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): May 10, 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 May 10, 2022, Prelude Therapeutics Incorporated issued a press release announcing its financial results for the three months ended March 31, 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 March 31, 2022, dated May 10, 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: May 10, 2022

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

Exhibit 99.1

Prelude Therapeutics Announces First Quarter 2022 Financial Results and Operations Update

Prelude remains on track for clinical data readouts and next steps for the PRMT5 program, MCL1 inhibitor PRT1419, and CDK9 inhibitor PRT2527 in 2H2022

Strong cash and cash equivalents of $266.2 million as of March 31, 2022, expected to fund operations into 2H2024

Wilmington, DE – May 10, 2022 – Prelude Therapeutics Incorporated ("Prelude") (Nasdaq: PRLD), a clinical-stage precision oncology company, today reported financial results for the first quarter ended March 31, 2022, and provided an update on recent clinical and development pipeline progress.

"Prelude continues to make great progress in discovering and advancing a diverse pipeline of differentiated small molecules, and with our current cash runway, we have the opportunity to deliver on numerous meaningful milestones. I'm delighted to have Jane onboard and am confident in her leadership to guide focused clinical development of our pipeline and organizational growth," said Kris Vaddi, Ph.D., Chief Executive Officer.

"I'm excited to be a part of Prelude's continued progress" said Jane Huang, M.D., President and Chief Medical Officer. "Looking ahead, we remain on track with ongoing development of our PRMT5 program, that will drive strategic decisions in the second half of the year. In parallel, we are focused on rapidly progressing our MCL1 candidate, PRT1419 into expansion and combination cohorts and identifying a Phase 2 dose for PRT2527, our CDK9 inhibitor. We are also on track for Investigational New Drug (IND) submissions for both our SMARCA2 degrader, and PRT3645, our brain penetrant CDK4/6 inhibitor, in the second half of the year. It's clear that Prelude's discovery engine, depth and breadth of the pipeline, coupled with an experienced management team, will position us to deliver potential medicines for patients with underserved cancers."

Recent Highlights and Upcoming Objectives

- **2022 AACR Annual Meeting:** During the quarter, Prelude participated in the 2022 American Association for Cancer Research (AACR) Annual Meeting. Four posters and one oral presentation, providing data on Prelude's clinical and preclinical pipeline molecules, with highly potent, selective and differentiated properties, were presented as part of the scientific conference.

- **PRMT5 Inhibitor Program:** As previously announced, Prelude has prioritized PRT811 for clinical development in select expansion cohorts. Prelude intends to complete the data analyses of the ongoing expansion cohorts and expects to announce next steps for the PRMT5 program in 2H2022.

- **MCL1 Inhibitor Program:** As previously announced, Prelude has prioritized development of the intravenous formulation of PRT1419, which demonstrated a desirable pharmacokinetic, pharmacodynamic and safety profile, with potential for differentiation from competitor compounds. Prelude remains on track to begin evaluating combinations with PRT1419 by mid-year.

- **CDK9 Inhibitor Program**: Prelude remains on track to complete enrollment in the Phase 1 dose escalation study of PRT2527 and identify a recommended Phase 2 dose by 2H2022.

- **CDK4/6 Inhibitor Program**: Prelude continues to expect to file an IND application mid-year, with the initiation of a Phase 1 trial of PRT3645 to follow in 2H2022.

- **SMARCA2/BRM Protein Degrader Program**: Prelude remains on track to complete IND-enabling studies and submit an IND application by year-end 2022.

Corporate Update

- In March 2022, Prelude announced the appointment of Jane Huang, M.D., effective April 4, 2022, to the newly created position of President and Chief Medical Officer. Dr. Huang joins Prelude from BeiGene Ltd., where she served as Chief Medical Officer, Hematology. Currently, Dr. Huang serves as an Adjunct Clinical Assistant Professor in Thoracic Oncology at Stanford University.

First Quarter 2022 Financial Results

Cash, Cash Equivalents and Marketable Securities: Cash, cash equivalents, and marketable securities as of March 31, 2022, were $266.2 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 first quarter of 2022, R&D expense increased to $22.8 million from $16.5 million for the prior year period. Included in research and development expenses for the quarter ended March 31, 2022, was $3.2 million of non-cash expense related to stock-based compensation expense, including employee stock options, as compared to $1.8 million for the prior year period. The increase in research and development expense was primarily due to an increase in discovery-stage program expenses and from the growth and advancement of our clinical pipeline. 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 first quarter of 2022, G&A expense increased to $7.5 million from $5.5 million for the prior year period. Included in the G&A expenses for the quarter ended March 31, 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 prior year period. The increase in G&A expense was primarily due to an increase in our non-cash stock compensation expense along with professional fees as we expanded our operations to support our research and development efforts.

Net Loss: For the three months ended March 31, 2022, net loss was $29.5 million, or $0.63 per share of common stock, basic and diluted compared to $21.3 million, or $0.47 per share, respectively, for the prior year period. Included in the net loss for the quarter ended March 31, 2022, was $6.8 million of non-cash expense related to the impact of expensing share-based payments, including employee stock options, as compared to $3.9 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 and PRT543, highly selective, potent, orally bioavailable PRMT5 inhibitors; PRT1419, a potent, selective inhibitor of MCL1; and PRT2527, a potent and highly selective CDK9 inhibitor. Additionally, Prelude is progressing two novel preclinical candidates, PRT3645, a brain penetrant CDK4/6 inhibitor; and a potential first-in-class SMARCA2/BRM protein degrader.

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, the timing of the expansion portion for its Phase 1 clinical trial for PRT543, PRT811 and 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 March 31, 2022	2021
Operating expenses:		
Research and development	$ 22,821	$ 16,470
General and administrative	7,467	5,497
Total operating expenses	30,288	21,967
Loss from operations	(30,288)	(21,967)
Other income, net	823	667
Net loss	$ (29,465)	$ (21,300)
Per share information:		
Net loss per share of common stock, basic and diluted	$ (0.63)	$ (0.47)
Weighted average common shares outstanding, basic and diluted	47,066,427	45,121,955
Comprehensive loss		
Net loss	$ (29,465)	$ (21,300)
Unrealized gain (loss) on marketable securities, net of tax	(1,602)	—
Comprehensive loss	$ (31,067)	$ (21,300)

PRELUDE THERAPEUTICS INCORPORATED

BALANCE SHEETS
(UNAUDITED)

(in thousands, except share data)	March 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 51,634	$ 31,828
Marketable securities	214,555	259,405
Prepaid expenses and other current assets	3,783	3,882
Total current assets	269,972	295,115
Restricted cash	4,044	4,044
Property and equipment, net	4,122	3,929
Right-of-use asset	2,224	1,707
Other assets	309	303
Total assets	$ 280,671	$ 305,098
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 7,390	$ 7,840
Accrued expenses and other current liabilities	6,820	9,621
Operating lease liability	1,859	1,740
Total current liabilities	16,069	19,201
Other liabilities	2,400	—
Operating lease liability	390	—
Total liabilities	18,859	19,201
Commitments (Note 8)		
Stockholders' equity:		
Voting common stock, $0.0001 par value: 487,149,741 shares authorized; 36,293,331 and 36,200,299 shares issued and outstanding at March 31, 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 March 31, 2022 and December 31, 2021, respectively	1	1
Additional paid-in capital	512,705	505,723
Accumulated other comprehensive income (loss)	(2,313)	(711)
Accumulated deficit	(248,585)	(219,120)
Total stockholders' equity	261,812	285,897
Total liabilities and stockholders' equity	$ 280,671	$ 305,098

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