrant activation of C1q, the initiating molecule of the classical complement pathway. Annexon is advancing a portfolio of innovative product candidates designed to block the activity of C1q and the entire classical complement pathway: ANX005 (intravenous administration), ANX007 (intravitreal administration), and ANX009 (subcutaneous administration). Annexon is deploying a disciplined, biomarker-driven strategy designed to improve the probability of technical success of its portfolio. 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: continuing advancement of the company's innovative portfolio; timing of data from clinical trials and peer reviewed forum 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)
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Operating expenses:				
Research and development (1)	\$ 24,572	\$ 9,287	\$ 45,268	\$ 19,504
General and administrative (1)	6,801	2,950	12,307	5,189
Total operating expenses	31,373	12,237	57,575	24,693
Loss from operations	(31,373)	(12,237)	(57,575)	(24,693)
Other income, net	79	1	221	116
Net loss before taxes	(31,294)	(12,236)	(57,354)	(24,577)
Provision for income taxes	—	4	—	4
Net loss	(31,294)	(12,240)	(57,354)	(24,581)
Accretion on redeemable convertible preferred stock	—	281	—	560
Net loss attributable to common stockholders	\$ (31,294)	\$ (12,521)	\$ (57,354)	\$ (25,141)
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.82)	\$ (28.87)	\$ (1.50)	\$ (57.96)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	38,277,950	433,749	38,219,143	433,749

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

Research and development	\$ 2,402	\$ 335	\$ 3,948	\$ 660
General and administrative	2,115	428	3,531	766

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

	June 30, 2021	December 31, 2020
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	\$ 99,588	\$ 268,565
Short-term investments	202,798	82,641
Prepaid expenses and other current assets	2,007	2,805
Total current assets	304,393	354,011
Restricted cash	1,166	—
Property and equipment, less accumulated depreciation of \$3,047 and \$1,971 as of June 30, 2021 and December 31, 2020, respectively	5,129	1,935
Operating lease right-of-use assets	21,096	—
Total assets	<u>\$ 331,784</u>	<u>\$ 355,946</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 4,184	\$ 3,734
Accrued liabilities	5,850	6,497
Deferred rent, current	—	391
Operating lease liabilities, current	250	—
Total current liabilities	10,284	10,622
Deferred rent	—	1,046
Operating lease liabilities, non-current	26,165	—
Total liabilities	36,449	11,668
Commitments and contingencies		
Stockholders' equity:		
Common stock	38	38
Additional paid-in capital	518,708	510,309
Accumulated other comprehensive loss	(65)	(77)
Accumulated deficit	(223,346)	(165,992)
Total stockholders' equity	295,335	344,278
Total liabilities and stockholders' equity	<u>\$ 331,784</u>	<u>\$ 355,946</u>