

November 12, 2015

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# CymaBay Announces Third Quarter Financial Results

## Conference Call Today at 4:30 EST / 1:30 PST

NEWARK, Calif., Nov. 12, 2015 (GLOBE NEWSWIRE) -- CymaBay Therapeutics, Inc. (Nasdaq:CBAY), a clinical-stage biopharmaceutical company developing therapies to treat metabolic diseases with high unmet medical need, today announced financial results for the third quarter ended September 30, 2015.

"We continued to advance the development of our two key clinical assets in the third quarter. Our clinical studies for MBX-8025 are progressing well. Enrollment in our on-going Phase 2 study in homozygous familial hypercholesterolemia (HoFH) has been expanded and is now complete," said Harold Van Wart, Ph.D., President and Chief Executive Officer of CymaBay. "Three sites in Europe were operational in the third quarter and we added two new sites in Canada that completed enrolling patients in the fourth quarter. To date, we have enrolled 13 patients, compared with our original goal of 8. As a result, we now expect to complete this study and release top line data in the first quarter of 2016. Earlier this week, we announced the initiation of our Phase 2 study for MBX-8025 in the indication of primary biliary cholangitis (PBC)."

"Regarding arhalofenate, we held a positive End-of-Phase 2 meeting with the FDA in September to discuss next steps in our Phase 3 development program for the treatment of gout," continued Dr. Van Wart. "Arhalofenate is a dual-acting drug that both reverses hyperuricemia and reduces gout flares. We reached agreement with the FDA on the primary endpoints for our proposed Phase 3 studies to quantify serum uric acid (sUA) responder rate and flare rate and to provide data that the FDA could review to assess efficacy. In addition, it was agreed that a safety database of approximately 650 patients treated with arhalofenate for 12 months would be sufficient, together with the efficacy data, to assess the risk-benefit profile for arhalofenate. Our goal is to sign one or more partnerships in order to initiate the Phase 3 program in 2016."

## THIRD QUARTER 2015 AND RECENT CORPORATE HIGHLIGHTS

- Added clinical sites and expanded enrollment of patients in the on-going Phase 2 study for MBX-8025 in patients with homozygous familial hypercholesterolemia (HoFH). A total of 5 sites are now online, including 2 new sites in Canada. Thirteen patients have been enrolled.
- Initiated a dose ranging, placebo-controlled Phase 2 study of MBX-8025 in primary biliary cholangitis (PBC), formerly referred to as primary biliary cirrhosis.
- Held an End-of-Phase 2 meeting with the FDA to discuss the Phase 3 development program for arhalofenate for the treatment of gout.
- Received acceptance for two presentations on arhalofenate (one oral and one poster) at the American College of Rheumatology (ACR) annual meeting that took place November 6 – 11.

- Appointed Robert J. Wills, a pharmaceutical veteran with more than 25 years of senior leadership experience at Johnson & Johnson and Hoffmann-La Roche, as Chairman of the Board.

## **FINANCIAL HIGHLIGHTS FOR THE THREE MONTHS ENDED SEPTEMBER 30, 2015**

- Research and development expenses were \$4.5 million, an 18% increase over the \$3.8 million in the comparable period in 2014.
- General and administrative expenses were \$2.2 million, a 29% increase over the approximately \$1.7 million recorded in the same period of 2014.
- The net loss for the quarter was \$5.9 million, or (\$0.27) per diluted share, compared to a net loss of approximately \$6.0 million, or (\$0.44) per diluted share in the same period of 2014. The decrease in net loss was due in part to a non-cash gain of \$1.1 million for the three month period compared to a non-cash loss of \$0.3 million for the same period in 2014 from the mark to market valuation of the company's warrant liability.
- On July 27, 2015, the company completed a public offering of common stock, generating net proceeds, including the over-allotment option to underwriters, of approximately \$21 million.
- On August 7, 2015, the company refinanced its loan facility with Oxford Finance LLC and Silicon Valley Bank for an aggregate amount of \$15 million. The first \$10 million tranche was drawn at closing with a portion of the proceeds used to retire debt outstanding under the previous loan facility.
- At September 30, 2015, cash, cash equivalents, and short term investments were approximately \$46.9 million, as compared to approximately \$34.8 million at December 31, 2014.

## **FINANCIAL HIGHLIGHTS FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2015**

- Research & development expenses were \$13.0 million, a 24% increase over the approximately \$10.5 million in the same period of 2014.
- General and administrative expenses were \$7.1 million, a 20% increase over the \$5.9 million recorded in the same period of 2014.
- The net loss for the nine month period decreased 50%, to approximately \$9.6 million, or (\$0.58) per diluted share, compared to a net loss of approximately \$19.2 million, or (\$1.72) per diluted share in the same period in 2014. The decrease in net loss was due in part to a non-cash gain of \$11.0 million for the nine month period compared to a non-cash loss of \$2.3 million for the same period in 2014 from the mark to market valuation of the company's warrant liability.

The company will hold a conference call at 4:30 EST / 1:30 PST, today, November 12, 2015. To access the live conference call, please dial 877-407-0784 from the U.S. and Canada, or 201-689-8560 internationally, and use Conference ID #13623547. 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>.

## **Cautionary Statements**

The statements in this press release, including those statements regarding any future clinical trials, future performance of CymaBay's product candidates, the potential of arhalofenate to treat gout, the therapeutic and commercial potential of arhalofenate and MBX-8025, and the

anticipated timing and therapeutic and commercial potential of the product candidates of CymaBay Therapeutics, Inc. are forward looking statements that are subject to risks and uncertainties. Actual results and the timing of events regarding the further development of arhalofenate and MBX-8025 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 any future clinical trials of arhalofenate and MBX-8025; any delays or inability to obtain or maintain regulatory approval of CymaBay's product candidates in the United States or worldwide; the ability of CymaBay to attract funding partners or collaborators with development, regulatory and commercialization expertise; 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; and the market potential for CymaBay's product candidates. Additional risks relating to CymaBay are contained in CymaBay's Quarterly Report on Form 10-Q, filed with the Securities and Exchange Commission on November 12, 2015. CymaBay disclaims any obligation to update these forward-looking statements except as required by law.

## **About CymaBay**

CymaBay Therapeutics, Inc. (CBAY) is a clinical-stage biopharmaceutical company developing therapies to treat metabolic diseases with high unmet medical need, including serious rare and orphan disorders. Arhalofenate, has shown two therapeutic actions in a single drug in multiple Phase 2 gout studies. In gout patients, arhalofenate is intended to prevent painful flares in joints while at the same time promoting excretion of uric acid by the kidney, thereby addressing both the signs and symptoms of gout and the hyperuricemia that is the root cause of the disease. MBX-8025 is a potent, selective, orally active PPAR $\delta$  agonist. A Phase 2 study of MBX-8025 in patients with mixed dyslipidemia established that it has an anti-atherogenic lipid profile. CymaBay has two ongoing clinical studies for MBX-8025 including a pilot Phase 2 study in patients with homozygous familial hypercholesterolemia and a Phase 2 study in patients with primary biliary cholangitis.

For additional information about CymaBay visit [www.cymabay.com](http://www.cymabay.com).

**CymaBay Therapeutics, Inc.**

**Balance Sheet Data**

(In thousands, except share and per share amounts)

	<b>September 30,</b>	<b>December 31,</b>
	<b>2015</b>	<b>2014</b>
	<b>(unaudited)</b>	
Cash, cash equivalents and short-term investments	\$46,853	\$34,795
Working Capital	42,420	16,770
Total assets	48,863	37,474
Facility loan	9,271	4,542
Warrant Liability	1,356	13,596
Total liabilities	15,369	23,624
Common stock and additional paid-in capital	423,811	394,623
Total stockholders' equity	33,494	13,850

**CymaBay Therapeutics, Inc.**

**Financial Results**

*(In thousands, except share and per share information)*

*(unaudited)*

	<b>Three Months Ended</b>		<b>Nine Months Ended</b>	
	<b>September 30,</b>		<b>September 30,</b>	
	<b>2015</b>	<b>2014</b>	<b>2015</b>	<b>2014</b>
Operating expenses:				
Research and development	\$4,528	\$3,848	\$12,975	\$10,546
General and administrative	2,201	1,687	7,075	5,853
Total operating expenses	6,729	5,535	20,050	16,399
Loss from operations	(6,729)	(5,535)	(20,050)	(16,399)
Other income (expense):				
Interest income	46	19	99	48
Interest expense	(265)	(191)	(584)	(565)
Other income (expense), net	1,083	(254)	10,985	(2,279)
Net loss	<u><u>\$ (5,865)</u></u>	<u><u>\$ (5,961)</u></u>	<u><u>\$ (9,550)</u></u>	<u><u>\$ (19,195)</u></u>
Basic net loss per common share	<u><u>\$ (0.27)</u></u>	<u><u>\$ (0.44)</u></u>	<u><u>\$ (0.55)</u></u>	<u><u>\$ (1.72)</u></u>
Diluted net loss per common share	<u><u>\$ (0.27)</u></u>	<u><u>\$ (0.44)</u></u>	<u><u>\$ (0.58)</u></u>	<u><u>\$ (1.72)</u></u>
Weighted average common shares outstanding used to calculate basic net loss per common share	<u><u>21,674,742</u></u>	<u><u>13,468,081</u></u>	<u><u>17,368,309</u></u>	<u><u>11,148,695</u></u>
Weighted average common shares outstanding used to calculate diluted net loss per common share	<u><u>21,674,742</u></u>	<u><u>13,468,081</u></u>	<u><u>17,384,000</u></u>	<u><u>11,148,695</u></u>

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