February 28, 2024

CymaBay Reports Fourth Quarter and Year Ended December 31, 2023 Financial Results and Provides Corporate Update

Gilead Sciences, Inc. has proposed to acquire CymaBay for $32.50 per share in cash or a total equity value of $4.3 billion.

U.S. FDA accepted seladelpar NDA for priority review, and seladelpar marketing applications were submitted to the EMA and MHRA for review in Europe and the U.K.

Due to the pending transaction with Gilead, CymaBay will not be hosting a conference call to review the financial results for the fourth quarter ended December 31, 2023 or commenting on its financial guidance for the future quarters.

NEWARK, Calif., Feb. 28, 2024 (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 corporate updates and financial results for the year and fourth quarter ended December 31, 2023.

“2023 was a seminal year for CymaBay with critical achievements in the development of our investigational therapeutic, seladelpar. The Phase 3 RESPONSE data presented in 2023 and recently published in the New England Journal of Medicine, indicate that seladelpar has the potential to raise the bar in PBC second-line treatment and improve quality of life for people living with this debilitating condition,” said Sujal Shah, President and CEO of CymaBay. “Our team moved at speed to submit seladelpar to regulatory agencies and with an updated breakthrough therapy designation were able to secure FDA priority review. These accomplishments were recognized with the recent announcement of the pending acquisition of CymaBay by Gilead. I am incredibly proud of the team and everything that has been achieved in 2023 to help bring seladelpar to people living with PBC, and believe that through Gilead, seladelpar can reach a broad range of people that may benefit in 2024 and beyond.”

2023 and Recent Corporate Highlights

Pending Acquisition by Gilead:

- On February 11, 2024, CymaBay entered into a definitive agreement with Gilead Sciences, Inc. (Gilead) under which Gilead will acquire CymaBay for $32.50 per share in cash or a total equity value of $4.3 billion. The transaction is anticipated to close during the first quarter of 2024, subject to the receipt of regulatory approvals and the satisfaction of other customary closing conditions.

Regulatory Updates and Launch Readiness:

- In February 2024, the U.S. Food and Drug Administration (FDA) accepted a New Drug Application (NDA) for seladelpar, an investigational treatment for the management of primary biliary cholangitis (PBC) including pruritus in adults without cirrhosis or with compensated cirrhosis (Child Pugh A) who are inadequate responders or intolerant to ursodeoxycholic acid. The FDA has granted priority review and set a Prescription Drug User Fee Act target action date of August 14, 2024. The agency has notified the company that it is not currently planning to hold an advisory committee meeting to discuss the application.
- CymaBay has received validation of its application to the U.K. Medicines Healthcare products Regulatory Agency (MHRA) for seladelpar for the treatment of PBC. Seladelpar has also been submitted to the European Medicines Agency (EMA) and validation of the application is anticipated in H1 2024. Review by both agencies is anticipated to be completed in 2025.
- In the U.S., this application was further supported by the Breakthrough Therapy Designation for seladelpar, that was updated by the FDA in October 2023, with clinical results that indicate seladelpar may provide meaningful improvement over existing therapy based on a reduction in alkaline phosphatase (ALP) and improvement in pruritus in patients without cirrhosis or with compensated cirrhosis.
- In preparation for the potential launch of seladelpar in the U.S. in 2024, CymaBay hired, trained and deployed a medical affairs team with a range of expertise across PBC, rare disease and liver diseases to drive PBC education. Our pre-commercial launch planning efforts in the U.S. accelerated in the fourth quarter as we built strong commercial strategy, marketing, market access, commercial operations and analytics teams with experience in launching new treatments in rare diseases and competitive therapeutics areas and markets.

Clinical Development:

- In mid-2023, CymaBay announced initiation of the IDEAL study, a 52-week, placebo-controlled, randomized, Phase 3 study. The IDEAL study aimed to enroll 75 patients with PBC who have an incomplete response or intolerance to ursodeoxycholic acid (UDCA), with ALP levels greater than the upper limit of normal (ULN) but less than 1.67x ULN, and total bilirubin less than or equal to 2x ULN. To ensure IDEAL is well powered to effectively assess both liver biochemistry and pruritus impact we are now doubling the study size to 150 patients with a 2:1 ratio of patients receiving seladelpar vs. placebo. The primary outcome measure is the ALP composite of normalization and a greater than or equal to 15% decrease in ALP at 52 weeks. A key secondary endpoint is evaluating the change in pruritus Numerical Rating Scale (NRS) at six months in subjects with moderate to severe pruritus at baseline.
- Enrollment in the long-term ASSURE study continues. ASSURE is an open-label study of seladelpar in patients with PBC intended to collect additional long-term safety and efficacy data to further support registration. There are now over 300 patients taking seladelpar 10 mg daily, through the study including those from prior studies of seladelpar and patients who have completed RESPONSE.
- In 2023, CymaBay initiated AFFIRM, a randomized, placebo-controlled confirmatory study to evaluate the effect of seladelpar 10 mg daily on clinical outcomes in patients with compensated cirrhosis due to PBC. The AFFIRM study is planned to enroll approximately 192 patients with PBC who have compensated cirrhosis (Child-Pugh A or Child-Pugh B) based on prespecified clinical criteria. Patients will be randomly

assigned using a 2:1 ratio to seladelpar or placebo for a fixed duration of three years. The primary outcome measure is the time to the first occurrence of clinical events (all-cause death, liver transplant, hospitalization for other serious liver-related events, and progression to Child-Pugh C decompensated cirrhosis). Additional key outcomes include overall survival, liver transplant-free survival, and time to hospitalization for serious liver-related events.

Presentations and Publications:

- The pivotal Phase 3 RESPONSE study was presented at The Liver Meeting® 2023 of the American Association for the Study of Liver Diseases, in Boston Massachusetts, and later published online in the *New England Journal of Medicine* in February 2024. The clinical data includes:
    - RESPONSE was a double-blind, placebo-controlled, global study of one-year duration that randomized 193 PBC patients in a 2:1 ratio to seladelpar 10 mg or placebo, once daily. Eligible patients had an inadequate response or intolerance to ursodeoxycholic acid (UDCA) with serum alkaline phosphatase (ALP) ≥ 1.67× the upper limit of normal (ULN) after at least 12 months of treatment.
    - The primary endpoint was a composite of ALP and total bilirubin previously accepted by the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA) for registration studies in PBC. The composite endpoint was achieved in 61.7% of patients on seladelpar vs. 20.0% on placebo ($p<0.0001$).
    - The key secondary endpoint of ALP normalization occurred in 25% of patients receiving seladelpar vs. 0% for patients on placebo ($p<0.0001$). The average decrease in ALP for patients on seladelpar was -133.9 U/L vs. -16.9 U/L for patients on placebo ($p<0.0001$).
    - The study also measured the impact on patient-reported pruritus (itching), one of the most challenging symptoms experienced by people with PBC, as a key secondary endpoint using the daily numerical rating scale (NRS; 0-10). The pruritus endpoint was met at Month 6 among patients with baseline NRS > 4 reporting decreases of 3.2 points with seladelpar ($n=65$) vs. 1.7 for patients on placebo ($n=20$; $p<0.005$). Notably, these improvements were sustained through Month 12 ($p<0.005$). A statistically significant reduction in pruritus was also observed at Month 6 and at Month 12 for patients in the intent-to-treat population, which includes all patients irrespective of their NRS score at baseline.
- CymaBay published a post-hoc analysis of the Phase 3 ENHANCE study in the open access journal Hepatology, demonstrating the impact of seladelpar on serum interleukin-31 (IL-31) levels and its correlation with pruritus improvement in people with PBC.

Financial Updates:

Held $416.2 million in cash, cash equivalents and investments as of December 31, 2023.

Fourth Quarter and Year Ended December 31, 2023, Financial Results:

- Collaboration revenue recognized for the year ended December 31, 2023 was $31.1

million and was associated with the collaboration and license agreement with Kaken Pharmaceutical Co., Ltd. (Kaken) entered into in January 2023, to develop and commercialize seladelpar in Japan. As reported earlier, $31.0 million of this revenue was recognized upon completion of the initial technology transfer to Kaken in the second quarter of 2023. Of the $34.2M upfront payment received from Kaken, $2.7 million remains deferred as of December 31, 2023 and will be recognized upon completion of CymaBay's ongoing clinical data delivery and CMC development performance obligations.

- Research and development expenses for the three months ended December 31, 2023 and 2022 were $22.8 million, and $16.2 million, respectively. Research and development expenses for the years ended December 31, 2023, and 2022 were $80.8 million and $68.0 million, respectively. Research and development expenses for the three months and year ended December 31, 2023 increased compared to the corresponding periods in 2022 driven by higher clinical activities supporting our clinical studies and higher spend supporting our regulatory filings.
- General and administrative expenses for the three months ended December 31, 2023 and 2022 were $19.8 million and $7.2 million, respectively. General and administrative expenses for the years ended December 31, 2023 and 2022 were $51.9 million and $25.1 million, respectively. General and administrative expenses for the three months and year ended December 31, 2023 were higher than the corresponding periods in 2022 driven by investments to prepare for potential commercialization of seladelpar in PBC as well as increase in other corporate expenses.
- Net loss for the three months ended December 31, 2023 and 2022 was $41.9 million and $26.6 million, or ($0.35) and ($0.30) per share, respectively. Net loss for the year ended December 31, 2023 and 2022 was $105.4 million and $106.0 million, or ($0.99) and ($1.21) per share, respectively. Net loss for the three months ended December 31, 2023 was higher than the three months ended December 31, 2022 primarily due to higher operating expenses. Net loss in the year ended December 31, 2023 was slightly lower than the corresponding period in 2022 due primarily to $31.0 million of collaboration revenue related to the Kaken upfront payment during the second quarter of 2023 and higher interest income earned on our investments and other income due to refundable tax credits, offset in part by an increase in operating expenses and interest expense from the Abingworth development financing arrangement.

About CymaBay

CymaBay Therapeutics, Inc. is a clinical-stage biopharmaceutical company focused on improving the lives of people with liver and other chronic diseases that have high unmet medical need. Our deep understanding of the underlying mechanisms of liver inflammation and fibrosis, and the unique targets that play a role in their progression, have helped us receive breakthrough therapy designation (U.S. Food and Drug Administration), Priority Medicines status (European Medicines Agency) and orphan drug status (U.S. and Europe) for seladelpar, a first-in-class investigational treatment for people with PBC. A new drug application for seladelpar was submitted to the FDA in December 2023. Our evidence-based decision-making and commitment to the highest quality standards reflect our relentless dedication to the people, families, and communities we serve. To learn more, visit www.cymabay.com and follow us on X (formerly Twitter) and Linkedin.

Additional Information and Where to Find It

This communication is for informational purposes only and is neither an offer to purchase nor a solicitation of an offer to sell securities. On February 23, 2024, Gilead Sciences, Inc. ("Gilead") and Pacific Merger Sub, Inc., a wholly owned subsidiary of Gilead, filed a Tender Offer Statement on Schedule TO with the U.S. Securities and Exchange Commission (the "SEC") in connection with Gilead's pending acquisition of CymaBay Therapeutics, Inc. ("CymaBay"), and, on February 23, 2024, CymaBay filed a Solicitation/Recommendation Statement on Schedule 14D-9 with the SEC with respect to the tender offer. CYMABAY'S STOCKHOLDERS AND OTHER INVESTORS ARE URGED TO READ THE TENDER OFFER MATERIALS (INCLUDING AN OFFER TO PURCHASE, A RELATED LETTER OF TRANSMITTAL AND CERTAIN OTHER TENDER OFFER DOCUMENTS) AND THE SOLICITATION/RECOMMENDATION STATEMENT ON SCHEDULE 14D-9 BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION THAT SHOULD BE READ CAREFULLY BEFORE ANY DECISION IS MADE WITH RESPECT TO THE TENDER OFFER. The Tender Offer Statement on Schedule TO, the Solicitation/Recommendation Statement on Schedule 14D-9 and other related documents are available for free at the SEC's website at www.sec.gov. Investors and securityholders may also obtain, free of charge, the Solicitation/Recommendation Statement on Schedule 14D-9 and other related documents that CymaBay has filed with or furnished to the SEC under the "Investors & Media" section of CymaBay's website at www.cymabay.com

Forward-Looking Statements

This communication contains "forward-looking statements." These statements relate to future events and involve known and unknown risks, uncertainties and other factors which may cause the actual results, performance or achievements of CymaBay to be materially different from any future results, performances or achievements expressed or implied by the forward-looking statements. In some cases, you can identify forward-looking statements by terms such as "may," "will," "could," "expects," "plans," "anticipates," "believes," and similar expressions intended to identify forward-looking statements. These statements reflect CymaBay's current views with respect to future events and are based on assumptions and subject to risks and uncertainties. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Forward-looking statements include, without limitation, statements regarding Gilead's pending acquisition of CymaBay and other related matters, prospective performance and opportunities, the ability of Gilead to advance CymaBay's product pipeline and successfully commercialize seladelpar; the possibility of unfavorable results from clinical trials; regulatory applications and related timelines; and any assumptions underlying any of the foregoing. The following are some of the factors that could cause actual future results to differ materially from those expressed in any forward-looking statements: (i) uncertainties as to the timing of the tender offer and the subsequent merger; (ii) the risk that the tender offer or the subsequent merger may not be completed in a timely manner or at all; (iii) uncertainties as to the percentage of CymaBay's stockholders tendering their shares in the tender offer; (iv) the possibility that competing offers or acquisition proposals for CymaBay will be made; (v) the possibility that any or all of the various conditions to the consummation of the tender offer or the subsequent merger may not be satisfied or waived, including the failure to receive any required regulatory approvals from any applicable governmental entities (or any conditions, limitations or restrictions placed on such approvals); (vi) the occurrence of any event, change or other circumstance that could give rise to the termination of the merger agreement related to the tender offer and the subsequent merger, including in circumstances which would require CymaBay to

pay a termination fee or other expenses; (vii) the effect of the announcement or pendency of the transactions contemplated by such merger agreement on CymaBay's ability to retain and hire key personnel, its ability to maintain relationships with its suppliers and others with whom it does business, or its operating results and business generally; (viii) risks related to diverting management's attention from CymaBay's ongoing business operations; (ix) the risk that stockholder litigation in connection with the transactions contemplated by such merger agreement may result in significant costs of defense, indemnification and liability and (x) other factors as set forth from time to time in CymaBay's filings with the SEC, including its Form 10-K for the fiscal year ended December 31, 2023 and any subsequent Form 10-Qs. Any forward-looking statements set forth in this communication speak only as of the date of this communication. CymaBay does not intend to update any of these forward-looking statements to reflect events or circumstances that occur after the date hereof other than as required by law. You are cautioned not to place undue reliance on any forward-looking statements.

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

	Quarter Ended December 31,		Year Ended December 31,	
	2023	**2022**	**2023**	**2022**
	(unaudited)	**(unaudited)**		
Collaboration revenue	57	-	31,073	-
Operating expenses:				
Research and development	22,749	16,230	80,799	67,995
General and administrative	19,806	7,247	51,953	25,116
Total operating expenses	42,555	23,477	132,752	93,111
Loss from operations	(42,498)	(23,477)	(101,679)	(93,111)
Other income (expense), net:				
Interest income	5,680	921	13,490	2,017
Interest expense	(5,081)	(4,075)	(18,945)	(14,907)
Other income	(3)	(2)	1,764	-
Total other income (expense), net	596	(3,156)	(3,691)	(12,890)
Net loss	(41,902)	(26,633)	(105,370)	(106,001)
Basic and diluted net loss per common share	$ (0.35)	$ (0.30)	$ (0.99)	$ (1.21)
Weighted average common shares outstanding used to calculate basic and diluted net loss per common share	118,754,578	87,806,063	106,204,273	87,804,063

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

	December 31, 2023	**December 31, 2022**
Cash, cash equivalents and marketable securities	$ 416,187	$ 135,485
Working capital	366,959	122,632
Total assets	434,686	141,852
Total liabilities	142,430	105,698
Common stock and additional paid-in capital	1,270,339	909,337
Total stockholders' equity	292,256	36,154

Source: CymaBay Therapeutics, Inc.