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CymaBay Reports Third Quarter 2014 Financial Results

NEWARK, CA -- (Marketwired) -- 11/12/14 -- CymaBay Therapeutics, Inc.(NASDAQ: CBAY), a clinical-stage biopharmaceutical company located in the San Francisco Bay Area and focused on developing therapies to treat metabolic diseases with high unmet medical need, including serious rare and orphan disorders, today provided recent corporate highlights and announced financial results for the third quarter, 2014.

"Since CymaBay began operations as a public company in October 2013, we have made excellent progress in advancing the development of two of our clinical assets -- arhalofenate and MBX-8025," said Harold Van Wart, president and chief executive officer of CymaBay. "We are on track to read out important data from two Phase 2 studies with arhalofenate, and start a new clinical study with MBX-8025, in the first half of 2015."

Recent Business Highlights

Arhalofenate for Gout

Arhalofenate is an oral, once-daily dual-acting drug candidate for gout that both lowers serum uric acid through a uricosuric effect and has an anti-inflammatory activity that suppresses flares.

- CymaBay initiated a Phase 2b flare study for arhalofenate in patients with gout in March 2014 and completed enrollment ahead of schedule in September 2014. The study is a randomized, double-blind, active and placebo-controlled study evaluating the efficacy and safety of arhalofenate for preventing gout flares. The study has enrolled over 225 patients that have experienced three or more flares in the prior twelve month period.
- An independent Data Monitoring Committee reviewed the interim safety data from the Phase 2b study in September and recommended that the study continue as planned. CymaBay expects to report top-line data for this study in the second quarter of 2015.
- In August, the company initiated a Phase 2 study of arhalofenate in combination with febuxostat in patients with gout to assess the potential for drug interaction as well as to assess the uric acid lowering when these drugs are administered together. CymaBay expects to report data from this study in the first quarter of 2015.

MBX-8025 for Rare, Orphan Diseases

MBX-8025 is a potent, selective orally active PPAR-δ agonist with an anti-atherogenic lipid profile that may be useful in the treatment of a variety of rare and orphan diseases currently under evaluation.

- CymaBay has identified homozygous familial hypercholesterolemia (HoFH) as the first new indication for MBX-8025 and is planning a pilot Phase 2 study in Europe to start in the first half of 2015.

Corporate Update

- After successfully uplisting to NASDAQ, CymaBay raised an additional $25 million in gross proceeds through a public offering of 4.6 million shares of common stock at $5.50 per share in July 2014 to fund the development of MBX-8025 in rare and orphan diseases.
- Pursuant to a covenant requirement in CymaBay's loan security agreement entered into with Silicon Valley Bank and Oxford Finance LLC on September 30, 2013, the company also entered into an at-the-market facility on November 7, 2014, under a Form S-3 shelf registration statement filed with the Securities and Exchange Commission. CymaBay became Form S-3 eligible on November 1, 2014.

Third Quarter 2014 Financial Results

- Cash, cash equivalents and marketable securities as of September 30, 2014, were $42.6 million compared to $23.6 million as of June 30, 2014. CymaBay believes that its current cash, cash equivalents and marketable securities are sufficient to fund operating expenses and capital expenditure requirements until at least the end of 2015.

- Research and development expenses were $3.8 million in the third quarter of 2014 compared to $4.1 million in the second quarter of 2014.
- G&A expenses in the third quarter of $1.7 million were consistent with the $1.7 million incurred in G&A in the second quarter of 2014.
- Net loss for the third quarter was $6.0 million as compared to a net loss of $3.2 million for the second quarter of 2014. The difference was primarily due to a non-cash gain of $2.8 million in the second quarter compared to a non-cash loss of $0.3 million in the third quarter of 2014 from the mark to market valuation of the company's warrant liability.

Anticipated Upcoming Milestones

- CymaBay expects top line data from the Phase 2 drug interaction and uric acid lowering study of arhalofenate in combination with febuxostat in the 1Q 2015.
- CymaBay expects top line data from the Phase 2b flare study of arhalofenate in 2Q 2015.
- CymaBay expects to initiate the pilot Phase 2 study for MBX-8025 in HoFH in the 1H 2015.

Conference Call

CymaBay management will host a conference call today at 4:30 p.m. ET to discuss third quarter 2014 financial results and provide a business update. To access the live conference call, please dial (877) 407-8913 from the U.S. and Canada, or (201) 689-8201 internationally and refer to conference ID 13593925. A live webcast of the call can be accessed under 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 is a clinical-stage biopharmaceutical company developing therapies to treat metabolic diseases with high unmet medical need, including serious rare and orphan disorders. Arhalofenate, the company's lead product candidate, has shown two therapeutic actions in a single drug in Phase 2a gout studies. In gout patients, arhalofenate is intended to prevent painful flares in joints while at the same time promoting excretion of serum uric acid (sUA) by the kidney, thereby addressing both the signs and symptoms of gout and the hyperuricemia that is the root cause of the disease. CymaBay is currently investigating arhalofenate in a 12-week Phase 2b clinical trial in patients with gout. The company's second product candidate, MBX-8025 is a potent, selective, orally active PPAR-δ agonist. A Phase 2 study of MBX-8025 in patients with mixed dyslipidemia established that it has an anti-atherogenic lipid profile that may be useful in the treatment of a variety of rare and orphan diseases currently under evaluation.

For additional information about CymaBay visit www.cymabay.com.

Forward Looking Statements

The statements in this press release discussing the timing of commencement of clinical trials, availability of clinical data and reporting of clinical data, including under the heading "Anticipated Upcoming Milestones," and statements about the sufficiency of CymaBay's financial resources to fund its operations through at least the end of 2015, are "forward-looking" statements that involve risks, uncertainties and assumptions, and actual results may differ substantially from those projected or expected in the forward-looking statements. These statements are based on estimates and information available to CymaBay at the time of this press release and are not guarantees of future performance. Actual results could differ materially from CymaBay's current expectations as a result of many factors including, but not limited to, CymaBay may experience unexpected delays, results or costs in clinical trials for a variety of reasons currently not anticipated by CymaBay. You should read CymaBay's Quarterly Report on Form 10-Q filed with the SEC on August 14, 2014, especially under the caption "Risk Factors," which is available on the SEC web site at http://www.sec.gov, for a fuller discussion of these and other risks relating to an investment in CymaBay's common stock. CymaBay assumes no obligation for and does not intend to update these forward-looking statements, except as required by law.

CymaBay Therapeutics, Inc.
Unaudited Condensed Statements of Operations Data
(in thousands, except share and per share data)

	Three Months Ended September 30,		***Nine Months Ended September 30,***	
	2014	***2013***	***2014***	***2013***

Operating expenses:				
Research and development	$ 3,848	$ 703	$ 10,546	$ 3,162
General and administrative	1,687	683	5,853	2,780
Total operating expenses	5,535	1,386	16,399	5,942
Loss from operations	(5,535)	(1,386)	(16,399)	(5,942)
Other (expense) income:				
Interest income	19	-	48	1
Interest expense	(191)	(219)	(565)	(640)
Other (expense) income, net	(254)	298	(2,279)	422
Net loss	$ (5,961)	$ (1,307)	$ (19,195)	$ (6,159)
Net (loss) income attributable to common stockholders	$ (5,961)	$ 42,870	$ (19,195)	$ 16,478
Basic net (loss) income per common share	$ (0.44)	$ 422.95	$ (1.72)	$ 433.33
Diluted net loss per common share	$ (0.44)	$ (1.79)	$ (1.72)	$ (8.94)
Weighted average common shares outstanding used to calculate basic net loss per common share	13,468,081	101,358	11,148,695	38,027
Weighted average common shares outstanding used to calculate diluted net loss per common share	13,468,081	731,970	11,148,695	688,825

CymaBay Therapeutics, Inc.
Condensed Balance Sheet Data
(in thousands)

	September 30, 2014	***December 31, 2013***
	(unaudited)	
Cash, cash equivalents and short-term investments	$ 42,626	$ 31,244
Working Capital	29,367	22,751
Total assets	44,649	32,500
Facility loan	4,705	4,481
Warrant Liability	8,766	6,466
Total liabilities	18,518	13,904
Common stock and additional paid-in capital	394,183	367,436
Total stockholders' equity	26,131	18,596

Contact:
Sujal Shah Adam Cutler
CymaBay Therapeutics, Inc.
(510) 293-8800
investors@cymabay.com

or

Adam Cutler
The Trout Group, LLC
(646) 378-2936
CymaBay@troutgroup.com

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