

August 10, 2017

CymaBay Reports Second Quarter 2017 Financial Results and Provides Corporate Update

Conference call and webcast today, 4:30pm Eastern Time

NEWARK, Calif., Aug. 10, 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 six months ended June 30, 2017.

"We reached a significant clinical milestone last month with the announcement of positive interim data from our ongoing Phase 2 clinical trial of seladelpar in patients with primary biliary cholangitis, or PBC," said Sujal Shah, Interim President and Chief Executive Officer of CymaBay. "These results underscore the potent anti-cholestatic and anti-inflammatory effects of seladelpar. Furthermore, we are encouraged that the FDA has agreed to allow dosing of seladelpar beyond six months, essential for progressing to Phase 3. If results observed thus far are confirmed in Phase 3, we believe seladelpar could offer patients with PBC a more efficacious and better tolerated treatment alternative than existing second-line therapy."

"With the successful completion of our recent public stock offering the company is now well capitalized with more than \$100 million of cash and cash equivalents. We believe we have the resources necessary to begin funding the next stage of development for seladelpar in PBC and diversification of the program into other indications, including NASH," added Mr. Shah.

Second Quarter 2017 and Recent Business Highlights

- In July, announced positive interim results from the low-dose Phase 2 study of seladelpar in PBC
 - After 12 weeks of treatment, there was a significant alkaline phosphatase (AP) reduction of 39% and 45% from baseline in the 5 mg and 10 mg groups, respectively
 - 45% of patients in the 5 mg seladelpar 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 x ULN is a key component in the composite endpoint recently used for regulatory approval
 - Patients in both dose groups experienced decreases in other liver markers of cholestasis including gamma glutamyl transferase and total bilirubin, anti-inflammatory markers including alanine transaminase and high sensitivity C-reactive protein and metabolic parameters including low density lipoprotein-C
 - There were no serious adverse events and no safety transaminase signal was observed at either dose

- Consistent with prior studies, there was no signal for drug-induced pruritus
- The FDA has agreed to allow dosing of seladelpar beyond six months for 5 mg and 10 mg
- In April, presented additional clinical data, including markers of cholesterol absorption, cholesterol synthesis and bile acid synthesis, from the prior high-dose Phase 2 proof-of-concept study of seladelpar in PBC at the International Liver Congress™ sponsored by the European Association for the Study of Liver Diseases (EASL) conference in Amsterdam, The Netherlands
 - Title: Proof of efficacy for seladelpar, a selective PPAR δ agonist, in patients with primary biliary cholangitis non-responsive to ursodeoxycholic acid: results of an international Phase 2 randomised controlled clinical study
- In July, raised approximately \$91.1 million after deducting underwriting discounts, commissions, and other offering expenses in a public offering of 14.95 million shares of common stock at an offering price of \$6.50 per share
- Announced the appointment of Klara Dickinson as Sr. Vice President of Regulatory Affairs and Quality Assurance
- Promoted Daniel Menold to Vice President, Finance

Second Quarter 2017 Financial Results

- Cash, cash equivalents and marketable securities totaled \$16.7 million at the end of the second quarter of 2017
 - CymaBay believes that these funds, together with additional net proceeds of approximately \$91.1 million received from the equity financing completed in July, will allow the company to continue operations through at least the next twelve months
- Research and development expenses were \$4.0 million in the second quarter of 2017, as compared to \$4.1 million in the second quarter of 2016 and consisted primarily of Phase 2 PBC clinical trial expenses and drug manufacturing expenses for seladelpar in each period
- General and administrative expenses were \$3.6 million in the second quarter of 2017, as compared to \$2.2 million in the second quarter of 2016. The increase in G&A expenses was primarily due to a one-time, non-cash stock compensation expense associated with the retirement of the company's former CEO in April 2017.
- Net loss was \$8.9 million, or (\$0.31) per diluted share in the second quarter of 2017, as compared to \$7.0 million, or (\$0.30) per diluted share in the second quarter of 2016. The increase in net loss was primarily due to the non-cash severance expense associated with the retirement of the company's former CEO and a non-cash mark-to-market loss on the revaluation of the company's warrant liability.

Six-Month Period Ended June 30, 2017 Financial Results

- Research and development expense for the six months ended June 30, 2017, was \$8.1 million, compared to \$8.6 million for the prior year period
- General and administrative expense for the six months ended June 30, 2017, was \$7.3 million, compared to \$4.7 million for the prior year period
- Net loss for the six months ended June 30, 2017, was \$14.3 million, or (\$0.52) per diluted share, compared to \$13.8 million, or (\$0.59) per diluted share, for the prior year period

Conference Call

CymaBay management will host a conference call today at 4:30 p.m. ET to discuss second 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# 13667520. 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 PPAR δ agonist currently in development for the treatment of patients with the autoimmune liver disease, primary biliary cholangitis (PBC). A Phase 2 study of seladelpar established proof of concept in PBC. CymaBay is currently conducting a second Phase 2 study of seladelpar in PBC in order to support dose selection for Phase 3.

Cautionary Statements

The statements in this press release, including those statements regarding the structure and conduct of clinical trials, future performance of CymaBay's product candidates, the potential of seladelpar to treat primary biliary cholangitis or nonalcoholic steatohepatitis, the therapeutic and commercial potential of CymaBay's product candidates, and any of the targeted indications for the potential future development or commercialization of CymaBay's product candidates are forward looking statements that are subject to risks and uncertainties. Actual results and the timing of events regarding the further development of CymaBay's product candidates 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.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Collaboration revenue	\$ -	\$ -	\$ 4,793	\$ -
Operating expenses:				
Research and development	\$ 4,044	\$ 4,131	\$ 8,085	\$ 8,559
General and administrative	3,582	2,215	7,283	4,676
Total operating expenses	<u>7,626</u>	<u>6,346</u>	<u>15,368</u>	<u>13,235</u>
Loss from operations	(7,626)	(6,346)	(10,575)	(13,235)
Other income (expense):				
Interest income	44	48	81	101
Interest expense	(283)	(336)	(588)	(668)
Other income (expense), net	<u>(1,064)</u>	<u>(358)</u>	<u>(3,198)</u>	<u>(38)</u>
Net loss	<u><u>\$ (8,929)</u></u>	<u><u>\$ (6,992)</u></u>	<u><u>\$ (14,280)</u></u>	<u><u>\$ (13,840)</u></u>
Basic net loss per common share	\$ (0.31)	\$ (0.30)	\$ (0.52)	\$ (0.59)
Diluted net loss per common share	\$ (0.31)	\$ (0.30)	\$ (0.52)	\$ (0.59)
Weighted average common shares outstanding used to calculate basic net loss per common share*	28,752,451	23,447,003	27,687,110	23,447,003
Weighted average common shares outstanding used to calculate diluted net loss per common share*	28,752,451	23,447,003	27,687,110	23,447,003

* Does not include 14,950,000 common shares associated with our July 2017 financing.

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

	June 30, 2017	December 31, 2016
	(unaudited)	
Cash, cash equivalents and short-term investments*	\$ 16,726	\$ 16,994
Working Capital	5,881	9,217
Total assets	18,732	19,359
Facility loan	7,551	8,864
Warrant Liability	4,343	1,145
Total liabilities	16,593	15,422
Common stock and additional paid-in capital*	439,379	426,897
Total stockholders' equity*	2,139	3,937

* Does not include cash or equity associated with the sale of 14,950,000 common shares in our July 2017 financing that brought in approximately \$91.1 million net of fees and expenses.

Contacts:

Sujal Shah
CymaBay Therapeutics, Inc.
(510) 293-8800
sshah@cymabay.com

or

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



Source: CymaBay Therapeutics, Inc.