Prelude Therapeutics Announces First Quarter 2023 Financial Results and Operations Update

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Eight abstracts presented at AACR 2023 demonstrate progress of the pipeline

Cash runway unchanged, supporting operations into the fourth quarter of 2024

WILMINGTON, Del., May 08, 2023 (GLOBE NEWSWIRE) -- Prelude Therapeutics Incorporated (Nasdaq: PRLD), a clinical-stage precision oncology company, today reported financial results for the first quarter ended March 31, 2023, and provided an update on recent clinical and development pipeline progress.

"Our recent presentations at the 2023 AACR Annual Meeting highlight the meaningful progress we made across our clinical and preclinical pipeline programs. In addition to our clinical presentations on PRT2527 (CDK9 inhibitor) and PRT1419 (MCL-1 Inhibitor) that demonstrated differentiated and potential best-in-class PK/PD profiles of these molecules, our preclinical research demonstrated the promise of our pipeline in addressing unmet patient needs in cancer through combination approaches. Patient enrollment in the phase 1 dose escalation of PRT3789 (first-in-class SMARCA2 selective degrader) is now underway. Our teams are focused on advancing our pipeline to key milestones and we look forward to reporting further updates in the coming months," said **Kris Vaddi, Ph.D., Chief Executive Officer of Prelude**.

Recent Highlights

2023 AACR Annual Meeting: Prelude participated in the 2023 American Association for Cancer Research Annual Meeting, presenting two clinical and six preclinical poster presentations. Initial safety, pharmacokinetic and pharmacodynamic profiles in solid tumors for both PRT2527 and PRT1419 were presented. Preclinical data for both the Company's next generation CDK4/6 inhibitor, PRT3645, and the SMARCA2 degrader, PRT3789, in combination with other targeted therapies, demonstrated the combinability of these compounds with standard of care medicines and inform potential clinical development.

Program Updates and Upcoming Milestones

PRT2527- CDK9 Inhibitor Program
PRT2527, Prelude's potentially best in class CDK9 inhibitor, is completing a solid tumor dose escalation study. In adults with advanced solid tumors, PRT2527 was generally well-tolerated with manageable neutropenia and absence of significant gastrointestinal events or hepatotoxicity. The short half-life of PRT2527 enables acute CDK9 inhibition over a defined period making it potentially suitable for weekly administration without inducing significant toxicity. The observed dose-dependent downregulation of CDK9 transcriptional targets – MYC and MCL-1 mRNA expression in PBMCs isolated from patients treated with PRT2527 –was consistent with the degree of target engagement required for preclinical efficacy. The 15 m/mg2 QW dose of PRT2527 was selected for further evaluation in dose-confirmation cohort.

The overall safety profile observed in this study supports further development of PRT2527 in combination with other targeted therapies, including in hematologic malignancies. The Company is on track to establish a RP2D in hematological malignancies in 2H 2023.

PRT1419- MCL1 Inhibitor Program
PRT1419 demonstrated an acceptable safety and tolerability profile in patients with advanced and metastatic solid tumors, with the most common TRAEs of nausea, vomiting, and diarrhea. Neutropenia was deemed to be dose related. No cardiac toxicity was observed. Pharmacokinetics/pharmacodynamics and safety data in the 80 mg/m2 QW PRT1419 dose cohort support further evaluation of this dose in future studies. Induction of activated-BAX and cleaved caspase-3 was observed at 80 and 120 mg/m2 QW PRT1419, suggesting successful MCL-1 inhibition. No tumor reductions met response criteria. Further investigation of PRT1419 in patients with hematologic malignancy is ongoing. The Company is on track to determine the RP2D in hematological RP2D and will provide a clinical update at year end.

PRT3645-Next Generation CDK4/6 Inhibitor Program
Prelude showed that PRT3645 is highly efficacious when combined with KRAS/MEK inhibitors, and with a brain penetrant HER2 receptor kinase inhibitor in *in vivo* preclinical models.

Additionally, oral administration of PRT3645 induces tumor regression in palbociclib-resistant preclinical models. Dose escalation phase of PRT3645 is progressing per plan and the Company expects to provide an update by year end.

PRT3789 SMARCA2 Targeted Protein Degrader Program
Phase 1 dose escalation of PRT3789 (first-in-class selective SMARCA2 degrader) is ongoing. The Company recently presented preclinical data, showing that SMARCA2 selective degraders demonstrate anti-proliferation activity and promote cell differentiation in a wide range of indications demonstrating activity as monotherapy, as well as in combination with KRAS G12C inhibitors, chemotherapy and other targeted agents. Consistent with the Company's plans to nominate an orally bioavailable candidate in early 2024, preclinical data at AACR showed that oral administration of multiple internally developed compounds results in significant tumor growth inhibition of SMARCA4-deficient lung cancer xenografts at well-tolerated doses.

First Quarter 2023 Financial Results

Cash, Cash Equivalents and Marketable Securities: Cash, cash equivalents, and marketable securities as of March 31, 2023, were $172.3 million. Prelude anticipates that its existing cash, cash equivalents and marketable securities will fund the Company's operations into the fourth quarter of 2024.

Research and Development (R&D) Expenses: For the first quarter of 2023, R&D expense decreased to $21.8 million from $22.8 million for the prior year period. Research and development expenses decreased 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 2023, G&A expenses were relatively unchanged as compared to the three months ended March 31, 2022.

Net Loss: For the three months ended March 31, 2023, net loss was $27.7 million, or $0.58 per share compared to $29.5 million, or $0.63 per share, for the prior year period. Included in the net loss for the quarter ended March 31, 2023, was $6.3 million of non-cash expense related to the impact of expensing share-based payments, including employee stock options, as compared to $6.8 million for the same period in 2022.

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 four candidates currently in clinical development: PRT1419, a potent, selective inhibitor of MCL1, PRT2527, a potent and highly selective CDK9 inhibitor, PRT3645 a next generation CDK4/6 inhibitor**,** and PRT3789 an IV administered, potent and highly selective SMARCA2 degrader.

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, the timing and/or announcements relating to the reporting of expected findings for PRT1419, PRT2527, PRT3645 and PRT3789, 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 fourth quarter 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)

	Three Months Ended March 31,	
(in thousands, except share and per share data)	**2023**	**2022**
Operating expenses:		
Research and development	$ 21,834	$ 22,821
General and administrative	7,281	7,467
Total operating expenses	29,115	30,288
Loss from operations	(29,115)	(30,288)
Other income, net	1,397	823
Net loss	$ (27,718)	$ (29,465)
Per share information:		
Net loss per share of common stock, basic and diluted	$ (0.58)	$ (0.63)
Weighted average common shares outstanding, basic and diluted	47,737,190	47,066,427
Comprehensive loss		
Net loss	$ (27,718)	$ (29,465)
Unrealized gain (loss) on marketable securities, net of tax	1,294	(1,602)
Comprehensive loss	$ (26,424)	$ (31,067)

PRELUDE THERAPEUTICS INCORPORATED

BALANCE SHEETS
(UNAUDITED)

(in thousands, except share data)	**March 31, 2023**	**December 31, 2022**
Assets		
Current assets:		

Cash and cash equivalents	$ 18,201	$ 30,605
Marketable securities	154,054	171,123
Prepaid expenses and other current assets	3,008	2,652
Total current assets	175,263	204,380
Restricted cash	4,044	4,044
Property and equipment, net	5,371	4,908
Right-of-use asset	1,360	1,792
Prepaid expenses and other non-current assets	12,282	5,376
Total assets	$ 198,320	$ 220,500
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 7,082	$ 6,777
Accrued expenses and other current liabilities	11,190	13,093
Operating lease liability	1,390	1,832
Total current liabilities	19,662	21,702
Other liabilities	3,361	3,361
Total liabilities	23,023	25,063
Commitments		
Stockholders' equity:		
Voting common stock, $0.0001 par value: 487,149,741 shares authorized; 36,514,218 and 36,496,994 shares issued and outstanding at March 31, 2023 and December 31, 2022, 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, 2023 and December 31, 2022, respectively	1	1
Additional paid-in capital	537,966	531,682
Accumulated other comprehensive loss	(398)	(1,692)
Accumulated deficit	(362,276)	(334,558)
Total stockholders' equity	175,297	195,437
Total liabilities and stockholders' equity	$ 198,320	$ 220,500

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