UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 8-K

CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934

Date of Report (Date of earliest event reported): August 10, 2023

CymaBay Therapeutics, Inc.
(Exact name of Registrant as specified in its charter)

Delaware	**001-36500**	**94-3103561**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

7575 Gateway Blvd., Suite 110
Newark, CA 94560
(Address of principal executive offices)

(510) 293-8800
(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading symbol(s)**	**Name of each exchange on which registered**
Common stock, $0.0001 par value per share	CBAY	Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01 Other Events.

On September 7, 2023, CymaBay announced topline results from its Phase 3 RESPONSE study. The study evaluated the safety and efficacy of seladelpar for the treatment of PBC. The trial achieved the primary and all key secondary endpoints of the trial. A total of 61.7% of patients on seladelpar 10 mg (n=128) met the primary composite endpoint related to serum alkaline phosphatase and bilirubin at 12 months versus 20.0% on placebo (n=65; p<0.0001). Alkaline phosphatase at 12 months (key secondary endpoint) normalized in 25.0% of patients on seladelpar vs. zero on placebo (p<0.0001). The least-squares mean percent reduction in alkaline phosphatase at 12 months was 42.4% in the seladelpar group vs. 4.3% in the placebo group (p<0.0001). Seladelpar treatment compared to placebo also demonstrated a statistically significant reduction in pruritus, or itch (key secondary endpoint), after 6 months of treatment. Seladelpar-treated patients with a baseline Numerical Rating Scale (NRS) ≥4 (moderate to severe pruritus) had a least-square mean reduction of 3.2 points in pruritus NRS (n=49) compared to 1.7 points for patients in the placebo group (n=23; p<0.005). Overall, the safety profile was comparable between placebo and seladelpar groups and was consistent with previous studies. Treatment-emergent adverse events, serious adverse events, and patient discontinuations were generally balanced across the treatment and placebo arms. There were no treatment-related serious adverse events in the study. Seladelpar's tolerability profile appeared favorable and consistent with previous studies.

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× ULN after at least 12 months of treatment. The primary outcome measure was the responder rate defined as a patient who achieved an ALP level < 1.67× ULN with ≥ 15% decrease in ALP, and total bilirubin (TB) ≤ 1.0× ULN after 52 weeks. Secondary outcome measures were the proportion of patients with ALP ≤ 1.0× ULN at 12 months and the change from baseline at 6 months in the patient-reported level of pruritus as assessed by the NRS in those patients with baseline NRS ≥4. The NRS is a scale of 0 (no itching) to 10 (worst imaginable itching). At baseline, mean ALP levels were 314.3 U/L and TB 0.76 mg/dL and the mean baseline NRS was 6.3 in those patients evaluated for the pre-specified pruritus endpoint.

On August 10, 2023, CymaBay announced the initiation of a 52-week, placebo-controlled, randomized, Phase 3 study — "Intended to Determine the Effects of seladelpar on normalization of Alkaline phosphatase (ALP) Levels in subjects with Primary Biliary Cholangitis (PBC)" (IDEAL). The IDEAL study aims to enroll 75 patients with PBC who have an incomplete response or intolerance to UDCA, in each case with ALP greater than the upper limit of normal (ULN) but less than 1.67xULN, and total bilirubin less than or equal to 2xULN. Patients will be randomly assigned using a 2:1 ratio to oral, once daily seladelpar 10 mg or placebo. The primary outcome measure is the normalization of ALP at 52 weeks. Additional key outcomes evaluating efficacy include the percent change from baseline in ALP at 52 weeks and the level of self-reported pruritus at 6 months for patients with moderate to severe symptoms at baseline, assessed by NRS and recorded by electronic diary.

The current first line therapy for PBC is UDCA, a secondary bile acid. However, up to 60% of PBC patients will have only an incomplete (ALP > 1.67xULN) or partial (ALP 1 to 1.67xULN) response to UDCA treatment or will be intolerant to UDCA. From 3% to 5% of patients are intolerant to UDCA. Currently there is only one FDA-approved second-line treatment, obeticholic acid (Ocaliva) but 53%-54% of patients were inadequate responders in its pivotal registration trial. Current first and second line treatments have proven to be inadequate for a large portion of the patient population. It is estimated that approximately 130,000 people in the U.S. have PBC, with approximately 85,000 diagnosed with the disease, of which approximately 70,000 to 75,000 are currently being treated. In comparison, it is estimated that approximately 100,000 people are diagnosed with PBC in the largest European countries (Germany, United Kingdom, France, Italy and Spain) with approximately 93,000 people being treated. In China and Japan, it is estimated that there are between 300,000 and 415,000 people diagnosed with PBC, with approximately 285,000 to 390,000 people being treated. Within the U.S., of the treated PBC patients, approximately 21,000 are estimated to be partial responders to UDCA and approximately 21,000 are estimated to be incomplete responders to UDCA, of which approximately 9,000 are estimated to have taken second-line treatment.

Forward Looking Statements and Market Data

This Current Report on Form 8-K contains "forward-looking statements," including, but not limited to, statements regarding CymaBay's development plans for its IDEAL trial. These statements relate to future events and involve known and unknown risks, uncertainties and other factors which may cause CymaBay's actual results, performance or achievements 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. Any forward-looking statements set forth in this Current Report on Form 8-K speak only as of the date of this Current Report on Form 8-K. 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. Furthermore, this Current Report on Form 8-K contains market data and industry statistics and forecasts that are based on independent industry publications and other publicly available information along with third party marketing reports and internal analysis. Although CymaBay believes these sources and analysis are reliable, it does not guarantee the accuracy or completeness of this information and has not independently verified this information.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

CymaBay Therapeutics, Inc.

By: /s/ Paul Quinlan
Name: Paul Quinlan
Title: General Counsel

Dated: September 11, 2023