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# CymaBay Reports First Quarter 2016 Financial Results

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

NEWARK, Calif., May 11, 2016 (GLOBE NEWSWIRE) -- CymaBay Therapeutics, Inc. (NASDAQ:CBAY), a clinical-stage biopharmaceutical company focused on 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, 2016.

"The first quarter of 2016 was marked by continued momentum for our two lead development programs, MBX-8025 for rare orphan diseases, and arhalofenate for gout," said Dr. Harold Van Wart, Chief Executive Officer of CymaBay Therapeutics. "We were pleased to have seen positive signs of efficacy in our pilot Phase 2 study of MBX-8025 in homozygous familial hypercholesterolemia (HoFH) and look forward to having these data presented at the forthcoming European Atherosclerosis Society (EAS) congress in May. We are also expecting top-line results from our Phase 2 study of MBX-8025 in primary biliary cholangitis, or PBC, in the fourth quarter this year."

"For arhalofenate, our immediate goal is to enter into a partnership for its Phase 3 development and we are now in active discussions with interested parties and specifically with companies that have a presence in the primary care market," continued Dr. Harold Van Wart. "We concluded our End-of-Phase 2 discussions with the FDA and have reached agreement on the design of a Phase 3 program with endpoints that will evaluate the ability of arhalofenate to both reduce the risk of gout flares and lower serum uric acid (sUA). We believe that this dual mechanism of action will give arhalofenate a unique, differentiated profile that will make it attractive to physicians, patients and payers."

### ***Recent Business Highlights***

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

- MBX-8025 is being investigated in a dose-ranging, placebo-controlled Phase 2 study in primary biliary cholangitis (PBC). Top line results are expected in late fourth quarter this year.
- In March 2016, CymaBay reported positive results from a pilot Phase 2 clinical study that investigated MBX-8025 in patients with homozygous familial hypercholesterolemia (HoFH, an autosomal genetic disease characterized by loss-of-function mutations in both alleles of the LDL receptor gene).
  - The results showed that MBX-8025 provided a clinically meaningful reduction in low-density lipoprotein cholesterol (LDL-C) for a subset of patients.
  - A responder analysis showed that 7 of 12 (or 58%) patients exhibited a  $\geq 15\%$  decrease in LDL-C during one of the treatment periods, including one patient that

was LDL receptor negative.

- Treatment with MBX-8015 raised PCSK9 levels by an average of 43% (increased PCSK9 levels would be expected to reduce LDL receptor levels, potentially diminishing the observed reductions in LDL-C).
- A late breaking oral presentation of the results from this pilot study will be given at the 84<sup>th</sup> European Atherosclerosis Society (EAS) congress, to be held in Innsbruck, Austria on May 31.
- CymaBay is currently exploring the feasibility of conducting a second pilot Phase 2 clinical study to further understand the potential benefits of MBX-8025 in patients with HoFH that are currently being treated with a PCSK9 inhibitor.

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

- In January 2016, CymaBay completed its End-of-Phase 2 discussions with the FDA and reached agreement with the FDA on all of the key elements of the planned Phase 3 program, including the co-primary endpoints of sUA responder rate and flare rate.
- The Phase 3 program will consist of two studies of arhalofenate in combination with febuxostat in patients with chronic gout and a third study in patients with tophaceous gout.
- In March 2016, the results from the Phase 2b arhalofenate gout flare study was published in the journal *Arthritis & Rheumatology*. The publication was accompanied by an editorial describing the need for novel agents such as arhalofenate for the treatment of gout. These can be accessed online at the following web addresses:
  - <http://onlinelibrary.wiley.com/doi/10.1002/art.39684/abstract>
  - <http://onlinelibrary.wiley.com/doi/10.1002/art.39687/abstract>
- Discussions are ongoing with potential partners with the goal of signing a partnership agreement that would enable the initiation of Phase 3 development of arhalofenate.

**Corporate Highlights** - Strengthened the Board of Directors with key appointments.

- Dr. Evan Stein, M.D., Ph.D., a world-renowned expert in the area of lipid metabolism with a particular focus on the development of therapies to treat HoFH.
- Paul Truex, currently President and Chief Executive Officer of Anthera Pharmaceuticals, Inc. (NASDAQ:ANTH) with more than 20 years of experience in senior operational positions in the biotechnology and pharmaceutical industries.
- Robert Weiland, who last served as Vice President for Strategy and International Business Development at Baxter International and also brings more than 20 years of experience in business and product commercialization strategy in the pharmaceutical industry.

### **First Quarter Ended March 31, 2016 Financial Results**

- Cash, cash equivalents and short-term investments as of March 31, 2016, were \$35.3 million. The company believes that its existing cash is sufficient to fund operations and capital expenditures through at least the second quarter of 2017.
- Research and development expense for the three months ended March 31, 2016, was \$4.4 million compared to \$4.2 million for the prior year period.
- General and administrative expense for the three months ended March 31, 2016, was

\$2.5 million compared to \$2.6 million for the prior year period.

- Net loss for the three months ended March 31, 2016, was \$6.8 million compared to \$2.3 million for the prior year period. The increase in net loss was almost entirely related to a \$4.3 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 first 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. The conference I.D. is 13636131. 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 metabolic diseases with high unmet medical need, including serious rare and orphan disorders. 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 completed a pilot Phase 2 study of MBX-8025 in patients with homozygous familial hypercholesterolemia and has an ongoing Phase 2 study in patients with primary biliary cholangitis. 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](http://www.cymabay.com).

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**CymaBay Therapeutics, Inc.**  
**Financial Results**  
*(In thousands, except share and per share information)*  
*(unaudited)*

	Three Months Ended March 31,	
	2016	2015
Operating expenses:		
Research and development	\$ 4,428	\$ 4,187
General and administrative	2,461	2,589
Total operating expenses	<u>6,889</u>	<u>6,776</u>
Loss from operations	(6,889 )	(6,776 )
Other income (expense):		
Interest income	53	27
Interest expense	(332 )	(154 )
Other income, net	<u>320</u>	<u>4,575</u>
Net loss	<u>\$ (6,848 )</u>	<u>\$ (2,328 )</u>
Basic net loss per common share	<u>\$ (0.29 )</u>	<u>\$ (0.15 )</u>
Diluted net loss per common share	<u>\$ (0.29 )</u>	<u>\$ (0.44 )</u>
Weighted average common shares outstanding used to calculate basic net loss per common share	<u>23,447,003</u>	<u>15,099,567</u>
Weighted average common shares outstanding used to calculate diluted net loss per common share	<u>23,447,003</u>	<u>15,743,167</u>

**CymaBay Therapeutics, Inc.**  
**Balance Sheet Data**  
(In thousands)

	March 31, 2016 <hr/> (unaudited)	December 31, 2015 <hr/>
Cash, cash equivalents and short-term investments	\$ 35,254	\$ 41,480
Working Capital	29,743	36,648
Total assets	36,770	43,079
Facility loan	9,494	9,381
Warrant Liability	900	1,220
Total liabilities	14,924	14,964
Common stock and additional paid-in capital	424,983	424,424
Total stockholders' equity	21,846	28,115



Source: CymaBay Therapeutics, Inc.