Reata Pharmaceuticals, Inc. Announces Second Quarter 2016 Financial and Operating Results

August 11, 2016

IRVING, Texas, Aug. 11, 2016 (GLOBE NEWSWIRE) -- Reata Pharmaceuticals, Inc. (Nasdaq:RETA) ("Reata" or "the Company"), a clinical stage biopharmaceutical company, today announced financial results for the second quarter ended June 30, 2016 and provided an update on the Company's business and product development programs.

Financial Highlights

The Company incurred operating expenses of $13.8 million for the quarter ended June 30, 2016, with research and development accounting for $9.1 million. This compares to operating expenses of $13.6 million for the same period of the year prior, with research and development accounting for $9.7 million. A net loss of $0.9 million was reported by the Company for the quarter ended June 30, 2016, equating to a loss of $0.05 per share, compared to a net loss of $1.7 million or $0.11 per share in the same period of the year prior.

The Company incurred operating expenses of $26.5 million for the six months ended June 30, 2016, with research and development accounting for $18.4 million. This compares to operating expenses of $25.6 million for the same period of the year prior, with research and development accounting for $18.3 million. A net loss of $1.2 million was reported by the Company for the six-month period ended June 30, 2016, equating to a loss of $0.07 per share, compared to a net loss of $0.3 million or $0.02 per share in the same period of the year prior.

Corporate Highlights

Reata began trading on the NASDAQ Global Market under the symbol RETA on May 26, 2016 and closed its initial public offering ("IPO") on June 1, 2016, receiving $60.9 million of net proceeds.

As of June 30, 2016, the Company had $92.4 million in cash and cash equivalents, which reflects the proceeds from the Company's IPO completed in the second quarter of the year. In addition, the Company recorded a receivable from the Internal Revenue Service of approximately $17.2 million at June 30, 2016. The Company received payment of this receivable on July 1, 2016.

"The successful execution of our initial public offering this past quarter has enhanced our company's financial position and will allow us to continue our mission of developing novel therapeutics for patients with life threatening diseases and few, or no, approved therapies," said Warren Huff, Reata's Chief Executive Officer and President.

Product Development Highlights

The Company's strategy is to focus on rare and life threatening diseases with few or no approved therapies. Reata surveys for clinical benefit in patients with these severe diseases by running multiple Phase 2 proof-of-concept studies in parallel. Reata's goal is to build and maintain a broad pipeline of clinical candidates and development opportunities.

Bardoxolone Methyl in Pulmonary Hypertension

Reata is conducting clinical programs of the Company's lead drug, bardoxolone methyl, in patients with pulmonary hypertension that is caused by constriction of the pulmonary artery ("PAH"). Despite treatment with vasodilator therapy, PAH is a fatal disease with a five-year survival rate of only 68 percent of patients. PAH patients experience mitochondrial dysfunction, increased activation of NF-κB and related inflammatory pathways involved in ROS signaling, cellular proliferation, and fibrosis. Bardoxolone methyl, through the combined effect of Nrf2 activation and NF-κB suppression, has the potential to restore mitochondrial function, reduce oxidative stress, resolve inflammation and reduce the production of enzymes related to fibrosis and tissue remodeling.

Reata presented the initial results of the Company's PAH clinical study, called LARIAT, at the CHEST world congress during October 2015. The LARIAT data demonstrated that administration of bardoxolone methyl improved the function of patients when compared to placebo as assessed by 6-minute walk distance ("6MWD") through 16 weeks of treatment. Additionally, bardoxolone methyl was combined with current PAH therapies without increasing the risk of hypotensive events and had a favorable safety profile. Most important, bardoxolone methyl provided the greatest benefit to patients with a severe form of PAH, called CTD-PAH, that is caused by their underlying connective tissue disease (scleroderma, lupus, or mixed connective tissue disease). CTD-PAH patients respond less well to approved vasodilator therapies and have a higher morbidity rate than patients with other forms of PAH. The five-year survival rate of CTD-PAH patients is only 44 percent.

In October 2015, Reata met with the FDA concerning the initial Phase 2 data in PAH patients. The FDA concurred with the Company's plan to initiate a Phase 3 trial in CTD-PAH patients and stated that 6MWD is an acceptable primary endpoint. The Phase 3 trial, named CATALYST, will be an international, double-blind, randomized, placebo controlled trial in CTD-PAH patients. The planned enrollment for the study is between 120 and 220 patients. CATALYST is expected to begin this year, and data are expected to be available from the trial during the first half of 2018.

Because bardoxolone methyl was active in patients with CTD-PAH (a fibrotic disease), Reata believes that bardoxolone methyl may be effective in patients with pulmonary hypertension ("PH") that is caused by fibrosis of the lung (rather than the pulmonary artery as in PAH). These forms of PH are caused by interstitial lung diseases ("ILD") including idiopathic pulmonary fibrosis and sarcoidosis. Each one of these is a fatal disease with no approved therapy for their PH-ILD. During the last year, the Company initiated four Phase 2 programs testing bardoxolone methyl's effectiveness in PH from four subtypes of ILD. The Company expects to have data from these trials during the second half of 2017.

Omaveloxolone in Rare Neuromuscular Diseases and Immuno-Oncology

During the last year, Reata advanced the clinical development of omaveloxolone, a close analog of bardoxolone methyl that has improved blood-brain

barrier penetration. The Company believes that it may benefit patients with various types of neuromuscular diseases because impaired mitochondrial function and chronic inflammation have been shown to be key features of many of these diseases. The Company is initially targeting two rare genetic diseases: one is primarily neural, Friedrich's ataxia ("FA"), and one is primarily muscular, mitochondrial myopathy ("MM"). These are also severe and often fatal diseases with no approved therapy. Reata is conducting robust, double-blind, placebo-controlled, international Phase 2 studies in each disease. The FA study is known as MOXIe, and the MM study is known as MOTOR. Initial data from MOXIe and MOTOR are expected in the first half of 2017.

The Company is also conducting an open-label Phase 1b/2 trial, known as REVEAL, to evaluate the safety, pharmacodynamics, and efficacy of omaveloxolone in combination with existing immunotherapies for the treatment of metastatic melanoma. The Company is using omaveloxolone in combination with checkpoint inhibitors to restore an immune response against the tumor in the presence of so called myeloid derived suppressor cells ("MDSCs"). MDSCs mask the tumor from the immune system by production of mitochondrial ROS. Through this approach, Reata hopes to significantly increase the proportion of patients that respond to immunotherapy. Data from REVEAL are expected during the second half of 2017.

Other Programs

In addition to the Company's current clinical programs, Reata is advancing two new classes of drugs that address important molecular pathways involved in mitochondrial function and inflammation. The Company is pursuing preclinical development of neuroprotective Hsp90 inhibitors, including RTA 901, for the potential treatment of ALS, diabetic neuropathy, spinocerebellar ataxia, and spinal bulbar muscular atrophy, and RORγT inhibitors for the potential treatment of a variety of autoimmune and inflammatory conditions.

About Reata Pharmaceuticals, Inc.

Reata Pharmaceuticals, Inc. is a clinical-stage biopharmaceutical company focused on identifying, developing, and commercializing product candidates that modulate the activity of key regulatory proteins involved in the biology of mitochondrial function, oxidative stress, and inflammation to address the unmet medical needs of patients with a variety of serious or life-threatening diseases. Reata focuses on drugs with novel mechanisms of action that modulate important regulatory proteins, called transcription factors, which coordinate the cellular response to stressors by activating or suppressing the activity of many target proteins.

Forward-Looking Statements

This press release includes certain disclosures which contain "forward-looking statements," including, without limitation, statements regarding the success, cost and timing of our product development activities and clinical trials, our plans to research, develop and commercialize our product candidates, and our ability to obtain and retain regulatory approval of our product candidates. You can identify forward-looking statements because they contain words such as "believes," "will," "may," "aims," "plans" and "expects." Forward-looking statements are based on Reata's current expectations and assumptions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that may differ materially from those contemplated by the forward-looking statements, which are neither statements of historical fact nor guarantees or assurances of future performance. Important factors that could cause actual results to differ materially from those in the forward-looking statements are set forth in Reata's filings with the U.S. Securities and Exchange Commission, including its Registration Statement on Form S-1, as amended from time to time, under the caption "Risk Factors." The forward-looking statements speak only as of the date made and, other than as required by law, we undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise.

	Three Months ended June 30,		Six Months ended June 30,	
	2016	2015	2016	2015
Unaudited Consolidated Statements of Operations	**(in thousands, except share and per share data)**			
Collaboration revenue				
License and milestone	$ 12,365	$ 12,365	$ 24,730	$ 25,294
Other revenue	1	-	74	-
Total collaboration revenue	12,366	12,365	24,804	25,294
Expenses				
Research and development	9,075	9,688	18,381	18,266
General and administrative	4,537	3,369	7,744	6,223
Depreciation and amortization	179	529	367	1,062
Total expenses	13,791	13,586	26,492	25,551
Other income				
Investment income	28	8	51	16
Total other income	28	8	51	16
Loss before (benefit) provision for taxes on income	(1,397)	(1,213)	(1,637)	(241)
(Benefit) provision for taxes on income	(461)	482	(443)	96
Net loss	$ (936)	$ (1,695)	$ (1,194)	$ (337)
Net loss per share—basic	$ (0.05)	$ (0.11)	$ (0.07)	$ (0.02)

Net loss per share—diluted	$ (0.05)	$ (0.11)	$ (0.07)	$ (0.02)
Weighted-average number of common shares used in net loss per share basic	18,562,302	15,973,020	17,274,574	15,970,022
Weighted-average number of common shares used in net loss per share diluted	18,562,302	15,973,020	17,274,574	15,970,022

	As of June 30, 2016 (unaudited) (in thousands)	As of December 31, 2015
Condensed Consolidated Balance Sheet Data		
Cash and cash equivalents	$ 92,365	$ 42,008
Federal income tax receivable	17,170	31,926
Working capital	52,923	16,439
Total Assets	114,420	78,954
Deferred revenue (including current portion)	316,042	340,771
Accumulated deficit	(284,321)	(283,127)
Total stockholders' equity	$ (212,144)	$ (273,156)

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