

August 9, 2018

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# CymaBay Reports Second Quarter 2018 Financial Results and Provides Corporate Update

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

NEWARK, Calif., Aug. 09, 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 six months ended June 30, 2018.

“Having completed a significant capital raise to start the year, we are now laser focused on high quality execution as we continue to advance novel treatment alternatives to patients suffering from liver diseases with significant unmet needs,” said Sujal Shah, President and Chief Executive Officer of CymaBay. “We have collected feedback from regulatory agencies and finalized our design for our planned Phase 3 study of seladelpar in primary biliary cholangitis (PBC) and we are on track to initiate this study in the second half of the year.

Data from the ongoing Phase 2 study of seladelpar in patients with PBC were presented in a late-breaking presentation at The International Liver Congress™ in April, and we believe these data support the potential of seladelpar to provide improved efficacy and better tolerability over existing second-line therapy. We are also excited to expand development of seladelpar into non-alcoholic steatohepatitis (NASH) with the recent initiation of a Phase 2b proof-of-concept study. We believe seladelpar’s PPAR-delta mechanism of action may be particularly well suited to treat NASH given its beneficial impacts on lipid, glucose, and sterol metabolism, as well as its effects on inflammation and fibrogenesis.”

## Second Quarter 2018 Business Highlights

- Announced plans to proceed with a double-blind, placebo-controlled Phase 3 pivotal study of seladelpar in PBC. The study intends to enroll approximately 240 patients randomized to receive either 5 mg or 10 mg seladelpar, or placebo. Patients who have an inadequate response on the 5 mg dose will have the potential to increase to 10 mg after 6 months.
- Presented new 12-week and 26-week results from the ongoing Phase 2 study of seladelpar in primary biliary cholangitis (PBC) at The International Liver Congress™ in April.
  - The results showed potent anti-cholestatic and anti-inflammatory activities, with no drug-induced pruritus, through 26 weeks of treatment.
  - 52-week data from this study are expected to be announced in the fourth quarter of 2018.
- Initiated a Phase 2b proof-of-concept study of seladelpar for the treatment of NASH. This randomized, placebo-controlled, parallel, dose-ranging study is intended to enroll approximately 175 patients with liver biopsy proven NASH. The primary efficacy outcome is change in liver fat content from baseline to 12 weeks as measured by

magnetic resonance imaging. The secondary analysis includes evaluation of histological improvement in NASH and fibrosis as assessed by comparing liver biopsy samples taken at baseline and 52 weeks.

- Added CBAY to the Russell 3000® and the Russell 2000® Indexes at the conclusion of the Russell US Indexes annual reconstitution.
- Expanded workforce with clinical, regulatory, scientific and administrative personnel necessary to support expansion of clinical programs, notably the Phase 3 PBC registration study, and business operations.
- Amended the existing corporate office lease to extend it for an additional 5-year term and relocate to a larger facility within current corporate campus location.

## **Second Quarter 2018 Financial Results**

- Cash, cash equivalents and marketable securities totaled \$212.1 million at June 30, 2018. Based on current projections, existing cash is expected to fund the current operating plan into 2021.
- Term loan facility repaid in full resulting in a debt-free balance sheet at June 30, 2018.
- No collaboration revenue was recognized in the second quarter of 2018.
- Research and development expenses were \$14.4 million in the second quarter of 2018 as compared to \$4.0 million in the same period of 2017 and consisted primarily of higher clinical trial expenses related to ongoing PBC Phase 2 and extension studies, start-up activities for the planned PBC Phase 3 study, and enrollment activities associated with the recently initiated NASH Phase 2b study. Additionally, higher seladelpar drug manufacturing expenses were incurred to provide clinical supplies to these studies.
- General and administrative expenses were unchanged at \$3.6 million in the second quarter of 2018 and 2017.
- Net loss was \$17.5 million, or (\$0.30) per share in the second quarter of 2018, as compared to \$8.9 million, or (\$0.31) per share in the second quarter of 2017. Net loss was higher primarily due to increased research and development expenses incurred to support expanding clinical studies.

## **First Half 2018 Financial Results**

- No collaboration revenue was recognized in the first half of 2018 as compared to \$4.8 million in the same period of 2017. Revenue associated with the collaboration arrangement with Kowa Pharmaceuticals America was recognized in 2017 upon transfer of a license and know how to Kowa.
- Research and development expenses were \$23.9 million in the first half of 2018 as compared to \$8.1 million in the same period of 2017 and consisted primarily of higher clinical trial expenses related to ongoing PBC Phase 2 and extension studies, start-up activities for the planned PBC Phase 3 study, and enrollment activities associated with the recently initiated NASH Phase 2b study. Additionally, higher seladelpar drug manufacturing expenses were incurred to provide clinical supplies to these studies.
- General and administrative expenses were \$6.9 million in the first half of 2018, as compared to \$7.3 million in the first half of 2017. Expenses were higher in 2017 primarily due to severance expenses associated with the retirement of CymaBay's former CEO.
- Net loss was \$34.5 million, or (\$0.61) per share in the first half of 2018, as compared to

\$14.3 million, or (\$0.52) per share in the second quarter of 2017. Net loss was higher primarily due to increased research and development expenses incurred to support the expanding clinical studies and lower collaboration revenue.

### **Conference Call Details**

CymaBay management will host a conference call today at 4:30 p.m. ET to discuss second quarter 2018 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# 13680965. 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 non-alcoholic steatohepatitis (NASH).

### **Cautionary Statements**

The statements in this press release regarding the potential for seladelpar to treat PBC and NASH, the potential benefits to patients, CymaBay's expectations and plans regarding ongoing and future clinical trials, including timing in regard thereto, 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 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).

### **Contact:**

Hans Vitzthum  
LifeSci Advisors, LLC  
212-915-2568  
[Hans@LifeSciAdvisors.com](mailto:Hans@LifeSciAdvisors.com)

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

	<b>Three Months Ended June 30,</b>		<b>Six Months Ended June 30,</b>	
	<b>2018</b>	<b>2017</b>	<b>2018</b>	<b>2017</b>
Collaboration revenue	\$ -	\$ -	\$ -	\$ 4,793
Operating expenses:				
Research and development	14,397	4,044	23,874	8,085
General and administrative	3,574	3,582	6,947	7,283
Total operating expenses	17,971	7,626	30,821	15,368
Loss from operations	(17,971 )	(7,626 )	(30,821 )	(10,575 )
Other income (expense):				
Interest income	1,061	44	1,769	81
Interest expense	(128 )	(283 )	(336 )	(588 )
Loss on extinguishment of debt	(407 )	-	(407 )	-
Other income (expense), net	(86 )	(1,064 )	(4,741 )	(3,198 )
Net loss	<u>\$ (17,531 )</u>	<u>\$ (8,929 )</u>	<u>\$ (34,536 )</u>	<u>\$ (14,280 )</u>
Basic net loss per common share	\$ (0.30 )	\$ (0.31 )	\$ (0.61 )	\$ (0.52 )
Diluted net loss per common share	\$ (0.30 )	\$ (0.31 )	\$ (0.61 )	\$ (0.52 )
Weighted average common shares outstanding used to calculate basic net loss per common share	58,833,647	28,752,451	56,307,236	27,687,110
Weighted average common shares outstanding used to calculate diluted net loss per common share	58,905,898	28,752,451	56,307,236	27,687,110

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

	<b>June 30, 2018 (unaudited)</b>	<b>December 31, 2017</b>
Cash, cash equivalents and short-term investments	\$ 212,079	\$ 97,210
Working capital	199,799	87,234
Total assets	218,168	104,247
Facility loan	-	6,098
Warrant liability	5,632	6,091
Total liabilities	18,955	19,300
Common stock and additional paid-in capital	684,332	535,507
Total stockholders' equity	199,213	84,947



Source: CymaBay Therapeutics, Inc.