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 12, 2021

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**	**19803**
(Address of principal executive offices)	**(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 12, 2021, Prelude Therapeutics Incorporated issued a press release announcing its financial results for the three months ended June 30, 2021. 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, 2021, dated August 12, 2021.

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 12, 2021

By: /s/ Brian Piper
Brian Piper
Chief Financial Officer

Exhibit 99.1

Prelude Therapeutics Announces Second Quarter 2021 Financial Results and Operations Update

- Data from Dose Escalation Portion of Phase 1 Trials of Lead Oral PRMT5 Inhibitors PRT543 and PRT811 to be Presented in 4Q21 –

- Enrollment Ongoing in Multiple Expansion Cohorts in Phase 1 Trial of PRT543; Dose Expansion Portion of Phase 1 Trial of PRT811 Expected to Commence in 3Q21 –

- Dose Escalation Portion of Phase 1 Trials of Oral and IV Formulations of MCL1 Inhibitor PRT1419 Ongoing –

-Strong Cash Position of $343 Million to Support Clinical and Discovery Pipeline Advancement –

Wilmington, DE – Aug 12, 2021 – Prelude Therapeutics Inc. (Nasdaq: PRLD), a clinical-stage precision oncology company, today announced its financial results for the second quarter ended June 30, 2021 and provided an update on recent clinical and development pipeline progress.

“Prelude’s second quarter was marked by solid operational execution, continued innovation, and organizational growth. We made meaningful progress advancing our pipeline of novel, internally discovered precision oncology therapeutics aimed at addressing several cancers with high unmet need,” said Kris Vaddi, PhD, Chief Executive Officer. “Our ongoing clinical programs, including the Phase 1 trials of PRT543 and PRT811, for which we expect to present clinical data in the fourth quarter, and PRT1419 are advancing as planned. In addition, we continue to maintain focus on the advancement of our preclinical and discovery programs, with an IND application submission for PRT2527, our CDK9 inhibitor, and initiation of IND-enabling studies for our discovery programs expected by year end.”

Recent Highlights and Upcoming Milestones

PRT543

- **Dose Expansion Portion of Phase 1 Trial Ongoing; Data from Dose Escalation Portion to be Presented at the AACR-NCI-EORTC Annual Meeting:** The Company will present data from the dose escalation portion of the Phase 1 trial in unselected patient populations, including safety, PK and PD data and markers of target engagement, at the AACR-NCI-EORTC Annual Meeting in October. PRT543 is designed to be a potent and selective inhibitor of PRMT5. Patient enrollment is continuing in specific biomarker-selected solid tumor and hematologic malignancy expansion cohorts representing cancers of high unmet need, including adenoid cystic carcinoma (ACC), spliceosome mutated and HRD+ solid tumors and spliceosome-mutated myeloid malignancies. The Company expects to present data from the expansion cohorts at medical meetings throughout 2022.

PRT811

- **Dose Expansion Portion of Phase 1 Trial Expected to Commence in 3Q21; Data from Dose Escalation Portion to be Presented at the AACR-NCI-EORTC Annual Meeting:** The Company will present data from the dose escalation portion of the Phase 1 trial in unselected patient populations, including safety, PK and PD data and markers of target engagement, at the AACR-

NCI-EORTC Annual Meeting in October. PRT811 is designed to be a potent, selective, and brain penetrant PRMT5 inhibitor. Prelude anticipates beginning the dose expansion portion of the Phase 1 trial in the third quarter in selected patients with central nervous system cancers, including high grade gliomas and CNS metastatic cancers. The Company expects to present data from the expansion cohorts at medical meetings throughout 2022.

PRT1419

- **Oral Formulation: Dose Escalation Portion of Phase 1 Trial Ongoing**. The dose escalation portion of the Company's first-in-human Phase 1 study of oral PRT1419, the Company's third clinical candidate, in patients with relapsed/refractory hematologic malignancies, including acute myeloid leukemia and high-risk myelodysplastic syndromes, remains ongoing. PRT1419 is designed to be an orally available, potent, and selective MCL1 inhibitor. The Company expects to add dose expansion and combination cohorts to the Phase 1 clinical trial in the second half of 2021.

- **IV Formulation: Dose Escalation Portion of Phase 1 Trial is Now Underway.** The Phase 1 trial of an intravenous (IV) formulation of PRT1419, which leverages the optimized physicochemical properties of PRT1419, is now underway in patients with solid tumors.

Discovery Programs

- **Earlier-Stage Candidates Expected to Advance in 2021.** The Company remains on track to submit an Investigational New Drug (IND) application in 2021 for PRT2527, which is designed to be a potent and selective CDK9 inhibitor. In addition, the Company continues to expect to initiate IND-enabling studies for PRT-SCA2, which is designed to be a SMARCA2 protein degrader, by the end of the year.

Corporate Updates

- **Martin Babler Appointed to Board of Directors.** In July 2021, the Company announced the appointment of Martin Babler to its Board of Directors. Mr. Babler brings to Prelude over 25 years of pharmaceutical and biotech experience, most recently serving as President and Chief Executive Officer of Principia Biopharma until its acquisition by Sanofi S.A. in October 2020. Mr. Babler will serve as a member of the audit committee of the Board.

- **Michele Porreca Appointed as Chief People Officer.** Prelude today announced the recent appointment of Michele Porreca as Chief People Officer. In this newly created role, she will lead all aspects of the Company's human resources management, including, talent management and strategy, organizational effectiveness, total rewards, culture, inclusion, and employee communications. Ms. Porreca brings to Prelude over 20 years of human resources experience, most recently serving as Chief Human Resources Officer at Nabriva Therapeutics.

Second Quarter 2021 Financial Results

- **Cash and Cash Equivalents:** Cash and cash equivalents as of June 30, 2021 were $343.1 million.

- **Research and Development (R&D) Expenses**: For the second quarter of 2021, R&D expense increased by $12.6 million to $22.4 million for the three months ended June 30, 2021 from $9.8 million for the three months ended June 30, 2020. The increase was mainly due to increased clinical research costs for the PRT543, PRT811 and PRT1419 (Oral and IV). Our chemistry, manufacturing and other costs for those trials also increased.

- **General and Administrative (G&A) Expenses**: For the second quarter of 2021, G&A expense increased by $3.9 million to $5.5 million for the three months ended June 30, 2021 from $1.6 million for the three months ended June 30, 2020. The increase was primarily due to an increase in personnel related expense due to an increase in employee headcount and an increase in our professional fees as we expanded our operations to support our research and development efforts and incurred additional costs to operate as a public company

- **Net Loss:** For the second quarter of 2021, net loss was $26.9 million, or $0.58 per share, compared with a net loss of $11.4 million, or $5.50 per share, for the same period in 2020.

- **Financial Guidance:** The Company believes that its current cash and cash equivalents will be sufficient to fund operating expenses and capital expenditure requirements [into mid-2023].

About Prelude Therapeutics

Prelude Therapeutics is a clinical-stage precision oncology company developing innovative drug candidates targeting critical cancer cell pathways. The Company's lead product candidates are designed to be oral, potent, and selective inhibitors of PRMT5. Prelude's first clinical candidate, PRT543, is in Phase 1 development for advanced solid tumors and select myeloid malignancies. Prelude is also advancing PRT811, a second PRMT5 inhibitor optimized for high brain exposure, in a Phase 1 clinical trial including glioblastoma multiforme (GBM). The Company's pipeline also includes its third clinical candidate, PRT1419, an orally available MCL1 inhibitor in Phase 1 development for patients with relapsed/refractory hematologic malignancies, and its two most advanced preclinical candidates, PRT2527, a CDK9 inhibitor, and PRT-SCA2, a SMARCA2 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 IND-related activities for PRT2527 and PRT-SCA2 and the potential benefits of the Company's product candidates and platform. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. Although the Company believes that the expectations reflected in such forward-looking statements are reasonable, the Company 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 the Company's actual activities or results to differ significantly from those expressed in any forward-looking statement, including risks and uncertainties related to the Company'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 the Company's business, clinical trial sites, supply chain and manufacturing facilities, the Company's ability to maintain and recognize the benefits of certain designations received by product candidates, the timing and results of preclinical and clinical trials, the Company's ability to fund development activities and achieve development goals, the Company's ability to protect intellectual property, and other risks and uncertainties described under the heading "Risk Factors" in documents the Company 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 the Company undertakes no obligation to revise or update any forward-looking statements to reflect events or circumstances after the date hereof.

STATEMENTS OF OPERATIONS
(UNAUDITED)

(in thousands, except share and per share data)	Three Months Ended June 30, 2021	2020
Operating expenses:		
Research and development	$ 22,409	$ 9,776
General and administrative	5,513	1,660
Total operating expenses	27,922	11,436
Loss from operations	(27,922)	(11,436)
Other income, net	1,057	28
Net loss	$ (26,865)	$ (11,408)
Per share information:		
Net loss per share of common stock, basic and diluted	$ (0.58)	$ (5.50)
Weighted average common shares outstanding, basic and diluted	46,057,112	2,074,108

BALANCE SHEETS
(UNAUDITED)

(in thousands, except share data)	June 30, 2021	
Assets		
Current assets:		
Cash and cash equivalents	$ 343,119	$
Prepaid expenses and other current assets	1,456	
Total current assets	344,575	
Property and equipment, net	3,109	
Right-of-use asset	1,897	
Deferred offering costs	—	
Total assets	$ 349,581	$
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 6,844	$
Accrued expenses and other current liabilities	6,430	
Operating lease liability	1,403	
Total current liabilities	14,677	
Other liabilities	—	
Operating lease liability	543	
Total liabilities	15,220	
Stockholders' equity:		
Voting common stock, $0.0001 par value: 487,149,741 shares authorized; 35,636,695 and 32,595,301 shares issued and outstanding at June 30, 2021 and December 31, 2020, respectively	4	
Non-voting common stock, $0.0001 par value; 12,850,259 shares authorized; 11,402,037 and 11,110,371 shares issued and outstanding at June 30, 2021 and December 31, 2020, respectively	1	
Additional paid-in capital	489,947	
Accumulated deficit	(155,591)	
Total stockholders' equity	334,361	
Total liabilities and stockholders' equity	$ 349,581	$

Contact

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