Cortexyme Announces Third Quarter 2019 Financial Results and Provides Business Update

November 12, 2019

—Lead investigational medicine COR388, a potentially transformative new paradigm for addressing Alzheimer's disease, continues to advance in Phase 2/3 GAIN clinical trial

—Following successful May 2019 initial public offering, Cortexyme is well capitalized and focused on high quality execution of the GAIN Trial

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Nov. 12, 2019-- Cortexyme, Inc. (Nasdaq: CRTX), a clinical stage biopharmaceutical company pioneering a novel, disease-modifying therapeutic approach to treat what it believes to be a key underlying cause of Alzheimer's and other degenerative diseases, today announced financial results for the third quarter 2019 and provided an update on its business.

"The GAIN Trial has been met with enthusiasm from the Alzheimer's clinical and patient communities since its launch this past spring in the U.S. and, last quarter, in Europe," said Casey Lynch, Cortexyme's chief executive officer, co-founder, and chair. "We look forward to delivering a steady cadence of milestones in the coming quarters. Supported by a strong balance sheet and our experienced and growing professional team, we are well positioned to advance toward our goal of stemming the tide of Alzheimer's disease by halting its progression."

Recent Business Updates

GAIN Trial

- The GAIN Trial, the company's Phase 2/3 study of COR388 versus placebo in patients with mild to moderate Alzheimer's disease, is anticipated to continue on track in 2020. The trial is targeting an enrollment of 570 patients across 90 sites in the United States and Europe, with top-line results from the trial expected in the fourth quarter of 2021. In addition, the company is evaluating the feasibility of conducting an interim analysis, and plans to discuss this strategy with the U.S. Food and Drug Administration (FDA).
- In September, Cortexyme announced the start of screening in Europe for the GAIN Trial. Cortexyme expects to enroll subjects in five European countries; sites in the UK, Spain, France, and Poland are already active. An updated listing can be found on www.clinicaltrials.gov.

Advancing a New Understanding of Alzheimer's Causation and Treatment

- Earlier this month, Cortexyme announced that research on COR388's impact on ApoE in Alzheimer's disease patients will be the subject of an oral presentation at the 12th Clinical Trials on Alzheimer's (CTAD) conference, which is being held December 4-7, 2019, in San Diego. Michael Detke, M.D., Ph.D., Cortexyme's chief medical officer, will deliver the presentation (abstract OC28) at 10:00 a.m. PST on Saturday, December 7th. Additionally, the company will host a lunch symposium on Thursday, December 5th, from 12:30-1:30 p.m. PST. More details, including registration info, are available here.
- In July, COR388 was the subject of a research abstract presented at the Alzheimer's Association International Conference (AAIC) 2019 in Los Angeles. In a Developing Topics poster that was included in the AAIC press program, researchers highlighted the Phase 1b clinical development experience of COR388 and provided an overview of the design for the GAIN trial. AAIC is the largest international meeting dedicated to advancing dementia science.
- In June, Cortexyme expanded its Clinical Advisory Board (CAB) with four new key clinical and regulatory experts. The CAB includes leading experts on Alzheimer's, neurodegenerative disorders, and central nervous system drug development. Cortexyme has benefited from the group's insights as it advanced COR388 through Phase 1 testing and laid the groundwork for the GAIN trial. Recently, Cortexyme's regulatory advisor David Hosford, M.D., Ph.D. rejoined the FDA Division of Neurology Products. Thomas Laughren, M.D., a consultant and previous Division Director at the FDA, will now be advising the company on regulatory matters.

Corporate Updates

- In May, Cortexyme completed a successful initial public offering, raising approximately $77.8 million after expenses.

Financial Results for the Quarter Ended September 30, 2019

Cash, Cash Equivalents and Marketable Securities: Cash, cash equivalents, and short and long-term marketable securities as of September 30, 2019, were $127.8 million. Cortexyme expects current cash, cash equivalents and marketable securities will be sufficient to fund its operating and capital expenditures through 2021 and the completion of the GAIN Trial.

Research and Development (R&D) Expenses: For the quarter ended September 30, 2019, R&D expenses were $8.3 million, including $0.6 million of stock-based compensation, compared to R&D expenses of $2.3 million for the quarter ended September 30, 2018. The increase was primarily due to costs related to the research and development of COR388, the GAIN Trial, and stock-based compensation.

General and Administrative (G&A) Expenses: For the quarter ended September 30, 2019, G&A expenses were $2.3 million, which included $0.3 million of stock-based compensation. This compared to G&A expenses of $0.6 million for the quarter ended September 30, 2018. The increase was primarily attributable to personnel-related expenses, professional and legal fees, and stock-based compensation.

Net Loss: For the quarter ended September 30, 2019, net loss was $9.9 million, or a loss of $0.37 per basic share.

About the GAIN Trial

The GAIN Trial is a Phase 2/3 randomized, double-blind, placebo-controlled study assessing the efficacy, safety, and tolerability of two dose levels of COR388 oral capsules in subjects with mild to moderate AD. The trial is currently enrolling subjects in the U.S. and Europe, and top-line results from the trial are anticipated in the fourth quarter of 2021. More information about the trial can be found at www.GAINtrial.com.

About Cortexyme, Inc.

Cortexyme (Nasdaq: CRTX) is a clinical stage biopharmaceutical company pioneering a novel, disease-modifying therapeutic approach to treat what it believes to be a key underlying cause of Alzheimer's disease and other degenerative diseases. Cortexyme is targeting a specific, infectious pathogen found in the brain of Alzheimer's patients and tied to neurodegeneration and neuroinflammation in animal models. The company's lead investigational medicine, COR388, is the subject of the GAIN Trial, an ongoing Phase 2/3 clinical study in patients with mild to moderate Alzheimer's. To learn more about Cortexyme, visit www.cortexyme.com or follow @Cortexyme on Twitter.

Forward-Looking Statements

Statements in this press release contain "forward-looking statements" that are subject to substantial risks and uncertainties. Forward-looking statements contained in this press release may be identified by the use of words such as "anticipate," "expect," "believe," "will," "may," "should," "estimate," "project," "outlook," "forecast" or other similar words. Forward-looking statements are based on Cortexyme's current expectations and are subject to inherent uncertainties, risks and assumptions that are difficult to predict. Further, certain forward-looking statements are based on assumptions as to future events that may not prove to be accurate. Factors that could cause actual results to differ include, but are not limited to, the risks and uncertainties described in the section titled "Risk Factors" in the final prospectus related to Cortexyme's initial public offering filed with the Securities and Exchange Commission on May 9, 2019 and Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on June 12, 2019. Forward-looking statements contained in this press release are made as of this date, and Cortexyme undertakes no duty to update such information except as required under applicable law.

Cortexyme, Inc. Condensed Statements of Operations
(Unaudited)
(In thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	**2018**	**2019**	**2018**
Operating expenses:				
Research and development	$ 8,253	$ 2,290	$ 20,187	$ 6,989
General and administrative	2,316	584	6,032	1,288
Total operating expenses	10,569	2,874	26,219	8,277
Loss from operations	(10,569)	(2,874)	(26,219)	(8,277)
Interest income	711	353	1,618	434
Interest expense	—	—	—	(957)
Change in fair value of derivative liability	—	—	—	(206)
Net loss	(9,858)	(2,521)	(24,601)	(9,006)
Other comprehensive income/ (loss):				
Unrealized gain / (loss) on available for sales securities	16	(16)	145	(16)

Total comprehensive income/(loss)	(9,842)	(2,537)	(24,456)	(9,022)
Net loss per share - basic and diluted	(0.37)	(0.75)	(1.59)	(2.68)
Weighted average shares of common stock outstanding - basic and diluted	26,841,149	3,361,029	15,489,216	3,360,683

Cortexyme, Inc. Condensed Balance Sheets
(Unaudited)
(In thousands, except share and per share amounts)

	September 30, 2019	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	$ 44,740	$ 24,872
Short term investments	75,730	46,844
Restricted cash	250	—
Prepaid expenses and other current assets	3,649	868
Total current assets	124,369	72,584
Property and equipment, net	270	283
Right-of-use assets	1,171	—
Long term investments	7,341	—
Other assets	263	10
Total assets	$ 133,414	$ 72,877
LIABILITIES AND STOCKHOLDERS' EQUITY / (DEFICIT)		
Current liabilities:		
Accounts Payable	$ 2,295	$ 495
Accrued expenses and other current liabilities	3,832	962
Total current liabilities	6,127	1,457
Total liabilities	6,127	1,457
Total stockholders' equity / (deficit)	127,287	(32,626)
Total liabilities and stockholders' equity / (deficit)	$ 133,414	$ 72,877

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