

March 23, 2017

# CymaBay Reports Fourth Quarter and Year End 2016 Financial Results

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

NEWARK, Calif., March 23, 2017 (GLOBE NEWSWIRE) -- CymaBay Therapeutics, Inc. (NASDAQ:CBAY), a clinical-stage biopharmaceutical company developing therapies to treat specialty and orphan diseases with high unmet medical need, today announced financial results and a corporate update for the quarter and twelve months ended December 31, 2016.

“In 2016, we made significant progress in our two clinical development programs, seladelpar for the treatment of primary biliary cholangitis, and arhalofenate, a unique Urate-Lowering Anti-Flare Therapy (ULAFT) candidate for the treatment of gout,” said Dr. Harold Van Wart, Chief Executive Officer of CymaBay Therapeutics. “We initiated a new dose-ranging Phase 2 study of seladelpar in patients with PBC to optimize dose selection on the strength of promising results from our earlier proof-of-concept study in this indication. At the end of 2016, we entered into an exclusive license agreement with Kowa Pharmaceuticals America, Inc. for the development and commercialization of arhalofenate in the U.S. Our accomplishments in 2016 have positioned us to advance our goal to become a leader in the development of novel therapies to treat liver diseases with high unmet medical need as we step forward into 2017.”

## Recent Business Highlights

**Seladelpar** - An oral, potent and selective PPAR $\delta$  agonist that has multiple complementary pharmacological actions that may be useful in the treatment of diseases with high unmet medical need, including primary biliary cholangitis (PBC) and nonalcoholic steatohepatitis (NASH).

- Clinical data from CymaBay’s first Phase 2 study with seladelpar in PBC were featured as a late-breaking oral presentation at the annual meeting of the American Association for the Study of Liver Diseases (AASLD), which took place in Boston, November 11-15.
- Preclinical data showing that seladelpar is effective at reversing NASH and inhibiting fibrosis in an animal model of NASH were also presented orally at the AASLD meeting.
- In October, seladelpar received European Medicines Agency (EMA) PRiority MEDicines (PRIME) designation for the treatment of PBC.
- The U.S. Food & Drug Administration (FDA) granted Orphan Drug designation for seladelpar for the treatment of patients with PBC, recognizing the continuing unmet need for patients with this disease.
- In December, we randomized the first patient into our second dose-ranging Phase 2 study of seladelpar in patients with PBC.
- In this study, patients who have had an inadequate response to, or are intolerant to, ursodiol are being enrolled to receive seladelpar, either 5 or 10 mg, once-daily for 8

weeks.

- After review of the 8-week data, a third group of patients may be enrolled to receive seladelpar 25 mg, once-daily for 8 weeks.
- The study also incorporates an extension phase where patients are able to continue treatment for a total of 26 weeks during which it will be possible to adjust the dose of seladelpar.
- The primary efficacy outcome endpoint will be the change in alkaline phosphatase (ALP), a parameter that has been used in prior clinical studies with PBC and which reflects the status of the disease.

**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-1 $\beta$ ) activity that suppresses flares.

- Entered into an exclusive license agreement with Kowa Pharmaceuticals America, Inc. for the development and commercialization of arhalofenate in the United States and its territories and possessions.
  - Under the terms of the agreement, CymaBay received an up-front payment of \$5 million in January 2017, and is eligible to receive additional near term milestone payments of \$10 million based on the initiation of specific development activities. CymaBay is also eligible to receive up to an additional \$190 million in payments based upon the achievement of specific development and sales milestones.
  - CymaBay is eligible to receive tiered, double digit royalties on future sales of arhalofenate products.
  - Kowa will be responsible for all development and commercialization costs.
  - CymaBay retains full development and commercialization rights for the rest of the world.

## **Corporate Updates**

- Strengthened the Board of Directors with the appointments of Robert Booth, Ph.D. and Caroline Loewy.
  - Dr. Booth is a veteran of the biotechnology industry with wide ranging expertise in both large cap pharma and biotechnology companies.
  - Ms. Loewy brings years of financial and operational experience with development stage biotechnology companies and a particular focus in supporting the advancement of therapies for rare diseases.
- In February 2017, raised approximately \$9.2 million after deducting underwriting discounts, commissions, and other offering expenses in a public offering of 5.2 million shares of common stock at a public offering price of \$1.93 per share.

## **Fourth Quarter and Full Year 2016 Financial Results**

- As of December 31, 2016, CymaBay had cash, cash equivalents and marketable securities of approximately \$17.0 million. CymaBay believes that these funds, together with additional proceeds of approximately \$14.4 million received from the arhalofenate licensing deal and financings in January and February of 2017, will allow CymaBay to

continue operations through at least the next twelve months.

- For the quarters ended December 31, 2016 and 2015, research and development expenses were \$3.8 million and \$4.1 million, respectively. For the years ended December 31, 2016 and 2015, research and development expenses were \$15.9 million and \$17.0 million, respectively. The decrease in R&D expenses for the year ended December 31, 2016 as compared to December 31, 2015 was primarily due to completion of arhalofenate Phase 2 clinical trials in 2015, partially offset by higher costs for PBC Phase 2 clinical program due to the initiation of CymaBay's second study with lower doses of seladelpar in 2016.
- General and administrative expenses for the quarters ended December 31, 2016 and 2015 were \$2.8 million, and \$1.8 million, respectively. General and administrative expenses increased by \$0.7 million, to \$9.6 million from \$8.9 million, for the years ended December 31, 2016 and 2015, respectively, primarily as a result of higher labor costs and consulting expenses related to the licensing agreement with Kowa Pharmaceuticals America, Inc.
- Net loss for the quarters ended December 31, 2016 and 2015 was \$7.0 million, or \$0.30 per diluted share, and \$6.0 million, or \$0.26 per diluted share, respectively. Net loss for the years ended December 31, 2016 and 2015 was \$26.7 million, or \$1.14 per diluted share, and \$15.5 million, or \$0.83 per diluted share, respectively. The increase in net loss for 2016 was primarily due to a decrease in non-cash gains of \$11.0 million as compared to 2015 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 fourth quarter and full year 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 CymaBay website at <http://ir.cymabay.com/events>. A replay of the webcast will be available on the CymaBay website for 14 days following the live event.

### **About CymaBay**

CymaBay Therapeutics, Inc. (CBAY) is a clinical-stage biopharmaceutical company focused on developing therapies to treat metabolic diseases with high unmet medical need, including serious rare and orphan disorders. Seladelpar is a potent, selective, orally active PPAR $\delta$  agonist. A Phase 2 study of seladelpar in patients with mixed dyslipidemia established that it has an anti-atherogenic lipid profile. CymaBay has completed Phase 2 studies for seladelpar in subjects with primary biliary cholangitis and homozygous familial hypercholesterolemia, establishing proof-of-concept in both indications. Arhalofenate, CymaBay's other product candidate, is a potential Urate-Lowering Anti-Flare Therapy that has completed five Phase 2 studies in subjects with gout. Arhalofenate has been found to reduce painful flares in joints while at the same time lowering serum uric acid by 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. Arhalofenate has been licensed in the U.S. to Kowa Pharmaceuticals America, Inc. CymaBay retains full development and commercialization rights for arhalofenate outside the U.S.

### **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 seladelpar to treat primary biliary cholangitis or nonalcoholic steatohepatitis, 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 seladelpar 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 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).

**CymaBay Therapeutics, Inc.**

**Balance Sheet Data**

(In thousands, except share and per share amounts)

	<b>December 31, 2016</b>	<b>December 31, 2015</b>
Cash, cash equivalents and short-term investments	\$ 16,994	\$ 41,480
Working Capital	9,217	36,128
Total assets	19,359	43,079
Facility loan	8,798	9,308
Warrant Liability	1,145	1,220
Total liabilities	15,422	14,964
Common stock and additional paid-in capital	426,897	424,424
Total stockholders' equity	3,937	28,115

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

	Quarter Ended December 31,		Year Ended December 31,	
	2016	2015	2016	2015
Operating expenses:				
Research and development	\$ 3,848	\$ 4,051	\$ 15,941	\$ 17,026
General and administrative	2,839	1,796	9,645	8,871
Total operating expenses	6,687	5,847	25,586	25,897
Loss from operations	(6,687 )	(5,847 )	(25,586 )	(25,897 )
Other income (expense):				
Interest income	30	61	176	160
Interest expense	(328 )	(329 )	(1,337 )	(913 )
Other income (expense), net	33	136	76	11,121
Net loss	\$ (6,952 )	\$ (5,979 )	\$ (26,671 )	\$ (15,529 )
Basic net loss per common share	\$ (0.30 )	\$ (0.26 )	\$ (1.14 )	\$ (0.82 )
Diluted net loss per common share	\$ (0.30 )	\$ (0.26 )	\$ (1.14 )	\$ (0.83 )
Weighted average common shares outstanding used to calculate				
basic net loss per common share	23,447,003	23,447,003	23,447,003	18,900,473
Weighted average common shares outstanding used to calculate				
diluted net loss per common share	23,447,003	23,447,003	23,447,003	18,917,213

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Source: CymaBay Therapeutics, Inc.