# Reata Pharmaceuticals, Inc. Announces Third Quarter 2017 Financial and Operating Results

November 13, 2017

IRVING, Texas, Nov. 13, 2017 (GLOBE NEWSWIRE) -- Reata Pharmaceuticals, Inc. (Nasdaq:RETA) (Reata or Company), a clinical-stage biopharmaceutical company, today announced financial results for the third quarter ended September 30, 2017, and provided an update on the Company's business and product development programs.

**Financial Highlights**

The Company incurred operating expenses of $24.6 million for the quarter ended September 30, 2017, with research and development accounting for $18.3 million. This compares to operating expenses of $13.5 million for the same period of the year prior, when research and development accounted for $9.3 million. A net loss of $12.3 million was reported by the Company for the quarter ended September 30, 2017, equating to a loss of $0.50 per share, compared to net loss of $0.9 million or $0.04 per share in the same period of the year prior.

The Company incurred operating expenses of $68.5 million for the nine months ended September 30, 2017, with research and development accounting for $50.8 million. This compares to operating expenses of $40.0 million for the same period of the year prior, when research and development accounted for $27.7 million. A net loss of $31.0 million was reported by the Company for the nine month period ended September 30, 2017, equating to a loss of $1.34 per share, compared to net loss of $2.1 million or $0.11 per share in the same period of the year prior.

**Corporate Highlights**

As of September 30, 2017, the Company had $154.6 million in cash and cash equivalents.

On November 3, 2017, the Company amended its loan agreement (Amended Loan Agreement) with Oxford Finance LLC and Silicon Valley Bank to increase its Term B Loan amount from $15.0 million to either $20.0 million or $25 million. The Company may, at its sole discretion, borrow $20 million under Term B Loan. An additional $5 million will be available under the Term B Loan for a total of $25 million upon the achievement of one of two milestones. The Company may borrow the Term B Loan by the earlier of 90 days after the achievement of a milestone or June 29, 2018. If the Term B Loan is drawn, the interest-only payment period would be extended by six months.

**Product Development Highlights**

*Bardoxolone Methyl in Rare Kidney Diseases*

Chronic Kidney Disease (CKD) Caused by Alport Syndrome

In August, 2017, Reata began enrolling patients in the Phase 3 portion of CARDINAL, a double-blind, randomized, placebo-controlled, multi-center, international trial in patients with CKD caused by Alport syndrome. The trial will enroll approximately 150 patients randomized evenly to either bardoxolone methyl or placebo. The primary endpoint of the trial will be the change from baseline in estimated glomerular filtration rate (eGFR) at 48 weeks while the patient is on treatment, or on-treatment eGFR, and again at 52 weeks after the patient has stopped taking the study drug for a four-week withdrawal period, or retained eGFR. Based upon guidance from the United States Food and Drug Administration (FDA), the year one retained eGFR benefit data may support accelerated approval under subpart H. After withdrawal, patients will be restarted on study drug with their original treatment assignments and will continue on study for a second year, with on-treatment eGFR change measured at 100 weeks, and the retained eGFR benefit after withdrawal of drug for four weeks at week 104. Based upon guidance from the FDA, the year two retained eGFR benefit data may support full approval.

On November 3, 2017, the Company presented positive primary and other 12-week data from the 30 patients in the Phase 2 portion of CARDINAL at the 2017 American Society of Nephrology Kidney Week Annual Meeting (ASN). The Phase 2 study met its primary efficacy endpoint with bardoxolone significantly increasing eGFR after 12 weeks of treatment ($p<0.000000001$). All patients had an increase from baseline, with a mean increase of 13.4 mL/min/1.73 $m^2$, and 87% had an increase of at least 4 ml/min/1.73 $m^2$, which is the approximate annual rate of decline in kidney function in patients with Alport syndrome. The increases in eGFR translated to an improvement in CKD stage for 22/30 (73%) patients. No serious adverse events were reported, and adverse events were generally mild to moderate in intensity.

On November 4, 2017, Reata's partner, Kyowa Hakko Kirin, presented results of the TSUBAKI study at ASN. In TSUBAKI, bardoxolone demonstrated statistically significant and clinically meaningful increases in directly-measured glomerular filtration rate (GFR) in patients with type 2 diabetes and CKD using the "gold standard" inulin clearance method. The observed increase in GFR demonstrates that historical increases in eGFR produced by bardoxolone in various forms of CKD, including Alport syndrome, reflect a true increase in kidney function. Bardoxolone demonstrated a favorable safety profile with no effect on blood pressure, urinary volume or sodium retention, and no evidence of overt fluid overload or cardiac toxicity.

Bardoxolone Methyl in Other Rare Kidney Diseases

Based upon results of the Phase 2 portion of CARDINAL, Reata began activating sites in October, 2017 for PHOENIX, a Phase 2 trial of bardoxolone methyl in various rare forms of CKD, including autosomal dominant polycystic kidney disease, IgA nephropathy, type 1 diabetic CKD, and focal segmental glomerulosclerosis. Similar to the Phase 2 portion of CARDINAL, PHOENIX is an open-label trial of bardoxolone orally-administered once-daily for 12 weeks. The primary efficacy endpoint is change from baseline in eGFR at week 12. Approximately 20 to 30 patients will be enrolled per cohort.

*Omaveloxolone in Friedreich's Ataxia (FA)*

In October, 2017, the Company began enrolling patients in part 2 of the Phase 2 MOXIe trial, a double-blind, randomized, placebo-controlled, multi-

center, international trial in patients with FA. The trial will enroll approximately 100 FA patients randomized evenly to either omaveloxolone or placebo. The primary endpoint of the trial will be the change from baseline in modified Friedreich's Ataxia Rating Scale (mFARS) of omaveloxolone compared to placebo at 48 weeks. Based upon communications with the FDA, it may consider either accelerated or full approval of omaveloxolone for FA based upon the overall results of the trial and strength of the data.

*Bardoxolone Methyl in Pulmonary Arterial Hypertension associated with Connective Tissue Disease*

In October, 2016, Reata began enrolling patients in CATALYST, an international, randomized, double-blind, placebo-controlled Phase 3 trial in patients with pulmonary arterial hypertension associated with connective tissue disease (CTD-PAH). Patients will be on up to two standard-of-care vasodilator therapies and will be randomized evenly to either bardoxolone methyl or placebo. The trial will enroll between 130 and 200 patients, with the final sample size determined by a pre-specified, blinded sample size re-calculation based upon 6MWD variability and baseline characteristics of the first 100 patients enrolled in the trial. The primary endpoint of the study is the change from baseline in 6-minute walk distance (6MWD) relative to placebo at Week 24.

**About Reata Pharmaceuticals, Inc.**

Reata is a clinical-stage biopharmaceutical company that develops novel therapeutics for patients with serious or life-threatening diseases by targeting molecular pathways involved in the regulation of cellular metabolism and inflammation. Reata's two most advanced clinical candidates, bardoxolone methyl and omaveloxolone, target the important transcription factor Nrf2 that promotes the resolution of inflammation by restoring mitochondrial function, reducing oxidative stress, and inhibiting pro-inflammatory signaling.

**Forward-Looking Statements**

*This press release includes certain disclosures that 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 include, but are not limited to, (i) the timing, costs, conduct, and outcome of our clinical trials and future preclinical studies and clinical trials, including the timing of the initiation and availability of data from such trials; (ii) the timing and likelihood of regulatory filings and approvals for our product candidates; (iii) the potential market size and the size of the patient populations for our product candidates, if approved for commercial use, and the market opportunities for our product candidates; and (iv) other factors set forth in Reata's filings with the U.S. Securities and Exchange Commission, including its Annual Report on Form 10-K, 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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| Unaudited Consolidated Statements of Operations | Three Months ended September 30, | | Nine Months ended September 30, | |
|---|---|---|---|---|
| | 2017 | 2016 | 2017 | 2016 |
| | (in thousands, except share and per share data) | | | |
| **Collaboration revenue** | | | | |
| License and milestone | $ 12,501 | $ 12,500 | $ 37,594 | $ 37,230 |
| Other revenue | 56 | 51 | 500 | 125 |
| Total collaboration revenue | 12,557 | 12,551 | 38,094 | 37,355 |
| Expenses | | | | |

| | | | | |
|---|---|---|---|---|
| Research and development | 18,326 | 9,300 | 50,830 | 27,681 |
| General and administrative | 6,151 | 4,039 | 17,312 | 11,783 |
| Depreciation and amortization | 98 | 170 | 336 | 537 |
| Total expenses | 24,575 | 13,509 | 68,478 | 40,001 |
| Other income (expense) | | | | |
| Investment income | 198 | 62 | 352 | 113 |
| Interest expense | (484) | - | (956) | - |
| Other income (expense) | (3) | - | (3) | - |
| Total other income (expense) | (289) | 62 | (607) | 113 |
| Loss before taxes on income | (12,307) | (896) | (30,991) | (2,533) |
| Provision (benefit) for taxes on income | 1 | 1 | 2 | (442) |
| Net loss | $ (12,308) | $ (897) | $ (30,993) | $ (2,091) |
| Net loss per share—basic and diluted | $ (0.50) | $ (0.04) | $ (1.34) | $ (0.11) |
| Weighted-average number of common shares used in net loss per share basic and diluted | 24,845,364 | 22,324,374 | 23,196,293 | 18,970,128 |

| | As of September 30, 2017 (unaudited) (in thousands) | As of December 31, 2016 |
|---|---|---|
| **Condensed Consolidated Balance Sheet Data** | | |
| Cash and cash equivalents | $ 154,600 | $ 84,732 |
| Working capital | 108,243 | 27,652 |
| Total Assets | 160,380 | 89,093 |
| Deferred revenue (including current portion) | 253,947 | 291,041 |
| Accumulated deficit | (320,463) | (289,354) |
| Total stockholders' deficit | $ (132,422) | $ (215,048) |

Source: Reata Pharmaceuticals, Inc.