



## REATA PHARMACEUTICALS, INC. ANNOUNCES THIRD QUARTER 2016 FINANCIAL AND OPERATING RESULTS

**IRVING, Texas—November 14, 2016**—Reata Pharmaceuticals, Inc. (Nasdaq:RETA) (“Reata” or “the Company”), a clinical-stage biopharmaceutical company, today announced financial results for the third quarter ended September 30, 2016 and provided an update on the Company's business and product development programs.

### Financial Highlights

The Company incurred operating expenses of \$13.5 million for the quarter ended September 30, 2016, with research and development accounting for \$9.3 million. This compares to operating expenses of \$12.0 million for the same period of the year prior, when research and development accounted for \$8.6 million. A net loss of \$0.9 million was reported by the Company for the quarter ended September 30, 2016, equating to a loss of \$0.04 per share, compared to net income of \$0.6 million or \$0.04 per share in the same period of the year prior.

The Company incurred operating expenses of \$40.0 million for the nine months ended September 30, 2016, with research and development accounting for \$27.7 million. This compares to operating expenses of \$37.6 million for the same period of the year prior, when research and development accounted for \$26.8 million. A net loss of \$2.1 million was reported by the Company for the nine month period ended September 30, 2016, equating to a loss of \$0.11 per share, compared to net income of \$0.3 million or \$0.02 per share in the same period of the year prior.

### Corporate Highlights

As of September 30, 2016, the Company had \$95.7 million in cash and cash equivalents, which reflects the payment of \$17.2 million the Company received from the Internal Revenue Service in the third quarter of the year.

### Product Development Highlights

Reata is a clinical stage biopharmaceutical company focused on identifying, developing, and commercializing product candidates to address rare and life-threatening diseases with few or no approved therapies by targeting molecular pathways that regulate cellular metabolism and inflammation. Our lead product candidates, bardoxolone methyl and omaveloxolone, are members of a class of small molecules called antioxidant inflammation modulators, or AIMs, and target an important transcription factor, called Nrf2, to restore mitochondrial function, reduce oxidative stress, and resolve inflammation.

#### *Bardoxolone Methyl in Pulmonary Hypertension*

On October 6, 2016, the first patient was enrolled in CATALYST, an international, randomized, double-blind, placebo-controlled Phase 3 trial examining the safety, tolerability, and efficacy of bardoxolone methyl in patients with WHO Group 1 PAH associated with connective tissue disease (“CTD-PAH”) when added to standard-of-care vasodilator



therapy. Patients will be on up to two background therapies and will be randomized one-to-one to bardoxolone methyl or placebo, administered once daily for 24 weeks. The primary endpoint is the change from baseline in 6-minute walk distance ("6MWD") relative to placebo at Week 24. The trial will enroll between 130 and 200 patients. Data from CATALYST are expected to be available during the first half of 2018.

In advance of the initiation of CATALYST, Reata analyzed data for all CTD-PAH patients treated with doses of up to 10 mg who had completed the 16-week treatment period (or terminated early), a total of 22 CTD-PAH patients (15 randomized to bardoxolone methyl and seven randomized to placebo) in the Company's ongoing PAH Phase 2 trial, LARIAT. Of these 22 patients, 19 meet the final criteria for inclusion in the CATALYST trial. Three did not meet the criteria because they had moderate to severe anemia at baseline.

Reata performed an analysis applying the statistical methods for CATALYST to the available end-of-treatment (Week 16) change in 6MWD data from these 19 CTD-PAH patients in LARIAT. Excluding patients with moderate to severe anemia at screening, the patients treated with bardoxolone methyl demonstrated a statistically significant mean increase in 6MWD compared to baseline of 42.7 meters ( $p < 0.001$ ). Placebo-treated patients had a non-significant mean change from baseline in 6MWD of -5.8 meters ( $p = 0.68$ ). The placebo-corrected change in 6MWD at Week 16 was 48.5 meters ( $p = 0.005$ ).

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") 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 in LARIAT to test 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.

#### *Bardoxolone Methyl in Chronic Kidney Disease Caused by Alport Syndrome*

During a meeting with the U.S. Food and Drug Administration ("the FDA") in October 2016, Reata received guidance from the FDA on key elements of a single, pivotal trial that would study the safety and efficacy of bardoxolone methyl in patients with CKD caused by Alport syndrome.

Reata is in the process of designing the Phase 2/3 pivotal trial. The clinical trial will be an international, multi-center, double-blind, randomized, placebo-controlled Phase 2/3 trial studying the safety and effectiveness of bardoxolone methyl in slowing, halting, or reversing renal function decline in patients with Alport syndrome. The trial will enroll patients from age 12 to 60 with eGFR values between 30 to 90 mL/min/1.73 m<sup>2</sup>. The Phase 2 portion of the trial will be open-label, and the primary endpoint will assess estimated glomerular filtration rate ("eGFR") change at 12 weeks. These patients will be followed for two years and will not be included in the Phase 3 portion of the trial. The Phase 3



portion will be designed to support registration and will randomize patients evenly to either bardoxolone methyl or placebo. The Phase 3 primary efficacy endpoint will be the change from baseline in eGFR in bardoxolone methyl-treated patients relative to placebo after one year. The eGFR change after one year will be measured while the patients are on treatment, and the key secondary endpoints will be the change from baseline in eGFR after withdrawal of drug for four weeks (off treatment) after one and two years. After the initial withdrawal, patients will be restarted on study drug with their original treatment assignments and will continue on study drug for a second year. Based on FDA guidance, if the trial is positive, the year one off treatment data could support accelerated approval under subpart H of the Federal Food, Drug, and Cosmetic Act, and the year two off treatment data could support full approval. Reata plans to initiate the Phase 2 portion of the integrated Phase 2/3 trial in the first half of 2017.

Alport syndrome is a rare and serious hereditary disease that affects approximately 12,000 children and adults in the United States and 40,000 globally. It is caused by mutations in the genes encoding type IV collagen, a major structural component of the glomerular basement membrane ("GBM"), in the kidney. The abnormal expression of type IV collagen causes loss of GBM integrity, abnormal leakage of proteins through the GBM, and excessive reabsorption of protein in the proximal tubules of the kidney. Like other forms of CKD, excessive reabsorption of protein in the tubules induces oxidative stress and renal interstitial inflammation and fibrosis.

Reata believes bardoxolone methyl has the potential to address the underlying causes of GFR loss in Alport syndrome patients because it activates molecular pathways that promote the resolution of inflammation by restoring mitochondrial function, reducing oxidative stress, and inhibiting ROS-mediated pro-inflammatory signaling. These anti-inflammatory and tissue-protective effects suppress multiple cellular processes that conspire to promote GFR loss. Bardoxolone methyl and closely related structural analogs have been shown to improve renal function, reduce inflammation, and prevent injury, remodeling, and fibrosis in many animal models of renal injury and disease

#### *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 myopathies ("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 MOXle, and the MM study is known as MOTOR. Initial data from MOXle 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 ROR $\gamma$ T 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 that develops novel therapeutics for patients with serious or life-threatening diseases by targeting molecular pathways involved in regulating cellular metabolism and inflammation. Our two most advanced clinical candidates (bardoxolone methyl and omaveloxolone) target important transcription factors, called Nrf2 and NF- $\kappa$ B, to restore mitochondrial function, reduce oxidative stress, and resolve inflammation.

#### **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, our ability to obtain and retain regulatory approval of our product candidates, estimates of our expenses and our needs for additional financing, and our ability to obtain additional financing for our product development activities and existing and future clinical trials and pre-clinical programs. 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.

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	Three Months ended September 30,		Nine Months ended September 30,	
	2016	2015	2016	2015
<b>Unaudited Consolidated Statements of Operations</b>				
<b>Collaboration revenue</b>				
License and milestone	\$ 12,500	\$ 12,500	\$ 37,230	\$ 37,794
Other revenue	51	-	125	-
Total collaboration revenue	12,551	12,500	37,355	37,794
<b>Expenses</b>				
Research and development	9,300	8,550	27,681	26,816
General and administrative	4,039	2,980	11,783	9,203
Depreciation and amortization	170	486	537	1,548
Total expenses	13,509	12,016	40,001	37,567
<b>Other income</b>				
Investment income	62	9	113	25
Total other income	62	9	113	25
(Loss) income before provision (benefit) for taxes on income	(896)	493	(2,533)	252
Provision (benefit) for taxes on income	1	(140)	(442)	(44)
Net (loss) income	<u>\$ (897)</u>	<u>\$ 633</u>	<u>\$ (2,091)</u>	<u>\$ 296</u>
Net (loss) income per share—basic	\$ (0.04)	\$ 0.04	\$ (0.11)	\$ 0.02
Net (loss) income per share—diluted	\$ (0.04)	\$ 0.04	\$ (0.11)	\$ 0.02
Weighted-average number of common shares used in net (loss) income per share basic	22,324,374	15,979,614	18,970,128	15,974,510
Weighted-average number of common shares used in net (loss) income per share diluted	22,324,374	16,149,149	18,970,128	16,082,963

	As of September 30, 2016 (unaudited)		As of December 31, 2015	
	(in thousands)			
<b>Condensed Consolidated Balance Sheet Data</b>				
Cash and cash equivalents	\$	95,660	\$	42,008
Federal income tax receivable		-		31,926
Working capital		39,849		16,439
Total Assets		101,823		78,954
Deferred revenue (including current portion)		303,542		340,771
Accumulated deficit		(285,218)		(283,127)
Total stockholders' equity	\$	(212,289)	\$	(273,156)