August 9, 2016

CymaBay Reports Second Quarter 2016 Financial Results

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

NEWARK, Calif., Aug. 09, 2016 (GLOBE NEWSWIRE) -- CymaBay Therapeutics, Inc. (NASDAQ:CBAY), a clinical-stage biopharmaceutical company focused on developing therapies to treat diseases with high unmet medical need, today provided recent corporate highlights and announced financial results for the quarter and six months ended June 30, 2016.

"The highlight of the second quarter was our announcement in May of topline data from our Phase 2 study that demonstrated proof of concept with MBX-8025 in patients with Primary Biliary Cholangitis (PBC)," said Dr. Harold Van Wart, Chief Executive Officer of CymaBay Therapeutics. "We now have clear and convincing data that MBX-8025 has potent anti-cholestatic activity with the potential for meaningful therapeutic benefit to patients with PBC. We are focused on dose optimization to maximize the benefit to risk ratio for MBX-8025 and are planning a second Phase 2 study exploring lower doses which we expect to begin by the end of 2016."

Recent Business Highlights

MBX-8025 - An oral, potent and selective PPAR-δ agonist that has a number of pharmacological actions that may be useful in the treatment of certain rare and orphan diseases currently under evaluation

- Proof of concept was demonstrated in a Phase 2 double-blind, placebo controlled, dose ranging study of MBX-8025 in patients with primary biliary cholangitis (PBC).
- The study demonstrated that MBX-8025 has potent anti-cholestatic activity resulting in large, statistically significant decreases in alkaline phosphatase (ALP).
- A responder analysis also showed a statistically significant benefit for MBX-8025 versus placebo. This was based on patients achieving composite criteria of serum ALP values less than 1.67xULN and a decrease of at least 15% and normal levels of total bilirubin (TBIL).
- The anti-cholestatic effect was achieved without evidence for treatment related pruritus and with additional lipid benefits both of which may differentiate MBX-8025.
- The Phase 2 study was stopped early after a treatment emergent signal of transaminase elevation was observed in 3 patients. All were reversible upon cessation of treatment and not accompanied by elevation of total bilirubin (TBIL).
- The Company is targeting initiation of a second Phase 2 study in order to explore lower doses of MBX-8025 in PBC by the end of 2016.

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.

Second Quarter Ended June 30, 2016 Financial Results

- Cash, cash equivalents and short-term investments as of June 30, 2016, were $29.1 million, compared to $41.5 million at December 31, 2015. These funds are expected to satisfy the Company's liquidity requirements through at least the second quarter of 2017.
- Research and development expense for the three months ended June 30, 2016, was $4.1 million compared to $4.3 million for the prior year period.
- General and administrative expense for the three months ended June 30, 2016, was $2.2 million compared to $2.3 million for the prior year period.
- Net loss for the three months ended June 30, 2016, was $7.0 million, or ($0.30) per diluted share, compared to $1.4 million, or ($0.09) per diluted share for the prior year period. The increase in net loss was primarily related to a $5.7 million decrease in non-cash gains from the mark-to-market valuation of the company's warrant liability.

Six-Month Period Ended June 30, 2016 Financial Results

- Research and development expense for the six months ended June 30, 2016, was $8.6 million compared to $8.4 million for the prior year period.
- General and administrative expense for the six months ended June 30, 2016, was $4.7 million compared to $4.9 million for the prior year period.
- Net loss for the six months ended June 30, 2016, was $13.8 million, or ($0.59) per diluted share, compared to $3.7 million, or ($0.88) per diluted share for the prior year period. The increase in net loss was primarily related to a $9.9 million decrease in non-cash gains 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 second 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 PPAR-δ agonist. CymaBay has recently completed 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 homozygous familial hypercholesterolemia or primary biliary cholangitis, 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 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.
Income Statement
(In thousands, except share and per share information)
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	**2015**	**2016**	**2015**
Operating expenses:				
Research and development	$ 4,131	$ 4,260	$ 8,559	$ 8,447
General and administrative	2,215	2,285	4,676	4,874
Total operating expenses	6,346	6,545	13,235	13,321
Loss from operations	(6,346)	(6,545)	(13,235)	(13,321)
Other income (expense):				
Interest income	48	26	101	53
Interest expense	(336)	(165)	(668)	(319)
Other (expense) income, net	(358)	5327	(38)	9902
Net loss	$ (6,992)	$ (1,357)	$ (13,840)	$ (3,685)
Net loss	(6,992)	(1,357)	(13,840)	(3,685)
Other comprehensive (loss) income:				
Unrealized (loss) gain on marketable securities	(4)	(6)	16	1
Other comprehensive (loss) income	(4)	(6)	16	1
Comprehensive loss	$ (6,996)	$ (1,363)	$ (13,824)	$ (3,684)
Basic net loss per common share	$ (0.30)	$ (0.09)	$ (0.59)	$ (0.24)
Diluted net loss per common share	$ (0.30)	$ (0.09)	$ (0.59)	$ (0.88)
Weighted average common shares outstanding used to calculate basic net loss per common share	23,447,003	15,258,363	23,447,003	15,179,404
Weighted average common shares outstanding used to calculate diluted net loss per common share	23,447,003	15,258,363	23,447,003	15,427,832

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

	June 30, 2016	**December 31, 2015**
	(unaudited)	
Cash, cash equivalents and short-term investments	$ 29,116	$ 41,480
Working Capital	22,622	36,648
Total assets	30,475	43,079
Facility loan	9,610	9,381
Warrant Liability	1,259	1,220
Total liabilities	15,054	14,964
Common stock and additional paid-in capital	425,554	424,424
Total stockholders' equity	15,421	28,115

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.