August 7, 2019

CymaBay Reports Second Quarter 2019 Financial Results and Provides Corporate Update

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

NEWARK, Calif., Aug. 07, 2019 (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 ended June 30, 2019.

“In the second quarter of 2019, we made significant progress advancing the development of seladelpar for PBC and NASH and began activities to further diversify development into PSC,” said Sujal Shah, President and CEO of CymaBay. “Enrollment in our ENHANCE Phase 3 registration study in PBC, expected to be completed by year-end, continued on track during the quarter. Topline 12-week results from our 52-week, dose-ranging Phase 2b study in NASH showed clinically meaningful reductions in multiple biomarkers of inflammation and liver injury despite minimal reductions in total liver fat. At two of the three doses being tested, mean reductions in alanine aminotransferase exceed thresholds that have been correlated to histologic improvement in NASH. In this ongoing study, the effects of seladelpar on the two key histologic endpoints, NASH resolution and fibrosis, will be assessed from a liver biopsy taken at 52 weeks. We expect to share these data in the second quarter of 2020. In June, we announced plans to initiate a Phase 2, dose-ranging study of seladelpar in patients with PSC in the third quarter of 2019.”

Second Quarter and Recent Business Highlights

- Janet Dorling joined the CymaBay executive team as Chief Commercial Officer
    - Ms. Dorling is a seasoned commercial leader with over 15 years of experience in pharmaceutical sales and marketing at Achaogen, Roche and Genentech.
- Continued enrollment of ENHANCE, a global, Phase 3 registration study of seladelpar for the treatment of primary biliary cholangitis (PBC).
    - ENHANCE is intended to establish the efficacy and safety of seladelpar for the treatment of PBC to support the submission of a global registration dossier with health authorities to obtain approval.
    - The study is expected to be fully enrolled by the end of 2019 with the 52-week treatment period targeted for completion by the end of 2020 and topline data in 2021.
- Topline data from our Phase 2b dose-ranging, paired liver biopsy study of seladelpar for the treatment of nonalcoholic steatohepatitis (NASH) was released in June 2019.
    - Treatment with seladelpar resulted in robust and clinically meaningful reductions in markers associated with liver injury.
    - Treatment with seladelpar resulted in minimal reductions in liver fat that were not significant when compared to placebo.

    - Seladelpar demonstrated a favorable safety and tolerability profile at all doses evaluated in this study.
- Announced FDA acceptance of an IND to initiate a Phase 2 clinical study of seladelpar in primary sclerosing cholangitis (PSC).
    - PSC is a rare, chronic cholestatic liver disease that is characterized by diffuse inflammation and fibrosis of the bile ducts for which there are no FDA-approved treatments.
    - The Phase 2 study is expected to be initiated in the third quarter of 2019 and will be a randomized, placebo-controlled, dose-ranging study that will enroll approximately 100 patients at 60 sites globally.

Second Quarter Financial Highlights & Results

- Held $241.2 million in cash, cash equivalents and marketable securities at June 30, 2019. Existing cash is expected to fund the current operating plan into 2021.
- Research and development expenses were $21.1 million in the second quarter of 2019 as compared to $14.4 million in the same period of 2018. The increase was primarily driven by increases in seladelpar-related clinical trial expenses including:
    - start-up and enrollment activities related to our ENHANCE PBC Phase 3 clinical study
    - continued treatment of patients in our PBC Phase 2 clinical study
    - start-up activities related to our PSC Phase 2 clinical study
    - execution of other NDA-enabling studies
- General and administrative expenses were $4.5 million in the second quarter of 2019 as compared to $3.6 million in the same period of 2018. The increase was driven primarily by higher employee compensation and other administrative expenses as we hired additional personnel to support our expanding operations.
- Net loss was $24.0 million, or ($0.35) per diluted share in the second quarter of 2019, as compared to $17.5 million, or ($0.30) per diluted share, in the same period of 2018. Net loss was higher primarily due to increased research and development expenses.

First Half Financial Highlights & Results

- Raised $107.7 million in net proceeds through our March public offering of common stock.
- Research and development expenses were $39.7 million in the first half of 2019 as compared to $23.9 million in the same period of 2018. The increase was primarily driven by increases in seladelpar-related clinical trial expenses including:
    - start-up and enrollment activities related to our ENHANCE PBC Phase 3 clinical study
    - final enrollment activities and ongoing treatment of patients in our NASH Phase 2b clinical study
    - continued treatment of patients in our PBC Phase 2 clinical study
    - start-up activities related to our PSC Phase 2 clinical study
    - execution of other NDA-enabling studies
- General and administrative expenses were $10.2 million in the first half of 2019 as compared to $6.9 million in the same period of 2018. The increase was driven primarily by higher employee compensation and other administrative expenses as we hired additional personnel to support our expanding operations.

- Net loss was $47.1 million, or ($0.72) per diluted share in the first quarter of 2019, as compared to $34.5 million, or ($0.61) per diluted share, in the same period of 2018. Net loss was higher primarily due to increased research and development expenses.

Conference Call Details

CymaBay management will host a conference call today at 4:30 p.m. ET to discuss second quarter 2019 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# 13692706. 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. is a clinical-stage biopharmaceutical company focused on developing therapies for liver and other chronic diseases with high unmet medical need. CymaBay's lead development candidate, seladelpar, is a potent, selective and orally active PPARδ agonist currently in development for the treatment of patients with primary biliary cholangitis (PBC), an autoimmune liver disease, and with nonalcoholic steatohepatitis (NASH). CymaBay is currently enrolling patients in a global, Phase 3 registration study of seladelpar for PBC. This study is a 52-week, placEbo-coNtrolled, randomized, pHAse 3 study to evaluate the safety aNd effiCacy of sEladelpar (ENHANCE) in patients with PBC. For more information about ENHANCE, please visit: www.pbcstudies.com. Seladelpar received orphan designation for PBC from the U.S. Food and Drug Administration (FDA) and the European Medicine Agency (EMA). Seladelpar also received Breakthrough Therapy Designation for early stage PBC from the FDA and PRIority MEdicine status from the EMA. CymaBay is also conducting a Phase 2b proof-of-concept study of seladelpar for patients with NASH, and plans to initiate a Phase 2 study of seladelpar for patients with primary sclerosing cholangitis (PSC) in the third quarter of 2019.

For additional information about CymaBay visitwww.cymabay.com.

Cautionary Statements

The statements in this press release regarding the potential for seladelpar to treat PBC, PSC and NASH, the potential benefits to patients, the timing of clinical trials and release of clinical results, CymaBay's expectations and plans regarding current and 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 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.

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

	Quarter Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
	(unaudited)	(unaudited)	(unaudited)	(unaudited)
Operating expenses:				
Research and development	21,119	14,397	39,707	23,874
General and administrative	4,529	3,574	10,192	6,947
Total operating expenses	25,648	17,971	49,899	30,821
Loss from operations	(25,648)	(17,971)	(49,899)	(30,821)
Other income (expense):				
Interest income	1,610	1,061	2,786	1,769
Interest expense	-	(128)	-	(336)
Loss on extinguishment of debt	-	(407)	-	(407)
Other expense, net	-	(86)	-	(4,741)
Total other income (expense)	1,610	440	2,786	(3,715)
Net loss	$ (24,038)	$ (17,531)	$ (47,113)	$ (34,536)
Basic net loss per common share	$ (0.35)	$ (0.30)	$ (0.72)	$ (0.61)
Diluted net loss per common share	$ (0.35)	$ (0.30)	$ (0.72)	$ (0.61)
Weighted average common shares outstanding used to calculate basic net loss per common share	68,697,735	58,833,647	65,312,988	56,307,236
Weighted average common shares outstanding used to calculate diluted net loss per common share	68,697,735	58,905,898	65,312,988	56,307,236

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

	June 30, 2019 (unaudited)	December 31, 2018
Cash, cash equivalents and marketable securities	$ 241,207	$ 178,664
Working capital	234,391	167,147
Total assets	253,435	186,747
Total liabilities	17,376	16,329
Common stock and additional paid-in capital	806,008	693,540
Total stockholders' equity	236,059	170,418

Source: CymaBay Therapeutics, Inc.