Annexon Biosciences Announces Business and Program Highlights and Reports Third Quarter 2021 Financial Results

November 9, 2021

$271 Million Cash and Investments at End of Third Quarter 2021 Supports Operating Runway into 2024, Including Several Key Clinical Milestones across the Portfolio

SOUTH SAN FRANCISCO, Calif., Nov. 09, 2021 (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 third quarter 2021 financial results.

"The third quarter marks another quarter of meaningful progress with our portfolio, including effectively advancing three clinical-stage product candidates in five clinical trials," said Douglas Love, Esq., president and chief executive officer of Annexon. "We're also pleased to have been granted Orphan Drug designation by the FDA for ANX005, underscoring the Agency's recognition of ANX005's potential as a novel therapy for the treatment of Huntington's disease. Additionally, in collaboration with multiple academic and physician key opinion leaders, we conducted two C1q Series R&D Events that highlighted the applicability of our platform and differentiated scientific approach targeting the classical complement cascade in a range of autoimmune and neurodegenerative diseases. The combination of a rich set of milestones, a strong balance sheet, and a talented team, lays the foundation for a transformational year ahead. We look forward to sharing the continued progress across our portfolio, including initial data from our Huntington's disease clinical trial, as we work to bring treatments to patients suffering from serious complement-mediated diseases."

Program Highlights

- **Second C1q Series R&D Event Highlights Neurodegeneration Franchise:** Annexon hosted its second C1q Series event, which spotlighted the company's neurodegeneration franchise and approach to treating complement-mediated neurodegenerative diseases. During the event, Annexon's leadership team and participating key opinion leaders shared their perspectives on:
  - The role of C1q and the classical complement pathway in neurodegenerative diseases, including Huntington's disease (HD) and amyotrophic lateral sclerosis (ALS);
  - Research on neurofilament light chain (NfL) and natural history data showing the association of a rise in NfL with clinical progression in both HD and ALS; and
  - Internal data demonstrating the ability to reduce NfL with ANX005, both clinically in Guillain-Barré syndrome (GBS), and preclinically in HD and ALS.
- **Initial Data from Phase 2 trial of ANX005 in HD Expected in the Fourth Quarter of 2021:** Annexon is studying its lead compound, ANX005, a clinical-stage investigational monoclonal antibody intended to treat patients with complement-mediated disorders, in a Phase 2 trial in patients with HD. The company anticipates initial data from the trial in the fourth quarter of 2021, which is expected to include data from a subset of 16 patients who have completed the six-month treatment period, including safety and tolerability, C1q target engagement in cerebral spinal fluid and serum, and impact on NfL levels. The full dataset from all patients who complete both the six-month on-treatment and three-month off-treatment periods are expected to be reported in the first half of 2022.
- **ANX005 Granted Orphan Drug Designation for the Treatment of HD:** The U.S. Food and Drug Administration (FDA) has granted Orphan Drug designation for ANX005 for the treatment of patients with HD. Orphan Drug designation provides orphan status to drugs or biologics that are intended to treat rare diseases or disorders affecting fewer than 200,000 people in the United States, and certain incentives to the product sponsor, including tax credits for qualified clinical trials and fee waivers. The designation confers eligibility for seven years of market exclusivity following FDA product approval.

Business Highlights

- **Leadership Team Strengthened by Appointment of Ted Yednock, Ph.D., as Chief Innovation Officer and Larry Mattheakis, Ph.D., as Chief Scientific Officer:** In the third quarter, Annexon appointed Ted Yednock, Ph.D., as chief innovation officer (CIO), and Larry Mattheakis, Ph.D., as chief scientific officer (CSO). Dr. Ted Yednock served as Annexon's CSO since 2013. As CIO, he will serve as chairman of the Scientific Advisory Board and continue to enhance and integrate Annexon's key scientific findings and collaborations. Dr. Larry Mattheakis brings decades of drug discovery and development expertise to the CSO role, supporting the advancement of Annexon's current and future pipeline.

Third Quarter 2021 Financial Results

- **Cash and Operating Runway:** Cash and cash equivalents and short-term investments were $271.4 million as of September 30, 2021. Annexon expects that its current cash position is sufficient to fund its operating plans into 2024.

- **Research and development (R&D) expenses:** R&D expenses were $27.6 million for the quarter ended September 30, 2021, compared to $11.8 million for the quarter ended September 30, 2020.
- **General and administrative (G&A) expenses:** G&A expenses were $8.1 million for the quarter ended September 30, 2021, compared to $3.8 million for the quarter ended September 30, 2020.
- **Net loss:** Net loss was $35.6 million or $0.93 per share for the quarter ended September 30, 2021, compared to $15.6 million or $0.77 per share for the quarter ended September 30, 2020.

About Annexon

Annexon (Nasdaq: ANNX) is a clinical-stage biopharmaceutical company developing a new class of complement medicines for patients with classical complement-mediated autoimmune, neurodegenerative, and ophthalmic 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; timing of completion of clinical studies and clinical development milestones; the company's ability to deliver on its objectives and the potential for a transformational year ahead; 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; cash position sufficient to fund its operating plans into 2024; the benefits of Orphan Drug designation; and leadership team service. 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 September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Operating expenses:				
Research and development (1)	$ 27,581	$ 11,775	$ 72,849	$ 31,279
General and administrative (1)	8,099	3,810	20,406	8,999
Total operating expenses	35,680	15,585	93,255	40,278
Loss from operations	(35,680)	(15,585)	(93,255)	(40,278)
Other income (expense), net	82	(52)	303	64
Net loss before taxes	(35,598)	(15,637)	(92,952)	(40,214)
Provision for income taxes	—	1	—	5
Net loss	(35,598)	(15,638)	(92,952)	(40,219)
Accretion on redeemable convertible preferred stock	—	(145)	—	(705)
Deemed dividend – beneficial conversion feature on redeemable convertible preferred stock	—	(6,219)	—	(6,219)
Net loss attributable to common stockholders	$ (35,598)	$ (22,002)	$ (92,952)	$ (47,143)

Net loss per share attributable to common stockholders, basic and diluted	$ (0.93)	$ (0.77)	$ (2.43)	$ (4.79)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	38,341,110	28,465,156	38,261,359	9,845,754

(1) Includes the following stock-based compensation expense:				
Research and development	$ 2,382	$ 624	$ 6,330	$ 1,284
General and administrative	$ 2,046	$ 847	$ 5,577	$ 1,613

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

	September 30, 2021 (Unaudited)	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 68,519	$ 268,565
Short-term investments	202,848	82,641
Prepaid expenses and other current assets	4,131	2,805
Total current assets	275,498	354,011
Restricted cash	1,166	—
Property and equipment, net	12,219	1,935
Operating lease right-of-use assets	20,680	—
Other assets	593	—
Total assets	$ 310,156	$ 355,946
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 4,797	$ 3,734
Accrued liabilities	7,059	6,497
Deferred rent, current	—	391
Operating lease liabilities, current	63	—
Total current liabilities	11,919	10,622
Deferred rent	—	1,046
Operating lease liabilities, non-current	33,760	—
Total liabilities	45,679	11,668
Commitments and contingencies		
Stockholders' equity:		
Common stock	38	38
Additional paid-in capital	523,458	510,309
Accumulated other comprehensive loss	(75)	(77)
Accumulated deficit	(258,944)	(165,992)
Total stockholders' equity	264,477	344,278
Total liabilities and stockholders' equity	$ 310,156	$ 355,946