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CymaBay Reports First Quarter 2015 Financial Results

NEWARK, CA -- (Marketwired) -- 05/07/15 -- CymaBay Therapeutics, Inc.(NASDAQ: CBAY), a clinical-stage biopharmaceutical company developing therapies to treat metabolic diseases with high unmet medical need, today provided recent corporate highlights and announced financial results for the quarter ended March 31, 2015.

"We are encouraged by the significant progress we've made so far in 2015, including the completion of our Phase 2 studies of arhalofenate in gout, obtaining Orphan Drug Designation for MBX-8025 in both severe hypertriglyceridemia and homozygous familial hypercholesterolemia (HoFH), and initiating a Phase 2 trial of MBX-8025 in HoFH," said Harold Van Wart, Chief Executive Officer of CymaBay. "We are now looking ahead to our end-of-Phase 2 meeting with the FDA for arhalofenate as well as completing our Phase 2 trial of MBX-8025 in HoFH patients, both before year end. We have initiated dialogue with potential partners to take arhalofenate forward into Phase 3 development as we shift our own resources towards continued development of MBX-8025. With the addition of Kirk Rosemark to the management team and Robert J. Wills, Ph.D. to our board, we are even better positioned for success in the coming year."

First Quarter and Recent Business Highlights

Arhalofenate for Gout

Arhalofenate is an oral, once-daily dual-acting drug candidate for gout. It lowers serum uric acid through a uricosuric effect and also has an anti-inflammatory activity that suppresses flares. It is the first compound in a new class of gout therapy that we refer to as Urate Lowering Anti-Flare Therapy (ULAFT).

- In January 2015, CymaBay announced positive results from its Phase 2 open label study of arhalofenate administered in combination with febuxostat in patients with gout. The combination of arhalofenate 800 mg and febuxostat 40 mg resulted in a statistically significant improvements in responder rate (% of patients with serum uric acid below the targets of both 6 and 5 mg/dL) versus febuxostat 40 mg.

- In February 2015, CymaBay announced positive results from its Phase 2b flare study for arhalofenate in patients with gout. Patients receiving arhalofenate 800 mg demonstrated a 46% reduction in gout flare rate ($p = .0056$) versus those receiving allopurinol 300 mg.

- CymaBay has now completed five Phase 2 studies of arhalofenate. The results support CymaBay's positioning of arhalofenate for the treatment of the inadequate serum uric acid responder population of over 2 million gout patients, with the unique additional benefit of simultaneously lowering gout flares. CymaBay has developed a path forward for Phase 3 development of arhalofenate that it is planning to discuss with the FDA at an end-of-Phase 2 meeting in the third quarter of 2015 and has initiated discussions

with potential partners to advance arhalofenate into Phase 3 development.

MBX-8025 for Rare, Orphan Diseases

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

- In January 2015, CymaBay announced results from a preclinical study indicating the potential for MBX-8025 to decrease low-density lipoprotein cholesterol (LDL-C) in patients with homozygous familial hypercholesterolemia (HoFH), an autosomal genetic disease characterized by loss-of-function mutations in both alleles of the LDL receptor (LDL-R) gene. Treatment with MBX-8025 resulted in a >40% reduction from baseline in LDL-C within 2-3 weeks of dosing in Watanabe-heritable hyperlipidemic (WHHL) rabbits, a preclinical model of HoFH.

- The FDA granted Orphan Drug Designation for MBX-8025 in HoFH in March 2015 and in severe hypertriglyceridemia in April. 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.

- In April 2015, CymaBay initiated a pilot Phase 2 study of MBX-8025 in HoFH. This study has an open label, dose-escalation design and will target enrollment of 8 patients at sites in Europe and North America. Following enrollment, patients will initially receive a 50 mg dose of MBX-8025 once daily that will be increased first to 100 mg and eventually 200 mg of MBX-8025 over the course of 3 months.

Corporate Highlights

In March 2015, CymaBay hosted a Key Opinion Leader meeting in New York City focused on gout. The meeting featured a keynote presentation by N. Lawrence Edwards, MD, MACP, FACR, Professor of Medicine in the Division of Rheumatology and Clinical Immunology, and the Program Director and Vice Chairman of the Department of Medicine at the University of Florida in Gainesville. Dr. Edwards provided an overview of the disease including current treatment options and remaining unmet medical need. CymaBay management followed with a brief overview of arhalofenate and highlighted how the ULAFT profile addressed the additional serum uric acid lowering and flare suppression needed to control the disease.

CymaBay strengthened its leadership team with the addition of two new key members. In March 2015, the Company announced the appointment of Robert J. Wills, Ph.D. to the Board of Directors. Dr. Wills brings with him over 25 years of experience at Johnson & Johnson, most recently as Vice President, Alliance Management, Janssen Pharmaceutical Companies of Johnson & Johnson. Before his retirement from Janssen, Dr. Wills was responsible for negotiating and managing strategic alliances for the worldwide Pharmaceutical Group. In April 2015, CymaBay announced the appointment of Kirk Rosemark to Vice President of Regulatory Affairs and Quality Assurance. Mr. Rosemark comes to CymaBay with 20 years of regulatory affairs experience. He served as VP of Regulatory Affairs and Quality Assurance for Exelixis, Inc., where he played a key role in the clinical development and approval of COMETRIQ™ (cabozantinib).

First Quarter 2015 Financial Results

- Cash, cash equivalents and short-term investments as of March 31, 2015 were $32.8 million. Cash used in CymaBay's operating activities totaled $6.2 million for the three months ended March 31, 2015. CymaBay management believes existing cash, cash equivalents and short-term investments are sufficient to fund operations through at least the end of the first quarter of 2016.

- Research and development expense for the three months ended March 31, 2015 was $4.2 million compared to $2.6 million for the three months ended March 31, 2014. The increase in R&D expense was primarily related to the increased spending associated with development of arhalofenate and MBX-8025.

- General and administrative expense for the three months ended March 31, 2015 was $2.6 million compared to $2.5 million for the three months ended March 31, 2014.

- Net loss for the three months ended March 31, 2015 was $2.3 million compared to $10.1 million for three months ended March 31, 2014. The difference in net loss between these periods was primarily due to a non-cash gain of $4.6 million for the three months ended March 31, 2015 compared to a non-cash loss of $4.8 million for the three months ended March 31, 2014, from the mark to market valuation of CymaBay's warrant liability.

Conference Call

CymaBay management will host a conference call today at 4:30 p.m. ET to discuss first quarter 2015 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. To access the live and subsequently archived webcast of the conference call, go to the Investors section of CymaBay's website at http://ir.cymabay.com/events. A replay of the webcast will be available on CymaBay's website for 14 days following the live event.

About CymaBay

CymaBay Therapeutics, Inc. (NASDAQ: 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, CymaBay's lead product candidate, 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. CymaBay's second product candidate, MBX-8025 is a potent, selective, orally active PPARδ agonist. A Phase 2 study of MBX-8025 in patients with mixed dyslipidemia established that it has an anti-atherogenic lipid profile. CymaBay has initiated a pilot study of MBX-8025 in patients with homozygous familial hypercholesterolemia.

Cautionary Statements

The statements in this press release, including those statements regarding any 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; 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 Annual Report on Form 10-K, filed with the Securities and Exchange Commission on March 23, 2015. CymaBay disclaims any obligation to update these forward-looking statements except as required by law.

For additional information about CymaBay visitwww.cymabay.com.

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

	Three Months Ended March 31,	
	2015	***2014***
Operating expenses:		
Research and development	$4,187	$2,615
General and administrative	2,589	2,500
Total operating expenses	6,776	5,115
Loss from operations	(6,776)	(5,115)
Other income (expense):		
Interest income	27	12
Interest expense	(154)	(184)
Other income (expense), net	4,575	(4775)
Net loss	$(2,328)	$(10,062)
Basic net loss per common share	$(0.15)	$(1.02)
Diluted net loss per common share	$(0.44)	$(1.02)
Weighted average common shares outstanding used to calculate basic net loss per common share	15,099,567	9,873,687
Weighted average common shares outstanding used to calculate diluted net loss per common share	15,743,167	9,873,687

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

	March 31, 2015	***December 31, 2014***
		(unaudited)
Cash, cash equivalents and short-term investments	$ 32,791	$ 34,795
Working Capital	20,828	16,770
Total assets	34,730	37,474
Facility loan	4,219	4,542
Warrant Liability	7,704	13,596
Total liabilities	16,462	23,624
Common stock and additional paid-in capital	401,362	394,623
Total stockholders' equity	18,268	13,850

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Source: CymaBay Therapeutics