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# CymaBay Reports Fourth Quarter and Fiscal 2017 Financial Results and Provides Corporate Update

Conference call and webcast today at 4:30p.m. ET

NEWARK, Calif., March 15, 2018 (GLOBE NEWSWIRE) -- CymaBay Therapeutics, Inc. (NASDAQ:CBAY), a clinical-stage biopharmaceutical company focused on developing therapies for liver and other chronic diseases with high unmet need, today announced financial results and a corporate update for the quarter and fiscal year ended December 31, 2017.

"We had a transformational year in 2017, with significant progress across clinical, operational and financial objectives, focused on advancing our pipeline," said Sujal Shah, President and Chief Executive Officer of CymaBay. "Our lead candidate, seladelpar, generated positive proof-of-concept data in primary biliary cholangitis (PBC), demonstrating it has the potential to offer patients improved efficacy and better tolerability compared to current second line treatment. The out-licensing of our Phase 3 ready gout asset, arhalofenate, to Kowa Pharmaceuticals America allowed us to monetize the value of that asset for stockholders and devote our full attention to developing therapies for liver diseases."

"In the second half of 2018 we plan to advance seladelpar into a Phase 3 registration study in PBC. We also plan to diversify development of seladelpar beyond PBC and into nonalcoholic steatohepatitis (NASH) with the planned initiation of a Phase 2b proof-of-concept study in the first half of the year," continued Mr. Shah. "We have strengthened our balance sheet considerably and now have the capital required to complete our planned Phase 3 study in PBC and Phase 2b study in NASH."

## Fourth Quarter 2017 Highlights

- In October 2017, interim results from an ongoing Phase 2 study of seladelpar in patients with PBC were presented in an oral late breaking session at The Liver Meeting® hosted by the American Association for the Study of Liver Diseases (AASLD)
  - The 5 mg and 10 mg/day dose groups demonstrated substantial reductions in alkaline phosphatase (AP) of 39% and 45%, respectively, from baseline to week 12. AP is a marker of cholestasis that has been correlated with improved liver transplant-free survival and is an established surrogate of disease progression in patients with PBC.
  - After 12 weeks of dosing, 45% of patients in the 5 mg group and 82% of patients in the 10 mg group had AP values less than 1.67 times the upper limit of normal (ULN). Reaching a level of less than 1.67 times ULN is a key component in the composite endpoint recently used for regulatory approval.
  - Reductions in other cholestatic markers, including gamma glutamyl transpeptidase

and total bilirubin, anti-inflammatory markers, including transaminases and high sensitivity C-reactive protein, and in low-density lipoprotein-C were also observed in both dose groups at week 12.

- Treatment with seladelpar was not associated with drug-induced pruritus, a key potential advantage over the current second line treatment.
- No serious adverse events and no safety transaminase signal were observed at either dose.
- In November 2017, Sujal Shah was appointed as President and Chief Executive Officer. Mr. Shah had served as interim President and Chief Executive Officer since March 2017
- In December 2017, Paul T. Quinlan was appointed as General Counsel and Corporate Secretary.
- In December 2017, the first PBC patients were enrolled in the seladelpar long-term extension study
  - The objectives of the study are to provide additional long-term safety and efficacy data that will support the seladelpar registration program.
  - The study provides continued access to seladelpar for PBC patients who are completing treatment in CymaBay's ongoing Phase 2 study and it will be open to patients completing the planned Phase 3 program.

### **Recent Business Highlights**

- In January 2018, CymaBay received a \$5 million payment from Kowa Pharmaceuticals America for the initiation of a study evaluating the pharmacokinetics of arhalofenate in subjects with renal impairment.
- In January 2018, CymaBay announced enrollment had commenced in a long-term extension study that provides uninterrupted access to seladelpar for PBC patients completing treatment with seladelpar in a previous or ongoing study.
- In February 2018, CymaBay completed a successful equity offering, raising \$135.5 million in net proceeds.

### **Fourth Quarter 2017 Financial Results**

- Cash, cash equivalents and marketable securities totaled \$97.2 million at December 31, 2017, compared to \$17.0 million at December 31, 2016. Existing cash, together with the \$135.5 million raised by the company in February 2018 and the \$5 million received from Kowa in January 2018, is expected to fund CymaBay's current operating plan into 2021.
- Collaboration revenue was \$5.2 million in the fourth quarter of 2017 and was primarily related to the achievement of a \$5.0 million collaboration milestone earned upon Kowa's initiation of a renal impairment study. There was no collaboration revenue in the fourth quarter of 2016.
- Research and development expenses were \$6.7 million in the fourth quarter of 2017, as compared to \$3.8 million in the same period of 2016 and consisted primarily of PBC clinical trial expenses and seladelpar drug manufacturing expenses in each period.
- General and administrative expenses were \$2.9 million in the fourth quarter of 2017, as compared to \$2.8 million in the fourth quarter of 2016.
- Net loss was \$5.0 million, or (\$0.11) per share in the fourth quarter of 2017, as compared to \$7.0 million, or (\$0.30) per share in the fourth quarter of 2016. Net loss in

the fourth quarter of 2017 was lower as compared to prior year primarily due to the recognition of collaboration revenue, offset in part by higher research and development expenses and a non-cash mark-to-market loss on the revaluation of CymaBay's warrant liability.

## **Fiscal Year 2017 Financial Results**

- Collaboration revenue was \$10.0 million in the year ended December 31, 2017 and was primarily due to a \$5.0 million upfront payment from Kowa, as well as the achievement of a \$5.0 million collaboration milestone earned upon Kowa's initiation of a renal impairment study. There was no collaboration revenue in the prior year period.
- Research and development expense for the year ended December 31, 2017, was \$18.9 million, compared to \$15.9 million for the prior year period and consisted primarily of PBC clinical trial expenses and seladelpar drug manufacturing expenses in each period.
- General and administrative expense for the year ended December 31, 2017, was \$12.4 million, compared to \$9.6 million for the prior year period. The increase in G&A expenses was primarily due to one-time, non-cash stock compensation expenses associated with the retirement of CymaBay's former CEO in April 2017.
- Net loss for the year ended December 31, 2017, was \$27.6 million, or (\$0.79) per share, compared to \$26.7 million, or (\$1.14) per share, for the prior year period.

## **Conference Call Details**

CymaBay management will host a conference call today at 4:30 p.m. ET to discuss fourth quarter and fiscal year 2017 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, Conference ID# 13676717. 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>.

## **About CymaBay**

CymaBay Therapeutics, Inc. (CBAY) is a clinical-stage biopharmaceutical company focused on developing therapies for liver and other chronic diseases with high unmet medical need. Seladelpar is a potent, selective, orally active PPAR $\delta$  agonist, currently in development for the treatment of patients with primary biliary cholangitis (PBC), an autoimmune liver disease, and with nonalcoholic steatohepatitis (NASH). Two Phase 2 studies of seladelpar established proof-of-concept in PBC. CymaBay is currently planning to advance development of seladelpar into Phase 3 for PBC and Phase 2 for NASH. Arhalofenate is a potential urate-lowering anti-flare therapy that 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 regarding the potential for seladelpar to treat PBC and NASH and the potential for arhalofenate to treat gout, the potential benefits to patients, CymaBay's expectations and plans regarding future clinical trials and CymaBay's ability to fund current and planned clinical trials are forward looking statements that are subject to

risks and uncertainties. Actual results and the timing of events regarding the further development of seladelpar and arhalofenate 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; effects observed in trials to date that 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).

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

	December 31, 2017	December 31, 2016
Cash, cash equivalents and marketable securities	\$ 97,210	\$ 16,994
Working capital	87,234	9,217
Total assets	104,247	19,359
Facility loan	6,098	8,798
Warrant liability	6,091	1,145
Total liabilities	19,300	15,422
Common stock and additional paid-in capital	535,507	426,897
Total stockholders' equity	84,947	3,937

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

	Quarter Ended December 31,		Year Ended December 31,	
	2017	2016	2017	2016
	(unaudited)	(unaudited)		
Collaboration revenue	\$ 5,207	\$ -	\$ 10,000	\$ -
Operating expenses:				
Research and development	\$ 6,669	\$ 3,848	\$ 18,938	\$ 15,941
General and administrative	2,894	2,839	12,387	9,645
Total operating expenses	9,563	6,687	31,325	25,586
Loss from operations	(4,356 )	(6,687 )	(21,325 )	(25,586 )
Other income (expense):				
Interest income	324	30	621	176
Interest expense	(234 )	(328 )	(1,080 )	(1337 )
Other income (expense), net	(777 )	33	(5,773 )	76
Net loss	<u>\$ (5,043 )</u>	<u>\$ (6,952 )</u>	<u>\$ (27,557 )</u>	<u>\$ (26,671 )</u>
Basic net loss per common share	<u>\$ (0.11 )</u>	<u>\$ (0.30 )</u>	<u>\$ (0.79 )</u>	<u>\$ (1.14 )</u>
Diluted net loss per common share	<u>\$ (0.11 )</u>	<u>\$ (0.30 )</u>	<u>\$ (0.79 )</u>	<u>\$ (1.14 )</u>
Weighted average common shares outstanding used to calculate basic net loss per common share	<u>43,970,598</u>	<u>23,447,003</u>	<u>34,903,960</u>	<u>23,447,003</u>
Weighted average common shares outstanding used to calculate diluted net loss per common share	<u>43,970,598</u>	<u>23,447,003</u>	<u>34,903,960</u>	<u>23,447,003</u>



Source: CymaBay Therapeutics, Inc.