

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549**

**SCHEDULE TO**

**TENDER OFFER STATEMENT UNDER SECTION 14(D)(1) OR 13(E)(1)  
OF THE SECURITIES EXCHANGE ACT OF 1934**

**CYMABAY THERAPEUTICS, INC.**  
(Name of Subject Company (Issuer))

**PACIFIC MERGER SUB, INC.**  
a wholly owned subsidiary of

**GILEAD SCIENCES, INC.**  
(Names of Filing Persons (Offeror))

**Common Stock, Par Value \$0.0001 Per Share**  
(Title of Class of Securities)

**23257D103**  
(Cusip Number of Class of Securities)

**Deborah H. Telman, Esq.**  
**Executive Vice President, Corporate Affairs and General Counsel**  
**Gilead Sciences, Inc.**  
**333 Lakeside Drive**  
**Foster City, CA 94404**  
**650-574-3000**

(Name, Address and Telephone Number of Person Authorized to  
Receive Notices and Communications on Behalf of Filing Persons)

**With copies to:**

**Paul S. Scrivano**  
**Davis Polk & Wardwell LLP**  
**1600 El Camino Real**  
**Menlo Park, CA 94025**  
**(650) 752-2008**

**Cheryl Chan**  
**Davis Polk & Wardwell LLP**  
**450 Lexington Avenue**  
**New York, NY 10017**  
**(212) 450-4503**

**CALCULATION OF FILING FEE**

<b>Transaction Valuation*</b>	<b>Amount of Filing Fee*</b>
N/A	N/A

\* A filing fee is not required in connection with this filing as it relates solely to preliminary communications made before the commencement of the tender offer.

Check box if any part of the fee is offset as provided by Rule 0-11(a)(2) and identify the filing with which the offsetting fee was previously paid. Identify the previous filing by registration statement number, or the Form or Schedule and the date of its filing.

Amount Previously Paid:	Not applicable	Filing Party:	Not applicable
Form or Registration No.:	Not applicable	Date Filed:	Not applicable

Check the box if the filing relates solely to preliminary communications made before the commencement of a tender offer.

Check the appropriate boxes below to designate any transactions to which the statement relates:

third-party tender offer subject to Rule 14d-1.

issuer tender offer subject to Rule 13e-4.

going-private transaction subject to Rule 13e-3.

amendment to Schedule 13D under Rule 13d-2.

Check the following box if the filing is a final amendment reporting the results of the tender offer.

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This filing relates solely to preliminary communications made before the commencement of a tender offer by Pacific Merger Sub, Inc., a Delaware corporation (“Purchaser”) and a wholly owned subsidiary of Gilead Sciences, Inc., a Delaware corporation (“Parent”), to acquire all of the outstanding shares of common stock of CymaBay Therapeutics, Inc., a Delaware corporation (the “Company”), at a price of \$32.50 per share, net to the seller in cash, without interest and subject to any withholding of taxes, pursuant to an Agreement and Plan of Merger, dated February 11, 2024, among the Company, Parent and Purchaser.

## **FORWARD-LOOKING STATEMENTS**

This communication contains forward-looking statements related to Gilead Sciences, Inc. (“Gilead”), CymaBay Therapeutics, Inc. (“CymaBay”) and the acquisition of CymaBay by Gilead that are subject to risks, uncertainties and other factors. All statements other than statements of historical fact are statements that could be deemed forward-looking statements, including all statements regarding the intent, belief or current expectation of Gilead and CymaBay and members of their respective senior management teams. Forward-looking statements include, without limitation, statements regarding the transaction and related matters, prospective performance and opportunities, post-closing operations and the outlook for the companies’ businesses, including, without limitation, 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; filings and approvals relating to the transaction; the expected timing of the completion of the transaction; the ability to complete the transaction considering the various closing conditions; difficulties or unanticipated expenses in connection with integrating the companies; and any assumptions underlying any of the foregoing. Investors are cautioned that any such forward-looking statements are not guarantees of future performance and involve risks and uncertainties and are cautioned not to place undue reliance on these forward-looking statements. Actual results may differ materially from those currently anticipated due to a number of risks and uncertainties. Risks and uncertainties that could cause the actual results to differ from expectations contemplated by forward-looking statements include: uncertainties as to the timing of the tender offer and merger; uncertainties as to how many of CymaBay’s stockholders will tender their stock in the offer; the possibility that competing offers will be made; the possibility that various closing conditions for the transaction may not be satisfied or waived, including that a governmental entity may prohibit, delay or refuse to grant approval for the consummation of the transaction; the effects of the transaction on relationships with employees, other business partners or governmental entities; the difficulty of predicting the timing or outcome of regulatory approvals or actions, if any; the impact of competitive products and pricing; other business effects, including the effects of industry, economic or political conditions outside of the companies’ control; transaction costs; actual or contingent liabilities; adverse impacts on business, operating results or financial condition in the future due to pandemics, epidemics or outbreaks; and other risks and uncertainties detailed from time to time in the companies’ periodic reports filed with the U.S. Securities and Exchange Commission (the “SEC”), including current reports on Form 8-K, quarterly reports on Form 10-Q and annual reports on Form 10-K, as well as the Schedule 14D-9 to be filed by CymaBay and the Schedule TO and related tender offer documents to be filed by Gilead and Pacific Merger Sub, Inc., a wholly owned subsidiary of Gilead. All forward-looking statements are based on information currently available to Gilead and CymaBay, and Gilead and CymaBay assume no obligation and disclaim any intent to update any such forward-looking statements.

## **ADDITIONAL INFORMATION AND WHERE TO FIND IT**

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In addition to the Offer to Purchase, the related Letter of Transmittal and certain other tender offer documents, as well as the Solicitation/Recommendation Statement, Gilead and CymaBay file annual, quarterly and current reports, proxy statements and other information with the SEC. Gilead’s and CymaBay’s filings with the SEC are also available for free to the public from commercial document-retrieval services and at the website maintained by the SEC at [www.sec.gov](http://www.sec.gov).

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## **EXHIBIT INDEX**

<b>Exhibit No.</b>	<b>Description</b>
<a href="#">99.1</a>	<a href="#">Tweet posted by Gilead on February 12, 2024.</a>
<a href="#">99.2</a>	<a href="#">LinkedIn Announcement posted by Gilead on February 12, 2024.</a>
<a href="#">99.3</a>	<a href="#">Investor Relations email sent by Gilead on February 12, 2024.</a>

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**Gilead Tweet (@GileadSciences), February 12, 2024**

#GileadNews: We announced today that we're acquiring @CymaBay Therapeutics, reinforcing our long-standing commitment to liver disease. Read the press release and important information: <http://gilead.inc/48baEtP>

**Forward-Looking Statements**

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**Gilead LinkedIn Post, February 12, 2024**

#GileadNews: We announced today that we're acquiring CymaBay Therapeutics, reinforcing our long-standing commitment to liver disease. We'll continue advancing a potential therapy for primary biliary cholangitis, a rare and chronic liver disease that impairs liver function and quality of life. Read the press release and important information: <https://gilead.inc/48baEtP>

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Good Morning –

Gilead just announced (full text at end of email) a definitive agreement to acquire CymaBay Therapeutics for \$4.3B (\$32.50/share), which, upon closing, will further expand our Liver Disease portfolio to include an investigational, oral PPAR $\delta$  agonist (seladelpar) for the treatment of primary biliary cholangitis (PBC). PBC is a progressive, inflammatory, autoimmune disease that can lead to the need for liver transplant or death.

The transaction has been approved by both Gilead and CymaBay's Boards of Directors, and is expected to close in Q124, subject to regulatory approvals and other customary closing conditions.

- Seladelpar has demonstrated statistically significant improvement in markers of cholestasis related to risk of progression and PBC-related pruritus in the Phase 3 ENHANCE and RESPONSE studies.
  - CymaBay filed a new drug application (NDA) with FDA in December 2023. The NDA filing was accepted with priority review, with a PDUFA target action date of August 14, 2024.
  - EMA and MHRA filings are expected in 1H24.
  - Seladelpar received Breakthrough Therapy Designation in the U.S. (Oct '23) and Orphan Drug Designation in both the U.S. (Nov '16) and Europe (Sept '17).
- If approved, seladelpar has the potential to become a preferred 2nd-line agent in PBC.
  - Seladelpar is the only potential treatment to demonstrate statistically significant reduction in pruritus (severe itching) in this patient population as measured by the pruritus numerical rating scale (NRS).
  - PBC is a rare, chronic, cholestatic liver disease mainly affecting women (1 in 1,000 women over the age of 40, or about 130,000 total people in the U.S.) that impairs liver function and quality of life. Progression of PBC is associated with an increased risk of liver-related mortality.
- The current standard of care for second-line treatment is obeticholic acid which is used on top of generic ursodeoxycholic acid ("UDCA") for inadequate responders or as a monotherapy for those intolerant to UDCA. Based on the obeticholic acid U.S. Prescribing Information:
  - Only ~50% of patients have an adequate response to obeticholic acid.
  - Additionally, obeticholic acid can cause or worsen PBC-related pruritus.
- Gilead will leverage its existing ~180-person strong Liver commercial infrastructure to support the anticipated launch later this year.
- The acquisition is expected to close in Q124 and is subject to regulatory approvals and other customary closing conditions. Upon FDA approval of seladelpar, the transaction is expected to enhance Gilead's revenue growth, and it is also expected that the transaction will be approximately neutral to earnings per share in 2025 and significantly accretive thereafter. We will update our 2024 guidance following close.

**Q. What were the Phase 3 trial results that supported seladelpar's NDA filing for PBC in December 2023? How might seladelpar be differentiated?**

- Seladelpar achieved its primary endpoint of biochemical response in 2 Phase 3 trials, demonstrated reduction in ALP levels, a key marker of disease progression, and key secondary endpoint of improved pruritus, a debilitating symptom of the disease.
  - We are confident seladelpar will be differentiated from other potential competitors, including elafibranor (currently under review by FDA), by its rate of ALP normalization, and statistically significant improvement in pruritus at 6 months that is sustained through 12 months measured by the daily numerical rating scale (NRS; 0-10). Currently, there are no effective anti-pruritic options for PBC. In the Phase 3 RESPONSE study, safety and tolerability profiles were comparable between treatment and placebo arms.

**Summary Table of Key Results from Phase 3 Trials:**

	RESPONSE (N=193)	ENHANCE (N=265)
Patient Population	Inadequate response to or intolerance to UDCA	Inadequate response to or intolerance to UDCA
Composite ALP & Bilirubin Response (%)	<i>Month 12</i> 10mg: 61.7% vs. Placebo: 20% p<0.0001	<i>Month 3</i> 10mg: 78.2% vs. Placebo: 12.5% p<0.0001
ALP Normalization (%)	<i>Month 12</i> 10mg: 25% vs PBO: 0% p<0.0001	<i>Month 3</i> 10mg: 27.3% vs. PBO: 0% P<0.0001
D Pruritus (NRS)	<i>Month 6</i> 10mg: -3.2 vs Placebo: -1.7 p<0.005	<i>Month 3</i> 10mg: -3.14 vs. Placebo: -1.55 p=0.02

**Q. What is the size of the commercial opportunity for seladelpar?**

- An estimated 130K patients are impacted by PBC in the U.S.
- An estimated 125K patients are impacted by PBC in Europe.
- Kaken has rights to exclusively develop and commercialize seladelpar in Japan.

**Q. Will you need to expand your sales organization or investment to support seladelpar?**

- This deal leverages our existing commercial infrastructure in Liver diseases, where Gilead has ~180 liver sales representatives that we estimate already cover ~80% of the estimated U.S. prescribers for PBC. We will adjust our sales organization accordingly to maximize this opportunity.

**Q. When do you expect seladelpar LOE?**

- Seladelpar's composition of matter patents expire in August 2025 (U.S.) and September 2024 (Europe), respectively. Additionally, method of use patents for seladelpar extend to 2035-2038. Our current expectation is that after approval, orphan drug exclusivity will extend 7 years and 10 years in the U.S. and Europe respectively.

**Q. How does this fit into your Liver portfolio?**

- Gilead is a recognized leader in viral hepatitis products, but it does not have any treatments for PBC. We estimate our current sales team covers ~80% of PBC treating physicians in the U.S.

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**Q. How many employees does CymaBay have and are they all joining the Gilead team?**

- CymaBay is based out of Newark, CA and has ~100 employees. We are actively working with CymaBay to evaluate the best operating model moving forward that leverages our combined infrastructure and expertise.

**Q. How is Gilead financing this transaction?**

- Gilead is financing this acquisition using cash on hand.

**Q. How will this transaction be accounted for in the P&L?**

- The acquisition will be accounted for as an asset acquisition and, as such, substantially all of the purchase price is expected to be expensed as acquired in-process research and development expenses on our Consolidated Statements of Income upon closing.

Please let me know if you have any questions.

Jacquie

**Jacquie Ross, CFA**

*VP, Investor Relations & Corporate Strategic Finance*

408.656.8793 Mobile

[jacquie.ross4@gilead.com](mailto:jacquie.ross4@gilead.com)



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## GILEAD SCIENCES EXPANDS LIVER PORTFOLIO WITH ACQUISITION OF CYMABAY THERAPEUTICS

-- *Gilead Adds Seladelpar to Portfolio, a PPAR $\delta$  Agonist for the Treatment of Primary Biliary Cholangitis (PBC) with FDA Priority Review and Anticipated U.S. Approval in Third Quarter of 2024 --*  
-- *Seladelpar Phase 3 Data Demonstrates a Best-in-Disease Profile for Second-Line PBC --*  
-- *Acquisition Expands Gilead's Long-Standing Commitment to Patients with Liver Diseases --*

**FOSTER CITY, Calif. & NEWARK, Calif.** – February 12, 2024 – Gilead Sciences, Inc. (Nasdaq: GILD) and CymaBay Therapeutics, Inc. (Nasdaq: CBAY) announced today a definitive agreement under which Gilead will acquire CymaBay for \$32.50 per share in cash or a total equity value of \$4.3 billion. The addition of CymaBay's investigational lead product candidate, seladelpar for the treatment of primary biliary cholangitis (PBC) including pruritus, complements Gilead's existing liver portfolio and aligns with its long-standing commitment to bringing transformational medicines to patients.

"We are looking forward to advancing seladelpar by leveraging Gilead's long-standing expertise in treating and curing liver diseases," said Daniel O'Day, Chairman and Chief Executive Officer, Gilead Sciences. "Building on the strong research and development work by the CymaBay team to date, we have the potential to address a significant unmet need for people living with PBC and expand on our existing broad range of transformational therapies."

PBC is a rare, chronic, cholestatic liver disease mainly affecting women (1 in 1,000 women over the age of 40 or about 130,000 total people in the U.S.) that impairs liver function and quality of life. The most common early symptoms of PBC are pruritus (itching) and fatigue, which can be debilitating for some patients. Progression of PBC is associated with an increased risk of liver-related mortality.

Seladelpar is an investigational, oral, selective peroxisome proliferator-activated receptor delta (PPAR $\delta$ ) agonist, shown to regulate critical metabolic and liver disease pathways. The United States Food and Drug Administration (FDA) has completed its filing review and accepted a New Drug Application for seladelpar and granted priority review with a Prescription Drug User Fee Act target action date of August 14, 2024.

Seladelpar received FDA Breakthrough Therapy Designation for use in the treatment of PBC including pruritus in patients without cirrhosis or with compensated cirrhosis and PRIME status (EMA), as well as Orphan Drug Designation in the U.S. and Europe for the treatment of patients with PBC.

In the pivotal Phase 3 RESPONSE trial, seladelpar achieved statistical significance over placebo across primary composite endpoints of biochemical response (61.7% for patients on seladelpar vs 20.0% for placebo), normalization of alkaline phosphatase at 12 months (25.0% for patients on seladelpar vs 0.0% for placebo) and statistically significant improvement in pruritus at six months among people living with moderate-to-severe itch that was sustained through 12 months.

"Today's agreement with Gilead is the culmination of years of focus and determination at CymaBay to advance seladelpar and bring new hope to people living with PBC and their families," said Sujal Shah, President, and CEO at CymaBay Therapeutics. "Now that seladelpar has achieved priority review with the FDA, we are excited that Gilead, with its long-standing commitment to patients with liver disease, can apply its regulatory and commercial expertise to bring seladelpar as quickly as possible to people with PBC."

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### Terms of the Transaction

The transaction was approved by both the Gilead and CymaBay Boards of Directors and is anticipated to close during the first quarter of 2024, subject to regulatory approvals and other customary closing conditions.

Under the terms of the merger agreement entered into in connection with the transaction, a wholly-owned subsidiary of Gilead will promptly commence a tender offer to acquire all of the outstanding shares of CymaBay's common stock at a price of \$32.50 per share in cash, which offer price represents a 27 percent premium to CymaBay's closing share price on February 9, 2024. Following successful completion of the tender offer, Gilead will acquire all remaining shares not tendered in the offer through a second step merger at the same price as in the tender offer. Upon FDA approval of seladelpar, the proposed transaction is expected to enhance Gilead's revenue growth, and it is also expected that the transaction will be approximately neutral to earnings per share in 2025 and significantly accretive thereafter.

Consummation of the tender offer is subject to a minimum tender of at least a majority of then-outstanding CymaBay shares, the expiration or termination of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act and other customary conditions.

BofA Securities, Inc. and Guggenheim Securities, LLC are acting as financial advisors to Gilead. Centerview Partners LLC and Lazard are acting as financial advisors to CymaBay.

### About Seladelpar

Seladelpar, an investigational treatment for people with PBC, is an oral, selective peroxisome proliferator-activated receptor delta (PPAR $\delta$ ) agonist shown to regulate critical metabolic and liver disease pathways in indications with high unmet medical need. Preclinical and clinical data support its ability to regulate genes involved in bile acid synthesis, inflammation, fibrosis and lipid metabolism, storage, and transport.

### About CymaBay Therapeutics

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 (FDA), PRIME status (EMA), 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](http://www.cymabay.com) and follow us on X (formerly Twitter) and LinkedIn.

#### **About Gilead Sciences**

Gilead Sciences, Inc. is a biopharmaceutical company that has pursued and achieved breakthroughs in medicine for more than three decades, with the goal of creating a healthier world for all people. The company is committed to advancing innovative medicines to prevent and treat life-threatening diseases, including HIV, viral hepatitis, COVID-19, and cancer. Gilead operates in more than 35 countries worldwide, with headquarters in Foster City, Calif.

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#### **Forward-Looking Statements**

This communication contains forward-looking statements related to Gilead, CymaBay and the acquisition of CymaBay by Gilead that are subject to risks, uncertainties and other factors. All statements other than statements of historical fact are statements that could be deemed forward-looking statements, including all statements regarding the intent, belief or current expectation of Gilead and CymaBay and members of their respective senior management teams. Forward-looking statements include, without limitation, statements regarding the transaction and related matters, prospective performance and opportunities, post-closing operations and the outlook for the companies' businesses, including, without limitation, 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; filings and approvals relating to the transaction; the expected timing of the completion of the transaction; the ability to complete the transaction considering the various closing conditions; difficulties or unanticipated expenses in connection with integrating the companies; and any assumptions underlying any of the foregoing. Investors are cautioned that any such forward-looking statements are not guarantees of future performance and involve risks and uncertainties and are cautioned not to place undue reliance on these forward-looking statements. Actual results may differ materially from those currently anticipated due to a number of risks and uncertainties. Risks and uncertainties that could cause the actual results to differ from expectations contemplated by forward-looking statements include: uncertainties as to the timing of the tender offer and merger; uncertainties as to how many of CymaBay's stockholders will tender their stock in the offer; the possibility that competing offers will be made; the possibility that various closing conditions for the transaction may not be satisfied or waived, including that a governmental entity may prohibit, delay or refuse to grant approval for the consummation of the transaction; the effects of the transaction on relationships with employees, other business partners or governmental entities; the difficulty of predicting the timing or outcome of regulatory approvals or actions, if any; the impact of competitive products and pricing; other business effects, including the effects of industry, economic or political conditions outside of the companies' control; transaction costs; actual or contingent liabilities; adverse impacts on business, operating results or financial condition in the future due to pandemics, epidemics or outbreaks; and other risks and uncertainties detailed from time to time in the companies' periodic reports filed with the U.S. Securities and Exchange Commission (the "SEC"), including current reports on Form 8-K, quarterly reports on Form 10-Q and annual reports on Form 10-K, as well as the Schedule 14D-9 to be filed by CymaBay and the Schedule TO and related tender offer documents to be filed by Gilead and Pacific Merger Sub, Inc., a wholly owned subsidiary of Gilead. All forward-looking statements are based on information currently available to Gilead and CymaBay, and Gilead and CymaBay assume no obligation and disclaim any intent to update any such forward-looking statements.

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*Gilead and the Gilead logo are trademarks of Gilead Sciences, Inc., or its related companies. The CymaBay name and logo are trademarks of CymaBay.*

*For more information about Gilead, please visit the company's website at [www.gilead.com](http://www.gilead.com), follow Gilead on X/Twitter (@Gilead Sciences) and LinkedIn (@Gilead-Sciences).*

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