

Annexon Biosciences Announces Program Highlights and Reports Fourth Quarter and Full Year 2021 Financial Results

March 1, 2022

Multiple Value-Creating Catalysts Across Complement-Targeted Portfolio Anticipated Through 2023

Encouraging Interim Data Reported from Phase 2 Study of ANX005 for Huntington's Disease; Full Data Expected in the Second Quarter of 2022

\$243 Million in Cash and Investments at End of 2021; Operating Runway into First Quarter of 2024

BRISBANE, Calif., March 01, 2022 (GLOBE NEWSWIRE) -- [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 recent highlights and reported fourth quarter and full year 2021 financial results.

"2021 was a year of marked progress across our pipeline, which is uniquely designed to provide greater protection against complement-mediated disorders of the body, brain and eye by stopping the classical complement pathway *at its start*, C1q," said Douglas Love, Esq., president and chief executive officer of Annexon. "The favorable early data generated with ANX005 in both Guillain-Barré Syndrome and Huntington's disease – autoimmune and neurodegenerative diseases, respectively – support our approach to fully inhibiting C1q and support the ongoing development with our lead candidate. In addition, given the known role that aberrant activation of C1q plays in driving a wide range of diseases, we are actively advancing our pipeline across three therapeutic franchises, with numerous clinical data readouts and new study initiations anticipated over the course of 2022 and 2023. This is an exciting time for Annexon, and I am confident in our potential to deliver game-changing medicines to patients in need."

Pipeline Highlights

- In January 2022, Annexon [reported interim data](#) from its ongoing, open-label Phase 2 clinical trial of ANX005 in patients with Huntington's disease (HD) who completed the 24-week treatment period. Interim data showed that treatment with ANX005 had been generally well-tolerated and showed full target engagement of C1q in serum and cerebrospinal fluid (CSF), notable improvements in clinical measures relative to baseline and NfL levels consistent with levels reported in natural history studies. Annexon anticipates reporting data from all patients treated, including data from the three-month follow-up period, in the second quarter of 2022.
- In December 2021 at the ASH Annual meeting, Annexon announced [safety and dose-response data](#) from its Phase 1 clinical trial of ANX009, the company's subcutaneously administered product candidate that is designed to selectively inhibit C1q in vascular and blood-based autoimmune diseases. In addition, Annexon reported preclinical data supporting the potential role of the complement pathway in warm autoimmune hemolytic anemia (wAIHA).

Corporate Highlights

- In February 2022, Dr. Bettina Cockroft joined the Annexon [board of directors](#) with over 20 years of experience in the biopharmaceutical industry.

Key Anticipated Milestones

Autoimmune

- Report data from Phase 2 trial of ANX005 in patients with warm autoimmune hemolytic anemia (wAIHA) in the second half of 2022
- Report initial data from Phase 1b trial of ANX009, the company's subcutaneously administered drug candidate, in patients with lupus nephritis in the second half of 2022
- Initiate first-in-human trial of ANX1502, a first-in-class oral small molecule drug candidate, in the second half of 2022, with data expected in 2023
- Report data from Phase 2/3 trial of ANX005 in patients with Guillain-Barré Syndrome (GBS) in 2023

Neurodegeneration

- Report data from Phase 2 trial of ANX005 in patients with HD, who completed the six-month treatment period and three-month follow-up period, in the second quarter of 2022
- Initiate first-in-human trial of ANX105, the company's next generation monoclonal antibody formulated for IV administration, in the first half of 2022, with data anticipated in 2023
- Report data from Phase 2 trial of ANX005 in patients with ALS in 2023

Ophthalmology

- Report data from Phase 2 trial of ANX007, a monoclonal antibody antigen-binding fragment, in patients with geographic

atrophy in 2023

Fourth Quarter and Full Year 2021 Financial Results

- **Cash and operating runway:** Cash and cash equivalents and short-term investments were \$242.7 million as of December 31, 2021. Annexon continues to expect that its current cash position is sufficient to fund its operating plans into the first quarter of 2024.
- **Research and development (R&D) expenses:** R&D expenses were \$27.2 million for the quarter ended December 31, 2021, and \$100.0 million for the year ended December 31, 2021, compared to \$18.0 million for the quarter ended December 31, 2020, and \$49.3 million for the year ended December 31, 2020.
- **General and administrative (G&A) expenses:** G&A expenses were \$10.2 million for the quarter ended December 31, 2021, and \$30.6 million for the year ended December 31, 2021, compared to \$5.2 million for the quarter ended December 31, 2020, and \$14.2 million for the year ended December 31, 2020.
- **Net loss:** Net loss was \$37.4 million for the quarter ended December 31, 2021, and \$130.3 million for the year ended December 31, 2021, compared to \$23.2 million for the quarter ended December 31, 2020, and \$63.4 million for the year ended December 31, 2020.

About Annexon

Annexon (Nasdaq: ANNX) is a clinical-stage biopharmaceutical company pioneering a new class of complement medicines designed to stop the classical complement pathway at its start, C1q, to bring therapies to patients with classical complement-mediated autoimmune, neurodegenerative, and ophthalmic disorders. The company's proprietary complement-targeting platform utilizes well-researched classical complement-mediated autoimmune and neurodegenerative processes triggered by aberrant activation of C1q, the initiating molecule of the classical complement pathway. Annexon is advancing a broad portfolio of innovative product candidates designed to block the activity of C1q and the entire classical complement pathway, which may provide more complete protection against complement-mediated disorders of the body, brain and eye. The company's pipeline includes three clinical-stage drug candidates, ANX005 (intravenous administration), ANX007 (intravitreal administration), and ANX009 (subcutaneous administration), as well as a robust early-stage pipeline of preclinical and discovery stage programs. 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," "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; initial findings and observations related to the interim data from the company's ongoing, open-label Phase 2 clinical trial of ANX005 in patients with HD; the potential benefits from treatment with anti-C1q therapy; timing of data reports and study initiation; 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.

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

Three Months Ended
December 31,

Year Ended
December 31,

	<u>2021</u> <u>(unaudited)</u>	<u>2020</u> <u>(unaudited)</u>	<u>2021</u>	<u>2020</u>
Operating expenses:				
Research and development (1)	\$ 27,217	\$ 17,992	\$ 100,066	\$ 49,271
General and administrative (1)	10,241	5,199	30,647	14,198
Total operating expenses	<u>37,458</u>	<u>23,191</u>	<u>130,713</u>	<u>63,469</u>
Loss from operations	(37,458)	(23,191)	(130,713)	(63,469)
Interest and other income (expense), net	87	(7)	390	57
Net loss before taxes	(37,371)	(23,198)	(130,323)	(63,412)
Provision for income taxes	—	(5)	—	—
Net loss	(37,371)	(23,193)	(130,323)	(63,412)
Accretion on redeemable convertible preferred stock	—	—	—	(705)
Deemed dividend – beneficial conversion feature on redeemable convertible preferred stock	—	—	—	(6,219)
Net loss attributable to common stockholders	<u>\$ (37,371)</u>	<u>\$ (23,193)</u>	<u>\$ (130,323)</u>	<u>\$ (70,336)</u>
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (0.97)</u>	<u>\$ (0.61)</u>	<u>\$ (3.40)</u>	<u>\$ (4.15)</u>
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	<u>38,479,221</u>	<u>38,157,618</u>	<u>38,316,273</u>	<u>16,962,398</u>
(1) Includes the following stock-based compensation expense:				
Research and development	\$ 2,280	\$ 990	\$ 8,610	\$ 2,274
General and administrative	\$ 2,075	\$ 1,001	\$ 7,652	\$ 2,614

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

	<u>December 31,</u>	
	<u>2021</u>	<u>2020</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 74,843	\$ 268,565
Short-term investments	167,872	82,641
Prepaid expenses and other current assets	4,978	2,805
Total current assets	<u>247,693</u>	<u>354,011</u>
Restricted cash	1,166	—
Property and equipment, net	17,848	1,935
Operating lease right-of-use assets	20,333	—
Total assets	<u>\$ 287,040</u>	<u>\$ 355,946</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 11,153	\$ 3,734
Accrued liabilities	9,250	6,497
Deferred rent, current	—	391
Operating lease liabilities, current	1,202	—
Other current liabilities	139	—
Total current liabilities	<u>21,744</u>	<u>10,622</u>
Deferred rent	—	1,046
Operating lease liabilities, non-current	33,387	—
Total liabilities	<u>55,131</u>	<u>11,668</u>
Stockholders' equity:		
Preferred stock	—	—
Common stock	39	38
Additional paid-in capital	528,365	510,309
Accumulated other comprehensive loss	(180)	(77)
Accumulated deficit	<u>(296,315)</u>	<u>(165,992)</u>
Total stockholders' equity	<u>231,909</u>	<u>344,278</u>
Total liabilities and stockholders' equity	<u>\$ 287,040</u>	<u>\$ 355,946</u>

