Prelude Therapeutics Reports First Quarter 2024 Financial Results and Provides Corporate Update

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First-in-class IV SMARCA2 degrader, PRT3789 and potentially best-in-class CDK9 inhibitor, PRT2527 remain on track to generate initial proof-of-concept data in 2024

New preclinical data presented at AACR 2024 included first characterization of PRT7732, a highly-selective, orally bioavailable SMARCA2 degrader

Operational leadership capabilities further strengthened by recent hires Chief Business Officer Sean Brusky and Senior Vice President, Investor Relations Robert Doody

Current cash runway into 2026 with $201.9 million in cash, cash equivalents and marketable securities as of March 31, 2024

WILMINGTON, Del., May 07, 2024 (GLOBE NEWSWIRE) -- Prelude Therapeutics Incorporated (Nasdaq: PRLD), a clinical-stage precision oncology company, today reported its financial results for the first quarter ended March 31, 2024 and provided an update on recent clinical development pipeline and other corporate developments.

“The first quarter of this year was marked by growing momentum for Prelude, led by the continued clinical progress of our two lead drug candidates, PRT3789, a highly-selective, first-in-class SMARCA2 degrader and PRT2527, a potentially best-in-class CDK9 inhibitor,” stated Kris Vaddi, Ph.D., Chief Executive Officer of Prelude. “We are on track to present initial Phase 1 data for both compounds in the second half of this year and to advance both into the next phase of development in cancers with patients who are in need of safe and effective new therapies, provided the data are supportive.”

Dr. Vaddi continued, “In addition to the continued advancement of our clinical compounds, we strengthened our leadership team with the additions of Sean Brusky, our new Chief Business Officer and Robert Doody, our new head of Investor Relations, both of whom bring proven operational capabilities and important strategic insights to the Prelude team in anticipation of our expected progress and growth over the coming years.”

Clinical Program Updates and Upcoming Milestones

SMARCA2 degrader PRT3789 on track to complete monotherapy dose escalation mid- year and combination with docetaxel has been initiated; initial proof-of concept data expected in second half of 2024.

PRT3789 is a potent and highly selective, first-in-class SMARCA2 degrader, designed to be used in patients with a SMARCA4 mutation. Cancers with a SMARCA4 mutation represent a high unmet medical need. Patients with the SMARCA4 mutation have poor prognosis and limited treatment options.

PRT3789 is in Phase 1 clinical development in biomarker selected SMARCA4 mutant patients. Enrollment remains on track, and the Company expects to conclude monotherapy dose escalation mid-2024 and identify recommended Phase 2 dose. In addition, enrollment of patients into back-fill cohorts enriched for NSCLC and SMARCA4 loss-of-function mutations is ongoing. Objectives for this first Phase 1 clinical trial are to establish the safety and tolerability profile of PRT3789 as both monotherapy and in combination with docetaxel, evaluate activity, pharmacokinetics and pharmacodynamics and determine a dose and potential indications for advancement into a registrational clinical trial.

Oral SMARCA2 degrader PRT7732 expected to enter Phase 1 clinical trial in the second half of 2024

Prelude’s discovery team has identified a series of highly selective and orally bioavailable SMARCA2 degraders. The lead oral molecule, PRT7732, is currently in investigational new drug (IND) enabling preclinical studies and on track to enter Phase 1 clinical development in the second half of 2024. PRT7732 is structurally distinct from PRT3789 and may provide clinically meaningful differences, including potential utility in earlier lines of therapy.

CDK9 inhibitor PRT2527 on track to complete monotherapy dose escalation mid-2024; initiated dosing in combination with zanubrutinib in first quarter of 2024; initial hematological proof-of-concept data expected in second half of 2024

PRT2527 is a potent and selective CDK9 inhibitor that has the potential to avoid off target toxicity. The Company is currently advancing PRT2527 as monotherapy in hematological indications such as B-cell malignancies and acute myeloid leukemia (AML) and has initiated the combination with zanubrutinib in B-cell malignancies.

PRT2527 is currently in Phase 1 clinical development and is expected to complete monotherapy dose escalation in B-cell malignancies mid-year. A second cohort of patients with AML is expected to initiate in the first half of 2024.

2024 AACR Annual Meeting: Prelude participated in the 2024 American Association for Cancer Research Annual Meeting, presenting three preclinical poster presentations. New preclinical data was presented for the company’s highly selective oral SMARCA2 degrader, its potentially best-in-class CDK9 inhibitor, and its next-generation oral CDK4/6 inhibitor. Copies of this information can be found on the Company’s website under Publications - Prelude Therapeutics (preludetx.com).

Corporate Updates: In April 2024, Prelude appointed Sean Brusky to the newly created position of Chief Business Officer. Mr. Brusky joins Prelude from Pardes Biosciences where he served as both Chief Commercial Officer and Chief Business Officer. Prior to Pardes, Mr. Brusky served in roles of increasing seniority at Genentech/Roche, Vertex Pharmaceuticals and Bain & Company.

Additionally, in April 2024, Prelude appointed Robert Doody to the newly created position of Senior Vice President, Investor Relations. Mr. Doody most recently served as Head of Investor Relations at Aclaris Therapeutics. Prior to Aclaris Therapeutics, Mr. Doody served as Investor Relations Lead at

Provention Bio, Idera Pharmaceuticals and ViroPharma Incorporated.

First Quarter 2024 Financial Results

Cash and Cash Equivalents:
Cash, cash equivalents and marketable securities as of March 31, 2024 were $201.9 million. The Company anticipates that its existing cash, cash equivalents and marketable securities will fund Prelude's operations into 2026.

Research and Development (R&D) Expenses:
For the first quarter of 2024, R&D expense increased to $27.4 million from $21.8 million for the prior year period. Research and development expenses increased primarily due to the timing of our clinical research programs. We expect our R&D 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 2024, G&A expenses decreased to $6.9 million from $7.3 million for the prior year period. The decrease is primarily due to a decrease in non-cash expense related to stock-based compensation, partially offset by an increase in professional fees incurred as we expand our operations to support our research and development efforts.

Net Loss:
For the three months ended March 31, 2024, net loss was $31.4 million, or $0.42 per share compared to $27.7 million, or $0.58 per share, for the prior year period. Included in the net loss for the quarter ended March 31, 2024, was $5.5 million of non-cash expenses related to the impact of expensing share-based payments, including employee stock options, as compared to $6.3 million for the same period in 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 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 three candidates currently in clinical development: an IV administered, potent and highly selective SMARCA2 degrader, PRT3789, a potent and highly selective CDK9 inhibitor, PRT2527, and a next generation CDK4/6 inhibitor, PRT3645. Prelude is also developing a potent, highly selective, orally bioavailable SMARCA2 degrader, PRT7732. The company is also collaborating with AbCellera to jointly discover, develop and commercialize up to five precision, next generation antibody drug conjugate (ADC) products combining AbCellera's antibody discovery and development engine with Prelude's expertise in medicinal chemistry and drug development. For more information, visit preludetx.com.

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 for Prelude's product candidates, the potential safety, efficacy, benefits and addressable market for Prelude's product candidates, the expected timeline for initial proof-of-concept data and clinical trial results for Prelude's product candidates, and the sufficiency of Prelude's cash runway into 2026. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. The words "believes," "anticipates," "estimates," "plans," "expects," "intends," "may," "could," "should," "potential," "likely," "projects," "continue," "will," "schedule," and "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements are predictions based on the Company's current expectations and projections about future events and various assumptions. 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, clinical trial sites and our ability to enroll eligible patients, 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 Prelude's Annual Report on Form 10-K for the year ended December 31, 2023, its Quarterly Reports on Form 10-Q and other documents that 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, except as may be required by law.

PRELUDE THERAPEUTICS INCORPORATED

STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(UNAUDITED)

	Three Months Ended March 31,	
(in thousands, except share and per share data)	**2024**	**2023**
Operating expenses:		
Research and development	$ 27,409	$ 21,834
General and administrative	6,934	7,281
Total operating expenses	34,343	29,115
Loss from operations	(34,343)	(29,115)
Other income, net	2,912	1,397
Net loss	$ (31,431)	$ (27,718)
Per share information:		
Net loss per share of common stock, basic and diluted	$ (0.42)	$ (0.58)
Weighted average common shares outstanding, basic and diluted	75,735,954	47,737,190
Comprehensive loss:		

Net loss	$ (31,431)	$ (27,718)
Unrealized (loss) gain on marketable securities, net of tax	(458)	1,294
Comprehensive loss	$ (31,889)	$ (26,424)

PRELUDE THERAPEUTICS INCORPORATED

BALANCE SHEETS
(UNAUDITED)

(in thousands, except share data)	March 31, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 24,707	$ 25,291
Marketable securities	177,217	207,644
Prepaid expenses and other current assets	3,442	2,654
Total current assets	205,366	235,589
Restricted cash	4,044	4,044
Property and equipment, net	7,294	7,325
Right-of-use asset	30,107	30,412
Other assets	295	295
Total assets	$ 247,106	$ 277,665
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 5,308	$ 4,580
Accrued expenses and other current liabilities	10,147	15,768
Operating lease liability	2,188	1,481
Total current liabilities	17,643	21,829
Other liabilities	3,277	3,339
Operating lease liability	15,452	15,407
Total liabilities	36,372	40,575
Commitments		
Stockholders' equity:		
Voting common stock, $0.0001 par value: 487,149,741 shares authorized; 42,071,505 and 42,063,995 shares issued and outstanding at March 31, 2024 and December 31, 2023, respectively	4	4
Non-voting common stock, $0.0001 par value: 12,850,259 shares authorized; 12,850,259 shares issued and outstanding at both March 31, 2024 and December 31, 2023	1	1
Additional paid-in capital	698,785	693,252
Accumulated other comprehensive (loss) income	(235)	223
Accumulated deficit	(487,821)	(456,390)
Total stockholders' equity	210,734	237,090
Total liabilities and stockholders' equity	$ 247,106	$ 277,665

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