Annexon Reports First Quarter 2023 Financial Results and Highlights Recent Pipeline Progress

May 8, 2023

Initial Clinical Data Expected from the Phase 2 ARCHER Trial of ANX007 in Geographic Atrophy in Mid-2023

Initial Clinical Data Anticipated from the Phase 1b Trial of ANX009
in Lupus Nephritis in 1H'23

Enrollment Expected to be Completed in Phase 3 Trial in Guillain-Barré Syndrome
During 2H'23, with Initial Topline Results Expected in 1H'24

Strong Financial Position with Operating Runway into 2025, with Multiple Mid-Stage and Pivotal Clinical Trial Readouts Expected Across 2023 and 2024

BRISBANE, Calif., May 08, 2023 (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 reported first quarter 2023 financial results and highlighted recent progress across its portfolio of complement therapies.

"The first quarter was another period of strong execution of our flagship and next-wave clinical-stage programs for the treatment of complement-mediated diseases of the body, brain and eye, thereby enabling multiple clinical catalysts over the next several quarters," said Douglas Love, president and CEO of Annexon. "Our platform approach of blocking classical complement-driven inflammation where it initiates on diseased tissue has demonstrated robust patient benefit in multiple autoimmune and neurodegenerative diseases. We are excited by the potential of demonstrating patient benefit in our first ophthalmologic indication with the Phase 2 ANX007 ARCHER trial in geographic atrophy, whereby stopping the initiation of the inflammatory classical complement cascade may reduce retinal inflammation and improve macular health. We are eagerly anticipating results from our pivotally designed and executed ARCHER trial in mid-2023."

"In autoimmune, we expect to report initial clinical results from our Phase 1b program in lupus nephritis during the first half of 2023 and share data during the second half of the year with ANX1502, our first-in-class, small molecule oral inhibitor of the classical pathway, which we anticipate advancing into several autoimmune conditions. Importantly, enrollment is progressing well in our pivotal ANX005 Phase 3 program in Guillain-Barré Syndrome with clinical results expected during the first half of 2024," Mr. Love continued. "With multiple clinical milestones expected over the next 18 months, these readouts have the potential to accelerate our transition into a leading late-stage biopharmaceutical company focused on the treatment of complement-mediated diseases."

Recent Highlights

Annexon has prioritized advancing four flagship programs with the goal of creating near-term value for patients and physicians: Guillain-Barré syndrome (GBS), Huntington's disease (HD), geographic atrophy (GA) and a first-in-kind oral small molecule, ANX1502, for autoimmune diseases. Beyond these programs, there is a range of next-wave programs for the treatment of amyotrophic lateral sclerosis (ALS), lupus nephritis (LN) and other earlier-stage autoimmune and neurodegenerative diseases, where additional investments are planned based upon meeting certain development and funding objectives.

Flagship Programs

ANX005 in GBS: Enrollment in the Phase 3 pivotal trial of ANX005 in patients with GBS is progressing and expected to be completed in second half of 2023, with initial topline clinical results anticipated during the first half of 2024.

ANX007 in GA: Last patient treated and initial clinical data from ANX007 ARCHER Phase 2 trial in GA expected to be reported mid-2023, followed by additional data after the conclusion of the six-month off-treatment period by the end of 2023.

ANX1502 in autoimmune diseases: Enrollment underway in second cohort of the multiple-ascending dose Phase 1a trial in healthy volunteers. Data expected to be reported in the second half of 2023.

ANX005 in HD: Initiate a planned Phase 2/3 trial in HD in 2023, upon obtaining funding for full program development.

Next Wave Programs

ANX009 in LN: Initial clinical data from Phase 1b signal-finding trial of ANX009 for LN expected during the first half of 2023.

ANX005 in ALS: Enrollment continues in the Phase 2a trial, following encouraging preliminary results which showed slowing of disease progression. Additional data expected in the second half of 2023.

ANX105: Report initial data from the single-ascending dose Phase 1 trial of ANX105 in healthy volunteers in 2023.

First Quarter 2023 Financial Results

Cash and operating runway: Cash and cash equivalents and short-term investments were $228.2 million as of March 31, 2023. Based on the current operating plan, Annexon continues to expect its cash, cash equivalents and marketable securities as of March 31, 2023, to be sufficient to fund the company's operating expenses and capital expenditure requirements related to currently ongoing clinical trials into 2025.

Research and development (R&D) expenses: R&D expenses were $32.3 million for the quarter ended March 31, 2023, reflecting the advancement

of our late-stage flagship programs, including GBS and GA. This compared to $27.0 million for the quarter ended March 31, 2022.

General and administrative (G&A) expenses: G&A expenses were $8.9 million for the quarter ended March 31, 2023, compared to $8.4 million for the quarter ended March 31, 2022.

Net loss: Net loss was $38.7 million or $0.52 per share for the quarter ended March 31, 2023, compared to $35.4 million or $0.92 per share for the quarter ended March 31, 2022.

About Annexon

Annexon (Nasdaq: ANNX) is a clinical-stage biopharmaceutical company seeking to bring game-changing medicines to patients with classical complement-mediated diseases of the body, brain and eye. The classical complement pathway within the immune system, when overactivated, drives inflammation in a host of autoimmune, neurodegenerative and ophthalmic diseases. Annexon is advancing a new class of complement medicines targeting the early classical cascade and all downstream pathway components that contribute to disease, while selectively preserving the beneficial immune functions of other complement pathways. Annexon is rigorously developing a pipeline of diversified product candidates across multiple mid- to late-stage clinical trials, with clinical data anticipated throughout 2023 and beyond.

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; obtaining funding for advancement of the company’s programs; cash operating runway; the potential benefits from treatment with anti-C1q therapy; timing of data reports; and continuing advancement of the company’s 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)
(unaudited)

	Three Months Ended March 31,	
	2023	**2022**
Operating expenses:		
Research and development (1)	$ 32,345	$ 26,998
General and administrative (1)	8,897	8,428
Total operating expenses	41,242	35,426
Loss from operations	(41,242)	(35,426)
Interest and other income, net	2,566	53
Net loss	$ (38,676)	$ (35,373)
Net loss per share, basic and diluted	$ (0.52)	$ (0.92)
Weighted-average shares used in computing net loss per share, basic and diluted	73,855,642	38,563,384

(1) Includes the following stock-based compensation expense:		
Research and development	$ 2,251	$ 1,959
General and administrative	$ 2,356	$ 2,293

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

	March 31, 2023 (Unaudited)	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 144,120	$ 140,020
Short-term investments	84,045	102,637
Prepaid expenses and other current assets	4,371	5,441
Total current assets	232,536	248,098
Restricted cash	1,032	1,032
Property and equipment, net	16,334	16,838
Operating lease right-of-use assets	18,864	19,128
Other non-current assets	12	—
Total assets	$ 268,778	$ 285,096
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 10,346	$ 7,416
Accrued liabilities	10,677	13,448
Operating lease liabilities, current	1,534	1,316
Other current liabilities	384	180
Total current liabilities	22,941	22,360
Operating lease liabilities, non-current	30,976	31,542
Total liabilities	53,917	53,902
Stockholders' equity:		
Common stock	53	48
Additional paid-in capital	691,963	669,780
Accumulated other comprehensive loss	(217)	(372)
Accumulated deficit	(476,938)	(438,262)
Total stockholders' equity	214,861	231,194
Total liabilities and stockholders' equity	$ 268,778	$ 285,096