UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 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 9, 2022

Prelude Therapeutics Incorporated

(Exact Name of Registrant as Specified in its Charter)

Delaware	**001-39527**	**81-1384762**
(State or other jurisdiction of incorporation or organization)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

200 Powder Mill Road **Wilmington, Delaware**	
(Address of principal executive offices)	**19803** **(Zip Code)**

Registrant's telephone number, including area code: (302) 467-1280

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

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:

☐ 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	PRLD	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 2.02 Results of Operations and Financial Condition.

On August 9, 2022, Prelude Therapeutics Incorporated issued a press release announcing its financial results for the three months ended June 30, 2022. A copy of the press release is attached as Exhibit 99.1 to this report.

The information in this Item 2.02, including Exhibit 99.1 to this report, shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended (the "Securities Act"). The information contained in this Item 2.02 and in the accompanying Exhibit 99.1 shall not be incorporated by reference into any other filing under the Exchange Act or under the Securities Act, except as shall be expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press release issued by Prelude Therapeutics Incorporated regarding its financial results for the three months ended June 30, 2022, dated August 9, 2022.
104	Cover Page Interactive Data File (embedded within the Inline XBRL Document)

SIGNATURE

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.

PRELUDE THERAPEUTICS INCORPORATED

Date: August 9, 2022

By: /s/ Laurent Chardonnet
Laurent Chardonnet
Chief Financial Officer

Exhibit 99.1

Prelude Therapeutics Announces Second Quarter 2022 Financial Results and Business Update

Prelude Announces Acceptance of IND For a Differentiated and Brain Penetrant CDK4/6 inhibitor PRT3645 by the US Food and Drug Administration (FDA)

Clinical data readouts and next steps for the PRMT5 program, MCL1 inhibitor PRT1419, and CDK9 inhibitor PRT2527 are on track for the second half of 2022

Strong cash and cash equivalents and marketable securities of $246.3 million as of June 30, 2022, expected to fund operations into the second half of 2024

WILMINGTON, Del. –August 9, 2022 – Prelude Therapeutics Incorporated (Prelude) (Nasdaq: PRLD), a clinical-stage precision oncology company, today reported financial results for the second quarter ended June 30, 2022 and provided an update on recent clinical and development pipeline progress.

"We continue to execute on building a deep portfolio of highly differentiated small molecules by delivering an IND submission every 12-18 months. Today, Prelude is pleased to announce the acceptance of our latest IND for PRT3645, a differentiated and highly brain penetrant CDK4/6 inhibitor. We believe PRT3645 has the potential to extend the reach of CDK4/6 inhibition beyond HR+ breast cancers, for which the first generation CDK4/6 inhibitors were approved," said Kris Vaddi, Ph.D., Chief Executive Officer of Prelude. "Our current cash runway is expected to fund our operations into the second half of 2024 enabling us to reach significant pipeline milestones."

Jane Huang, M.D., President and Chief Medical Officer of Prelude, shared "Having multiple programs in clinical development is a clear testament to the strength of Prelude's drug discovery engine and the research team. It's now the clinical organization's responsibility to take these highly potent and selective molecules from our research colleagues and execute efficient clinical trials. By adding a differentiated CDK4/6 inhibitor to our growing clinical portfolio, we strengthen our likelihood of achieving effective treatments for multiple cancers and underserved patient populations."

Recent Highlights and Upcoming Objectives

- **Brain Penetrant CDK4/6:** Phase 1 clinical trial, to begin in Q4, will include select cancer types including sarcomas, P16 mutated mesothelioma, gliomas, HPV negative head and neck cancers and CDK pathway-altered non-small cell lung cancer, in addition to HR+/HER2+ and HR+/HER2- breast cancer with or without brain metastases.

- **PRMT5 Inhibitor Program:** As previously announced, Prelude has prioritized PRT811 for clinical development in select expansion cohorts. Prelude will complete data analyses of the ongoing expansion cohorts and expects to announce next steps for the PRMT5 program in the second half of 2022.

- **MCL1 Inhibitor Program:** Prelude remains on track to begin evaluating combinations with PRT1419 and report early findings by the end of 2022. MCL1 inhibition has potential in hematologic indications such as acute myeloid leukemia, mantle cell lymphoma and chronic lymphocytic leukemia.

- **CDK9 Inhibitor Program**: Prelude remains on track to complete dose escalation and identify a recommended Phase 2 dose for PRT2527 in the upcoming months. CDK9 inhibition has shown strong preclinical activity in both prostate and MYC-amplified solid tumors and hematological malignancies.

- **SMARCA2/BRM Protein Degrader Program**: Prelude remains on track to complete IND-enabling studies and submit an IND application by year-end 2022. SMARCA2 inhibition has the greatest potential in patients with SMARCA4 deficient cancers, including up to 10% of all non-small cell lung cancers.

Second Quarter 2022 Financial Results

Cash, Cash Equivalents and Marketable Securities: Cash, cash equivalents, and marketable securities as of June 30, 2022, were $246.3 million. Prelude anticipates that its existing cash, cash equivalents and marketable securities will fund Prelude's operations into the second half of 2024.

Research and Development (R&D) Expenses: For the second quarter of 2022, R&D expense decreased by $1.1 million to $21.3 million for the three months ended June 30, 2022 from $22.4 million for the three months ended June 30, 2021. Included in research and development expenses for the quarter ending June 30, 2022, was $2.5 million of non-cash expense related to stock-based compensation expense, including employee stock options, compared to $2.2 million for the three months ended June 30, 2021. The decrease in research and development expense was primarily due to the wind down of PRT543 clinical development in the PRMT5 programs as we are concentrating further development efforts on our PRT811 candidate in biomarker-selected patients in specific cancer types. We expect our research and development expenses to vary from quarter to quarter, primarily due to the timing of our clinical development activities.

General and Administrative (G&A) Expenses: For the second quarter of 2022, G&A expenses increased to $8.2 million for the three months ended June 30, 2022, from $5.5 million for the three months ended June 30, 2021. Included in the general and administrative expenses for the quarter ended June 30, 2022, was $3.6 million of non-cash expense related to stock-based compensation expense, including employee stock options, as compared to $2.0 million for the same period in 2021. The increase in general and administrative expense was primarily due to an increase in non-cash stock-based compensation expense, and an increase in professional fees as we expanded our operations to support our research and development efforts.

Net Loss: For the three months ended June 30, 2022, net loss was $27.4 million, or $0.58 per share of common stock, basic and diluted compared to $26.9 million, or $0.58 per share, respectively, for the prior year period. Included in the net loss for the quarter ended June 30, 2022, was $6.0 million of non-cash expense related to the impact of expensing share-based payments, including employee stock options, as compared to $4.2 million for the prior year period.

About Prelude

Prelude is a clinical-stage precision oncology company developing innovative drug candidates targeting critical cancer cell pathways. Prelude's diverse pipeline is comprised of highly differentiated, potentially best-in-class proprietary small molecule compounds aimed at addressing clinically validated pathways for cancers with selectable underserved patients. Prelude's pipeline includes four candidates currently in clinical development: PRT811, a highly selective, potent, orally bioavailable PRMT5 inhibitor; PRT1419, a potent, selective inhibitor of MCL1; PRT2527, a potent and highly selective CDK9 inhibitor, and

PRT3645, a brain penetrant CDK4/6 inhibitor. Additionally, Prelude is progressing a potential first-in-class SMARCA2/BRM protein degrader, with an IND expected in the second half of 2022.

For more information, visit our website and follow us on LinkedIn and Twitter.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995, including, but not limited to, anticipated discovery, preclinical and clinical development activities, timing of availability and announcements of clinical results for PRT543, PRT811, PRT1419 and PRT3645, the timing of reporting expected findings related to PRT1419, the timing of the escalation portion for its Phase 1 clinical trial for PRT2527, the timing of IND-related activities for PRT3645 and the SMARCA2/BRM protein degrader, the potential benefits of Prelude's product candidates and platform, and the sufficiency of cash and cash equivalents to fund operating expenses and capital expenditures into the second half of 2024. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. Although Prelude believes that the expectations reflected in such forward-looking statements are reasonable, Prelude cannot guarantee future events, results, actions, levels of activity, performance or achievements, and the timing and results of biotechnology development and potential regulatory approval is inherently uncertain. Forward-looking statements are subject to risks and uncertainties that may cause Prelude's actual activities or results to differ significantly from those expressed in any forward-looking statement, including risks and uncertainties related to Prelude's ability to advance its product candidates, the receipt and timing of potential regulatory designations, approvals and commercialization of product candidates, the impact of the COVID-19 pandemic on Prelude's business, clinical trial sites, supply chain and manufacturing facilities, Prelude's ability to maintain and recognize the benefits of certain designations received by product candidates, the timing and results of preclinical and clinical trials, Prelude's ability to fund development activities and achieve development goals, Prelude's ability to protect intellectual property, and other risks and uncertainties described under the heading "Risk Factors" in documents Prelude files from time to time with the Securities and Exchange Commission. These forward-looking statements speak only as of the date of this press release, and Prelude undertakes no obligation to revise or update any forward-looking statements to reflect events or circumstances after the date hereof.

PRELUDE THERAPEUTICS INCORPORATED

STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(UNAUDITED)

(in thousands, except share and per share data)	Three Months Ended June 30, 2022	2021
Operating expenses:		
Research and development	$ 21,310	$ 22,409
General and administrative	8,151	5,513
Total operating expenses	29,461	27,922
Loss from operations	(29,461)	(27,922)
Other income, net	2,087	1,057
Net loss	$ (27,374)	$ (26,865)
Per share information:		
Net loss per share of common stock, basic and diluted	$ (0.58)	$ (0.58)
Weighted average common shares outstanding, basic and diluted	47,276,684	46,057,112
Comprehensive loss		
Net loss	$ (27,374)	$ (26,865)
Unrealized gain (loss) on marketable securities, net of tax	19	—
Comprehensive loss	$ (27,355)	$ (26,865)

PRELUDE THERAPEUTICS INCORPORATED

BALANCE SHEETS
(UNAUDITED)

(in thousands, except share data)	June 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 50,706	$ 31,828
Marketable securities	195,599	259,405
Prepaid expenses and other current assets	2,319	3,882
Total current assets	248,624	295,115
Restricted cash	4,044	4,044
Property and equipment, net	4,285	3,929
Right-of-use asset	1,793	1,707
Other assets	309	303
Total assets	$ 259,055	$ 305,098
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 6,273	$ 7,840
Accrued expenses and other current liabilities	7,716	9,621
Operating lease liability	1,822	1,740
Total current liabilities	15,811	19,201
Other liabilities	2,400	—
Total liabilities	18,211	19,201
Commitments		
Stockholders' equity:		
Voting common stock, $0.0001 par value: 487,149,741 shares authorized; 36,369,248 and 36,200,299 shares issued and outstanding at June 30, 2022 and December 31, 2021, respectively	4	4
Non-voting common stock, $0.0001 par value; 12,850,259 shares authorized; 11,402,037 and 11,402,037 shares issued and outstanding at June 30, 2022 and December 31, 2021, respectively	1	1
Additional paid-in capital	519,092	505,723
Accumulated other comprehensive income (loss)	(2,294)	(711)
Accumulated deficit	(275,959)	(219,120)
Total stockholders' equity	240,844	285,897
Total liabilities and stockholders' equity	$ 259,055	$ 305,098

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