Prelude Therapeutics Reports First Quarter 2025 Financial Results and Provides Corporate Update

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PRT3789 monotherapy and combination with docetaxel escalation enrollment is complete and the Company plans to present updated results in the second half of 2025

Enrollment of the Phase 1 study of Prelude's once daily, oral SMARCA2 degrader, PRT7732 is advancing rapidly, and an initial data update is anticipated in the second half of 2025

Current cash runway into the second quarter of 2026 with $103.1 million in cash, cash equivalents, restricted cash and marketable securities as of March 31, 2025

WILMINGTON, Del., May 06, 2025 (GLOBE NEWSWIRE) -- Prelude Therapeutics Incorporated (Nasdaq: PRLD), a clinical-stage precision oncology company, today reported its financial results for first quarter ended March 31, 2025, and provided an update on its clinical development pipeline and other corporate developments.

"The first quarter of 2025 represented another strong period of execution across our organization," stated Kris Vaddi, Ph.D., Chief Executive Officer of Prelude. "We are making rapid progress with the development of our SMARCA2 degraders and are on track to determine the most optimal path forward for the overall program as we continue to strengthen our knowledge and understanding of potential opportunities for these novel, first-in-class drug candidates in highly aggressive SMARCA4 mutated cancers."

Continued Vaddi, "Additionally, we were very pleased to present at the most recent American Association for Cancer Research Annual Meeting, the first preclinical data from our highly selective, oral KAT6A degraders. Selectively degrading KAT6A may hold the key to enhancing the efficacy and improving the safety profile for cancer patients beyond what has previously been demonstrated by non-selective KAT6A/B inhibitors. Our goal is to advance these potential growth driving assets towards points of value inflection in a strategic and financially disciplined manner."

Clinical Program Updates and Upcoming Milestones

PRT3789 – A first-in-class, highly selective, intravenous SMARCA2 Degrader
PRT3789 is designed to treat patients with a SMARCA4 mutation. Patients with SMARCA4-mutated cancer, a particularly aggressive form of the disease, have a very poor clinical prognosis. Approximately 10% of all non-small cell lung cancers and 5% of all cancers broadly, harbor a SMARCA4 mutation. In NSCLC, these patients tend to have poor response to standard of care chemoimmunotherapy and are largely ineligible for other targeted therapies. We believe that this represents an area of high unmet medical need.

PRT3789 is in Phase 1 clinical development in patients with biomarker selected SMARCA4-mutated cancers. The Company has completed enrollment of monotherapy dose escalation at the 665 mg once weekly IV dose and has selected 500 mg once weekly as the recommended Phase 2 dose. In addition, the Company has completed dose escalation in the combination of PRT3789 with docetaxel and is nearing completion of backfill cohorts. Updated data from the trial is expected to be presented at a major medical meeting in the second half of 2025.

The Company is enrolling patients in a Phase 2 clinical trial evaluating PRT3789 in combination with KEYTRUDA® (pembrolizumab) in patients with SMARCA4-mutated cancers, per the previously announced collaboration with Merck (known as MSD outside of the US and Canada).

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA.

Interim Phase 1 data presented at the 2025 Japanese Society of Medical Oncology Annual Meeting
As previously reported, the Company presented an encore oral presentation titled: PRT3789, a First-in-Class Intravenous SMARCA2 Degrader, in Advanced Solid Tumors with a SMARCA4 Mutation: Phase 1 Trial at the 2025 Japanese Society of Medical Oncology Annual Meeting on March 8, 2025, highlighting the favorable safety profile and responses seen in both NSCLC and upper GI cancers. The presentation can be found at Publications - Prelude Therapeutics.

PRT7732 – A potent, highly selective and orally bioavailable SMARCA2 Degrader
PRT7732 is a highly selective and orally bioavailable SMARCA2 degrader with a distinct chemical composition to PRT3789. In the fourth quarter of 2024, the Company initiated and enrolled the first patients in a phase 1 multi-dose escalation trial of PRT7732 (NCT06560645) in biomarker selected SMARCA4 mutated cancers. Enrollment has advanced rapidly, and the company is currently enrolling patients in the fifth dose escalation cohort (60 mg once daily). The Company expects to provide an initial first-in-human data update at a major medical meeting in the second half of 2025.

Highly selective KAT6A oral degrader program
Prelude discovered and is developing a series of highly potent, selective and orally bioavailable KAT6A degraders, which the Company believes is the industry's first report of a KAT6 degrader based on currently published patents and literature. Optimized lead compounds are advancing to candidate nomination in the second quarter of 2025 with intent to file an IND in 2026. KAT6 is a clinically validated target with promising activity in breast cancer and other solid tumors. Recently, a dual KAT6A/B inhibitor demonstrated robust clinical activity in combination with fulvestrant in previously treated ER+/HER2- breast cancer patients, albeit with potential safety and tolerability considerations, in particular neutropenia.[1] Hematologic toxicity is believed to be driven by the dual inhibition of KAT6A and KAT6B.

Prelude believes that selectively degrading KAT6A has the potential for improved efficacy, tolerability and combinability with other agents. The Company recently presented preclinical data validating this hypothesis at the AACR Annual Meeting 2025. The presentation can be found at Publications - Prelude Therapeutics.

Precision ADCs with SMARCA2/4 dual degrader payload
Prelude is developing potent SMARCA2/4 dual degraders that robustly inhibit cancer cell growth and induce cell death across multiple cancer types as payloads for precision ADCs. The Company presented the first preclinical data from its precision ADC platform at the 36th EORTC-NCI-AACR Symposium in October. These data demonstrated that SMARCA2/4 dual degrader antibody conjugates have potential for significantly better *in vivo* efficacy and tolerability when compared to a traditional cytotoxic ADCs when tested head-to-head in xenograft models. Prelude and its partner AbCellera anticipate nominating the first development candidate from this program in 2025. The presentation can be found at Publications - Prelude Therapeutics.

Upcoming Investor Conference
The Company will participate in the Citizens 2025 Life Sciences Conference taking place in New York. On Wednesday, May 7, 2025 at 11:00 AM ET, Kris Vaddi, Ph.D., Chief Executive Officer, and Jane Huang, M.D., President and Chief Medical Officer, and Peggy Scherle, Ph.D., Chief Scientific Officer, will participate in a fireside chat.

A live webcast of the fireside chat can be accessed on the Company's website under Events and Presentations. The recording will be archived and available on the Company's website for 90 days.

First Quarter 2025 Financial Results

Cash, Cash Equivalents, Restricted Cash and Marketable Securities:
Cash, cash equivalents, restricted cash and marketable securities as of March 31, 2025 were $103.1 million. The Company anticipates that its existing cash, cash equivalents, restricted cash and marketable securities will fund Prelude's operations into the second quarter of 2026.

Research and Development (R&D) Expenses:
For the first quarter of 2025, R&D expense increased to $28.8 million from $27.4 million for the prior year period. Included in the R&D expense for the three months ended March 31, 2025 was $2.3 million of non-cash expense related to stock-based compensation expense, including employee stock options, compared to $3.0 million for the three months ended March 31, 2024. Research and development expenses increased primarily due to an increase in expense related to our SMARCA2 clinical trials. Research and development expenses may fluctuate from period to period depending upon the stage of certain projects and the level of preclinical and clinical trial-related activities.

General and Administrative (G&A) Expenses:
For the first quarter of 2025, G&A expenses decreased to $5.8 million from $6.9 million for the prior year period. Included in general and administrative expenses for the three months ended March 31, 2025, was $1.6 million of non-cash expense related to stock-based compensation expense, including employee stock options, compared to $2.5 million for the three months ended March 31, 2024. The decrease in general and administrative expenses was primarily due to a decrease in stock-based compensation due to lower valuation on more recent grants due to the decrease in our stock price.

Net Loss:
For the three months ended March 31, 2025, net loss was $32.1 million, or $0.42 per share compared to $31.4 million, or $0.42 per share, for the prior year period. Included in the net loss for the three months ended March 31, 2025, was $3.8 million of non-cash expenses related to the impact of expensing share-based payments, including employee stock options, as compared to $5.5 million for the same period in 2024.

About Prelude Therapeutics
Prelude Therapeutics is a leading precision oncology company developing innovative medicines in areas of high unmet need for cancer patients. Our pipeline is comprised of several novel drug candidates including first-in-class, highly selective SMARCA2 and KAT6A degraders, and ongoing research into other precision oncology targets. We are also leveraging our expertise in targeted protein degradation to discover, develop and commercialize next generation degrader antibody conjugates (Precision ADCs) with partners. We are on a mission to extend the promise of precision medicine to every cancer patient in need. Our corporate presentation can be found at Events & Presentations - Prelude Therapeutics. 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 clinical trial results for Prelude's product candidates, and the sufficiency of Prelude's cash runway into the second quarter of 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.

1. "PF-07248144, a first-in-class KAT6 inhibitor, in patients with HR+ HER2− metastatic breast cancer: Updated results from phase 1 dose expansion study, Presented at SABCS, December 8th 2024, Abstract P4-10-28."

PRELUDE THERAPEUTICS INCORPORATED

STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(UNAUDITED)

(in thousands, except share and per share data)	Three Months Ended March 31, 2025	2024
Operating expenses		
Research and development	$ 28,816	$ 27,409
General and administrative	5,790	6,934
Total operating expenses	34,606	34,343
Loss from operations	(34,606)	(34,343)
Other income, net	2,521	2,912
Net loss	$ (32,085)	$ (31,431)
Per share information:		
Net loss per share of common stock, basic and diluted	$ (0.42)	$ (0.42)
Weighted average common shares outstanding, basic and diluted	75,986,281	75,735,954
Comprehensive loss:		
Net loss	$ (32,085)	$ (31,431)
Unrealized loss on marketable securities, net of tax	(23)	(458)
Comprehensive loss	$ (32,108)	$ (31,889)

PRELUDE THERAPEUTICS INCORPORATED

BALANCE SHEETS

(in thousands, except share data)	March 31, 2025	December 31, 2024
Assets	(unaudited)	
Current assets:		
Cash and cash equivalents	$ 40,269	$ 12,474
Marketable securities	58,805	121,140
Prepaid expenses and other current assets	3,329	2,281
Total current assets	102,403	135,895
Restricted cash	4,044	4,044
Property and equipment, net	6,388	6,767
Operating lease right-of-use asset	28,315	28,699
Other assets	110	110
Total assets	$ 141,260	$ 175,515
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 5,831	$ 7,732
Accrued expenses and other current liabilities	11,303	15,209
Operating lease liability	2,600	2,492
Finance lease liability	53	208
Total current liabilities	19,787	25,641
Other liabilities	3,028	3,090
Operating lease liability	15,267	15,325
Total liabilities	38,082	44,056
Commitments (Note 8)		
Stockholders' equity:		
Voting common stock, $0.0001 par value: 487,149,741 shares authorized; 43,604,202 and 42,298,859 shares issued and outstanding at March 31, 2025 and December 31, 2024, 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, 2025 and December 31, 2024	1	1
Additional paid-in capital	718,809	714,982
Accumulated other comprehensive income	12	35
Accumulated deficit	(615,648)	(583,563)
Total stockholders' equity	103,178	131,459
Total liabilities and stockholders' equity	$ 141,260	$ 175,515

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