November 8, 2017

CymaBay Reports Third Quarter 2017 Financial Results and Corporate Updates

Conference call today at 4:30pm EST

NEWARK, Calif., Nov. 08, 2017 (GLOBE NEWSWIRE) -- CymaBay Therapeutics, Inc. (NASDAQ:CBAY), a clinical-stage biopharmaceutical company focused on developing therapies for liver and other chronic diseases with high unmet need, today announced financial results and a corporate update for the three and nine months ended September 30, 2017.

“Positive interim data announced in the third quarter from the ongoing Phase 2 study of seladelpar in patients with Primary Biliary Cholangitis, or PBC, transformed CymaBay in several important ways,” said Sujal Shah, President and Chief Executive Officer of CymaBay Therapeutics. “The data announced from this study to date support the potential for seladelpar to offer improved efficacy and better tolerability as a second line treatment for PBC. We look forward to sharing these results with the regulatory authorities in the U.S. and Europe with the goal of advancing seladelpar into Phase 3 for PBC in 2018. With more than $100 million in cash on hand at September 30, we now have sufficient resources to begin the next stage of development for seladelpar in PBC and to initiate a proof of concept study of seladelpar in NASH.”

Third Quarter 2017 and Recent Business Highlights

- In July, positive interim results were announced from the low-dose Phase 2 study of seladelpar in PBC. In October, the results were featured in an oral, late breaking presentation given by Professor Gideon Hirschfield, an internationally recognized expert in PBC and a lead investigator in the study, at The Liver Meeting® hosted by the American Association for the Study of Liver Disease (AASLD).
  • 39% and 45% reductions in alkaline phosphatase (AP) from baseline to week 12 were observed in the 5 mg and 10 mg seladelpar groups, respectively.
  • 45% of patients in the 5 mg group and 82% of patients in the 10 mg group had AP values less than 1.67 times the upper limit of normal (ULN). AP is an established surrogate marker of disease progression in PBC, and reaching a level of less than 1.67 times ULN is a key component in the composite endpoint recently used for regulatory approval.
  • Treatment with seladelpar was not associated with drug induced pruritus, based on a pruritus Visual Analog Scale (VAS) evaluation completed by patients. Pruritus is expected to be a key potential point of differentiation for seladelpar over the current second line treatment.
  • No serious adverse events and no safety transaminase signal were observed at either dose. In addition, a decrease in transaminase levels, particularly in patients with elevated baseline transaminase, indicated an additional signal of efficacy.
  • The FDA has agreed to allow dosing of seladelpar beyond six months for 5 mg and 10 mg and preparations are under way for a Phase 3 start in 2018.

- In July, findings from a preclinical study of seladelpar in a diabetic, obese mouse model of NASH were published in the journal Hepatology Communications (Hyczeyni, et al. (2017) Hepatology Communications 1(7) 663-674). In these mice, seladelpar normalized hyperglycemia, hyperinsulinemia, and glucose intolerance. In addition, seladelpar reduced ALT by 50%, normalized serum lipids and hepatic levels of free cholesterol and other lipotoxic lipids. Seladelpar treated mice also experienced a reversal of NASH pathology, with significant improvement in liver fibrosis, reductions in inflammation and a complete abrogation of hepatocyte ballooning.
- In July, raised $91.1 million, net of offering expenses, in a public offering of 14.95 million shares of common stock at an offering price of $6.50 per share.
- In August, data from the first proof-of-concept study of seladelpar in PBC at higher doses were published in Lancet Gastroenterology and Hepatology, a prominent peer-reviewed journal featuring clinical advances in liver diseases (Jones, D., et al. (2017) The Lancet Gastroenterology & Hepatology 2(10) 716-726).
- In September, the European Medicines Agency's (EMA) Committee for Orphan Medicinal Products (COMP) issued a positive opinion on the application for orphan drug designation of seladelpar for treatment of primary biliary cholangitis (PBC). Seladelpar now has orphan drug designation in both the U.S. and Europe.
- In November, Sujal Shah appointed President and Chief Executive Officer.

Third Quarter 2017 Financial Results

- Cash, cash equivalents and marketable securities totaled $102.2 million at the end of the third quarter of 2017, compared to $17.0 million at December 31, 2016. Existing cash expected to fund operations into 2019.
- Research and development expenses were $4.2 million in the third quarter of 2017, as compared to $3.5 million in the third quarter of 2016 and consisted primarily of clinical trial and drug manufacturing expenses for seladelpar in PBC. Expenses rose due to increased manufacturing of seladelpar to support our ongoing lower dose Phase 2 study, and in preparation for our upcoming Phase 3 clinical trial activities.
- General and administrative expenses were $2.2 million in the third quarter of 2017, as compared to $2.1 million in the third quarter of 2016.
- Net loss was $8.2 million, or ($0.21) per diluted share in the third quarter of 2017, as compared to $5.9 million, or ($0.25) per diluted share in the third quarter of 2016. Net loss in the third quarter of 2017 increased $2.3 million as compared to the prior year period primarily due to a $1.8 million non-cash mark-to-market loss on the revaluation of the Company’s warrant liability.

Nine-Month Period Ended September 30, 2017 Financial Results

- Research and development expense for the nine months ended September 30, 2017, was $12.3 million, compared to $12.1 million for the prior year period.
- General and administrative expense for the nine months ended September 30, 2017, was $9.5 million, compared to $6.8 million for the prior year period.
- Net loss for the nine months ended September 30, 2017, was $22.5 million, or ($0.71) per diluted share, compared to $19.7 million, or ($0.84) per diluted share, for the prior year period.

Conference Call Details

CymaBay management will host a conference call today at 4:30 p.m. ET to discuss third

quarter 2017 financial results and provide a business update. To access the live conference call, please dial 877-407-0784 from the U.S. and Canada, or 201-689-8560 internationally, Conference ID# 13671795. To access the live and subsequently archived webcast of the conference call, go to the Investors section of the company's website at http://ir.cymabay.com/events.

About CymaBay

CymaBay Therapeutics, Inc. (CBAY) is a clinical-stage biopharmaceutical company focused on developing therapies for liver and other chronic diseases with high unmet medical need. Seladelpar is a potent and selective agonist of PPARδ, a nuclear receptor that regulates genes involved in bile acid/sterol, lipid and glucose metabolism and inflammation. Seladelpar is currently in development for the treatment of patients with the autoimmune liver disease, primary biliary cholangitis (PBC) and nonalcoholic steatohepatitis (NASH). Two Phase 2 studies of seladelpar established proof of concept in PBC. CymaBay is currently planning to advance development of seladelpar into Phase 3 for PBC and Phase 2 for NASH. Arhalofenate is a potential urate-lowering anti-flare therapy that has been found to reduce painful flares in joints while at the same time lowering serum uric acid by promoting excretion of uric acid by the kidney. This dual action addresses both the signs and symptoms of gout while managing the underlying pathophysiology of hyperuricemia. Arhalofenate has been licensed in the U.S. to Kowa Pharmaceuticals America, Inc. CymaBay retains full development and commercialization rights for arhalofenate outside the U.S.

Cautionary Statements

The statements in this press release regarding the potential for seladelpar to treat PBC and NASH, the potential benefits to patients, and the expectations regarding future clinical trials are forward looking statements that are subject to risks and uncertainties. Actual results and the timing of events regarding the further development of seladelpar could differ materially from those anticipated in such forward-looking statements as a result of risks and uncertainties, which include, without limitation, risks related to: the success, cost and timing of any of CymaBay's product development activities, including clinical trials; effects observed in trials to date which may not be repeated in the future; any delays or inability to obtain or maintain regulatory approval of CymaBay's product candidates in the United States or worldwide; and the ability of CymaBay to obtain sufficient financing to complete development, regulatory approval and commercialization of its product candidates in the United States and worldwide. Additional risks relating to CymaBay are contained in CymaBay's filings with the Securities and Exchange Commission, including without limitation its most recent Quarterly Report on Form 10-Q, Annual Report on Form 10-K and other documents subsequently filed with or furnished to the Securities and Exchange Commission. CymaBay disclaims any obligation to update these forward-looking statements except as required by law.

For additional information about CymaBay visit www.cymabay.com.

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CymaBay Therapeutics, Inc.
Financial Results
(In thousands, except share and per share information)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	**2016**	**2017**	**2016**
Collaboration revenue	$ -	$ -	$ 4,793	$ -
Operating expenses:				
Research and development	4,184	3,534	12,269	12,093
General and administrative	2,210	2,130	9,493	6,806
Total operating expenses	6,394	5,664	21,762	18,899
Loss from operations	(6,394)	(5,664)	(16,969)	(18,899)
Other income (expense):				
Interest income	216	45	297	146
Interest expense	(258)	(341)	(846)	(1,009)
Other income (expense), net	(1,798)	81	(4,996)	43
Net loss	$ (8,234)	$ (5,879)	$ (22,514)	$ (19,719)
Basic net loss per common share	$ (0.21)	$ (0.25)	$ (0.71)	$ (0.84)
Diluted net loss per common share	$ (0.21)	$ (0.25)	$ (0.71)	$ (0.84)
Weighted average common shares outstanding used to calculate basic net loss per common share	40,035,690	23,447,003	31,848,536	23,447,003
Weighted average common shares outstanding used to calculate diluted net loss per common share	40,035,690	23,447,003	31,848,536	23,447,003

CymaBay Therapeutics, Inc.
Balance Sheet Data
(In thousands, except share and per share amounts)

	September 30, 2017	December 31, 2016
	(unaudited)	
Cash, cash equivalents and short-term investments	$ 102,169	$ 16,994
Working Capital	89,631	9,217
Total assets	104,344	19,359
Facility loan	6,859	8,864
Warrant Liability	5,862	1,145
Total liabilities	17,840	15,422
Common stock and additional paid-in capital	531,990	426,897
Total stockholders' equity	86,504	3,937

Source: CymaBay Therapeutics, Inc.