May 8, 2018

CymaBay Reports First Quarter 2018 Financial Results and Provides Corporate Update

Conference call and webcast today at 4:30p.m. ET

NEWARK, Calif., May 08, 2018 (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 quarter ended March 31, 2018.

“We’ve had an eventful start to the year with the achievement of significant clinical and operational milestones thus far in 2018,” said Sujal Shah, President and Chief Executive Officer of CymaBay. “Having strengthened our balance sheet with a successful financing early in the first quarter, our teams have been singularly focused on advancing seladelpar in both primary biliary cholangitis (PBC) and non-alcoholic steatohepatitis (NASH). New data from our ongoing Phase 2 study of seladelpar in patients with PBC announced in a late-breaker presentation at The International Liver Congress™ 2018 in April continues to support the potential for seladelpar to offer patients improved efficacy and better tolerability over the only existing second-line treatment available. These data have been shared with regulatory agencies as we prepare to initiate a Phase 3 study for PBC in the second half of the year.”

“Today we also announced the initiation of a Phase 2b study of seladelpar for NASH,” continued Mr. Shah. “We are excited to expand development of seladelpar into NASH where there remains a large and growing unmet medical need and no currently approved therapies. The Phase 2b is a robust dose-ranging, proof-of-concept study incorporating innovative methods and technologies to evaluate the effects of seladelpar on inflammation, fibrosis and liver health as well as key metabolic parameters typically elevated in patients with NASH. We are very fortunate to have Dr. Stephen Harrison, a world-renowned expert in NASH, as principle coordinating investigator for the study.”

First Quarter 2018 and Recent Business Highlights

- In April, screening was initiated in a Phase 2b study of seladelpar in patients with NASH. The Phase 2b study is a randomized, placebo-controlled, parallel, dose-ranging study that is intended to enroll approximately 175 patients with liver biopsy proven NASH. The primary efficacy outcome will be liver fat content change from baseline to 12 weeks as measured by magnetic resonance imaging using the proton density fat fraction (MRI-PDFF) method. Among the secondary measures of efficacy, most notable is the evaluation of histological improvement in NASH and fibrosis as assessed by comparing liver biopsy samples taken at baseline and 52 weeks.
- In April, new 12-week and 26-week results from the ongoing Phase 2 study of seladelpar in patients with PBC were presented at The International Liver Congress™

that highlighted seladelpar's potent anti-cholestatic and anti-inflammatory activity, with no drug-induced pruritus, through 26 weeks of treatment. These results support the potential for improved efficacy and better tolerability over existing second-line therapy and reaffirm plans for advancing into Phase 3 in the second half of 2018.
- In February, $135.5 million in net proceeds were raised through a public offering of common stock.
- In January, a $5 million milestone payment for arhalofenate was received from Kowa Pharmaceuticals America.
- In January, start of enrollment was announced in the long-term safety extension study of seladelpar in patients with PBC. The study provides access to long-term seladelpar treatment for patients enrolled in a previous, ongoing or future study evaluating seladelpar for the treatment of PBC.

First Quarter 2018 Financial Results

- Cash, cash equivalents and marketable securities totaled $229.5 million at the end of the first quarter of 2018. Existing cash is expected to fund CymaBay's current operating plan into 2021.
- Research and development expenses were $9.5 million in the first quarter of 2018 as compared to $4.0 million in the same period of 2017 and consisted primarily of higher PBC and NASH clinical trial expenses and seladelpar drug manufacturing expenses.
- General and administrative expenses were $3.4 million in the first quarter of 2018, as compared to $3.7 million in the first quarter of 2017.
- Net loss was $17.0 million, or ($0.32) per share in the first quarter of 2018, as compared to $5.4 million, or ($0.20) per share in the first quarter of 2017. Net loss in the first quarter of 2018 was higher as compared to the prior year primarily due to higher research and development expenses, a non-cash mark-to-market loss on the revaluation of CymaBay's warrant liability, and lower collaboration revenue.

Conference Call Details

CymaBay management will host a conference call today at 4:30 p.m. ET to discuss first quarter 2018 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# 13678369. 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, selective, orally active PPARδ agonist, currently in development for the treatment of patients with primary biliary cholangitis (PBC), an autoimmune liver disease, and with non-alcoholic 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 has initiated a Phase 2b study 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 and the potential for arhalofenate to treat gout, the potential benefits to patients, CymaBay's expectations and plans regarding future clinical trials and CymaBay's ability to fund current and planned 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 and arhalofenate 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 that 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 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.

Contact:
Hans Vitzthum
LifeSci Advisors, LLC
212-915-2568
Hans@LifeSciAdvisors.com

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

	March 31, 2018 (unaudited)	December 31, 2017
Cash, cash equivalents and short-term investments	$ 229,536	$ 97,210
Working Capital	213,258	87,234
Total assets	232,259	104,247
Facility loan	5,361	6,098
Warrant Liability	7,648	6,091
Total liabilities	20,060	19,300
Common stock and additional paid-in capital	679,852	535,507
Total stockholders' equity	212,199	84,947

CymaBay Therapeutics, Inc.

Financial Results

(In thousands, except share and per share information)

(unaudited)

	Three Months Ended March 31,	
	2018	**2017**
Collaboration revenue	$ -	$ 4,793
Operating expenses:		
Research and development	$ 9,477	$ 4,041
General and administrative	3,373	3,701
Total operating expenses	12,850	7,742
Loss from operations	(12,850)	(2,949)
Other income (expense):		
Interest income	708	37
Interest expense	(208)	(305)
Other income (expense), net	(4,655)	(2,134)
Net loss	$ (17,005)	$ (5,351)
Basic net loss per common share	$ (0.32)	$ (0.20)
Diluted net loss per common share	$ (0.32)	$ (0.20)
Weighted average common shares outstanding used to calculate basic net loss per common share	53,752,753	26,609,931
Weighted average common shares outstanding used to calculate diluted net loss per common share	53,752,753	26,609,931

Source: CymaBay Therapeutics, Inc.