November 9, 2016

CymaBay Reports Third Quarter 2016 Financial Results

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

NEWARK, Calif., Nov. 09, 2016 (GLOBE NEWSWIRE) -- CymaBay Therapeutics, Inc. (NASDAQ:CBAY), a clinical-stage biopharmaceutical company focused on developing therapies for indications with high unmet medical need, including rare and orphan diseases, today provided recent corporate highlights and announced financial results for the quarter and nine months ended September 30, 2016.

"We made considerable progress during the third quarter with MBX-8025," said Dr. Harold Van Wart, Chief Executive Officer of CymaBay Therapeutics. "Earlier in the year, we demonstrated proof-of-concept with MBX-8025 in primary biliary cholangitis (PBC) and we look forward to sharing these data with the clinical community in a late-breaking oral presentation at the American Association for the Study of Liver Diseases (AASLD) meeting in Boston on November 15. Following our discussions with the FDA, we have completed the design of a second Phase 2 study for MBX-8025, with the goal of identifying the doses to carry forward into Phase 3. We are planning to initiate this Phase 2 study before year end."

Recent Business Highlights

MBX-8025 - An oral, potent and selective PPARδ agonist that has a number of pharmacological actions that may be useful in the treatment of multiple diseases with high unmet medical need, including primary biliary cholangitis (PBC) and nonalcoholic steatohepatitis (NASH).

- The Company announced plans to initiate a second Phase 2 study of MBX-8025 in PBC by year-end 2016. This decision was made following final analysis of data from a prior Phase 2 study in PBC and with input from the FDA.
- MBX-8025 was granted **PRI**ority **ME**dicines (PRIME) designation by the European Medicines Agency (EMA) for the treatment of PBC in patients who do not tolerate or respond to combination UDCA/obeticholic acid treatment.
- The FDA granted Orphan Drug Designation for MBX-8025 in PBC. MBX-8025 also has Orphan Drug Designation for homozygous familial hypercholesterolemia (HoFH) and hyperlipoproteinemia types I or V (Fredrickson classification). Among other benefits, the designation qualifies CymaBay for a potential seven year marketing exclusivity period upon approval for each indication, as well as exemption of FDA application fees and tax credits for qualified clinical trials.
- Two abstracts describing studies with MBX-8025 have been selected for oral presentations at the annual meeting of the American Association for the Study of Liver Diseases (AASLD) in Boston, November 11-15
    - "*A Phase 2 Proof-of-Concept Study of MBX-8025 in Patients with Primary Biliary Cholangitis (PBC) who are Inadequate Responders to Ursodeoxycholic acid (UDCA)*" will be presented in a late-breaking session on November 15 by

Professor David Jones, Professor of Liver Immunology, Institute of Cellular Medicine, Newcastle University in the U.K.
    - "*PPAR-δ Agonist MBX-8025 Abolishes Lipotoxicity and Reverses NASH in Diabetic Obese Mice.*" will be presented on November 14 by Fahrettin Haczeyni from the Liver Research Group, the Australian National University Medical School, Canberra, Australia
- The U.S. Patent & Trademark Office (USPTO) issued two new patents providing coverage on MBX-8025 through at least 2035 for methods of treating PBC as well as for treating NAFLD and NASH.

Arhalofenate - An oral, once-daily dual-acting drug candidate for gout that lowers serum uric acid (sUA) through a uricosuric effect and has an anti-inflammatory (anti-IL-1β) activity that suppresses flares.

- CymaBay has completed End-of-Phase 2 discussions with the FDA and reached agreement on all of the key elements of the planned Phase 3 program, including the co-primary endpoints of sUA responder rate and prevention of flare.
- Discussions are ongoing with potential partners with the goal of signing one or more partnership agreements that would support Phase 3 development of arhalofenate in 2017.

Third Quarter Ended September 30, 2016 Financial Results

- Cash, cash equivalents and short-term investments as of September 30, 2016, were $23.1 million, compared to $41.5 million at December 31, 2015.
- Research and development expense for the three months ended September 30, 2016, was $3.5 million compared to $4.5 million for the prior year period.
- General and administrative expense for the three months ended September 30, 2016, was $2.1 million compared to $2.2 million for the prior year period.
- Net loss for the three months ended September 30, 2016, was $5.9 million, or ($0.25) per diluted share, compared to $5.9 million, or ($0.27) per diluted share for the prior year period.

Nine-Month Period Ended September 30, 2016 Financial Results

- Research and development expense for the nine months ended September 30, 2016, was $12.1 million compared to $13.0 million for the prior year period.
- General and administrative expense for the nine months ended September 30, 2016, was $6.8 million compared to $7.1 million for the prior year period.
- Net loss for the nine months ended September 30, 2016, was $19.7 million, or ($0.84) per diluted share, compared to $9.6 million, or ($0.58) per diluted share for the prior year period. The increase in net loss for the nine months ended September 30, 2016 as compared to the prior year period was largely due to a decrease in non-cash gains of $10.9 million, from the mark-to-market valuation of the company's warrant liability.

Conference Call

CymaBay management will host a conference call today at 4:30 p.m. ET to discuss third quarter 2016 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. 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. A replay of the webcast will be available on the company's website for 14 days following the live event.

About CymaBay

CymaBay Therapeutics, Inc. (CBAY) is a clinical-stage biopharmaceutical company developing therapies to treat diseases with high unmet medical need, including serious rare and orphan disorders. MBX-8025 is a potent, selective, orally active PPARδ agonist. CymaBay has recently a Phase 2 study of MBX-8025 in patients with primary biliary cholangitis as well as a pilot Phase 2 study in patients with homozygous familial hypercholesterolemia, establishing proof-of-concept in both indications. Previously, a Phase 2 study of MBX-8025 in patients with mixed dyslipidemia established that it has an anti-atherogenic lipid profile. Arhalofenate, CymaBay's other product candidate, is a potential Urate-Lowering Anti-Flare Therapy that has completed five Phase 2 studies in gout patients. Arhalofenate has been found to reduce painful flares in joints while at the same time 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.

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 MBX-8025 to treat primary biliary cholangitis or nonalcoholic steatohepatitis, the potential of arhalofenate to treat gout, 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 of MBX-8025 and arhalofenate; 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 Annual Report on Form 10-K and Quarterly Report on Form 10-Q 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 September 30,		Nine Months Ended September 30,	
	2016	**2015**	**2016**	**2015**
Operating expenses:				
Research and development	$ 3,534	$ 4,528	$ 12,093	$ 12,975
General and administrative	2,130	2,201	6,806	7,075
Total operating expenses	5,664	6,729	18,899	20,050
Loss from operations	(5,664)	(6,729)	(18,899)	(20,050)
Other income (expense):				
Interest income	45	46	146	99
Interest expense	(341)	(265)	(1,009)	(584)
Other income (expense), net	81	1,083	43	10,985
Net loss	$ (5,879)	$ (5,865)	$ (19,719)	$ (9,550)
Basic net loss per common share	$ (0.25)	$ (0.27)	$ (0.84)	$ (0.55)
Diluted net loss per common share	$ (0.25)	$ (0.27)	$ (0.84)	$ (0.58)
Weighted average common shares outstanding used to calculate basic net loss per common share	23,447,003	21,674,742	23,447,003	17,368,309
Weighted average common shares outstanding used to calculate diluted net loss per common share	23,447,003	21,674,742	23,447,003	17,384,000

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

	September 30, 2016	December 31, 2015
	(unaudited)	
Cash, cash equivalents and short-term investments	$ 23,134	$ 41,480
Working Capital	16,729	36,648
Total assets	24,786	43,079
Facility loan	9,488	9,381
Warrant Liability	1,177	1,220
Total liabilities	14,574	14,964
Common stock and additional paid-in capital	426,221	424,424
Total stockholders' equity	10,212	28,115

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