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

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Interim Phase 1 data for its first-in-class, highly selective IV SMARCA2 degrader, PRT3789, selected for an oral presentation at the European Society for Medical Oncology (ESMO) Congress 2024 in September

Received investigational new drug (IND) authorization for PRT7732, its first-in-class oral SMARCA2 degrader, from the U.S. Food and Drug Administration (FDA)

Announced clinical collaboration with Merck to evaluate PRT3789 in combination with Merck's anti-PD-1 therapy KEYTRUDA ® (pembrolizumab) in patients with SMARCA4-mutated cancers

Potentially best-in-class CDK9 inhibitor, PRT2527, remains on track to report interim Phase 1 data in Q4 2024

Current cash runway into 2026 with $179.8 million in cash, cash equivalents and marketable securities as of June 30, 2024

WILMINGTON, Del., Aug. 12, 2024 (GLOBE NEWSWIRE) -- Prelude Therapeutics Incorporated (Nasdaq: PRLD), a clinical-stage precision oncology company, today reported its financial results for the second quarter ended June 30, 2024 and provided an update on its clinical development pipeline and other corporate developments.

"Our team continues to make solid progress towards the Company's ambitious R&D objectives that we established for 2024 and beyond. We are focused on advancing our two lead clinical programs, including the first-in-class, highly selective SMARCA2 degrader, PRT3789 and a potent and selective CDK9 inhibitor, PRT2527, both on track to report initial clinical results this year," stated Kris Vaddi, Ph.D., Chief Executive Officer of Prelude.

Dr. Vaddi continued, "We believe that targeting the SMARCA pathway has the potential to deliver a 'pipeline in a program.' We are building on our leadership position by advancing the industry's first highly selective oral SMARCA2 degrader, PRT7732, into the clinic, and will initiate a study of PRT3789 in combination with KEYTRUDA in collaboration with Merck later this year. Additionally, in collaboration with AbCellera, we are developing precision ADCs with SMARCA payloads to extend the reach of our molecules to an even broader set of cancers without SMARCA4 mutations."

"Regarding our clinical development programs, we are very pleased with the progress of both of our SMARCA2 degraders, PRT3789 and PRT7732," added Jane Huang, M.D., President and Chief Medical Officer of Prelude. "We are looking forward to sharing the initial clinical data from the Phase 1 study of our highly selective SMARCA2 degrader which has been chosen as the subject of an oral presentation at the upcoming ESMO Congress in September."

Dr. Huang continued, "Additionally, based on the continued progress of PRT2527, our selective CDK9 inhibitor, we intend to present interim phase 1 clinical data, including a potential best-in-class safety profile in the fourth quarter of this year."

Clinical Program Updates and Upcoming Milestones

PRT3789 – A first-in-class, highly selective, intravenous SMARCA2 Degrader

PRT3789 is a first-in-class SMARCA2 degrader, highly selective for SMARCA2 and designed to treat patients with a SMARCA4 mutation. Cancer patients whose tumors have SMARCA4 mutations have a poor prognosis and as a result, this is an area of high unmet medical need.

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 in 2024 and identify a recommended Phase 2 dose. In addition, enrollment of patients into back-fill cohorts enriched for NSCLC and SMARCA4 loss-of-function mutations is ongoing, as is enrollment of the combination with docetaxel cohort.

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 registrational clinical trial(s).

Prelude recently launched an educational video series focused on the science of SMARCA biology, the discovery of first-in-class, highly selective SMARCA2 degraders and the unmet medical need for patients with SMARCA4 mutated cancer. This series can be found on the Company's website under Highly Selective SMARCA2 Degraders - Prelude Therapeutics (preludetx.com).

Interim Phase 1 data selected for an oral presentation at the ESMO Congress 2024

The abstract titled *"First Clinical Results from a Phase 1 Trial of PRT3789, a First-in-Class Intravenous SMARCA2 Degrader, in Patients with Advanced Solid Tumors with a SMARCA4 Mutation,"* will be presented by Robin Guo, M.D. from Memorial Sloan Kettering Cancer Center. The ESMO Congress 2024 Scientific Committee selected the abstract as an oral presentation.

The presentation is scheduled for September 13th, 2024, at 4:00 PM CEST (10:00 AM EST) in the Santander Auditorium (Hall 5) as part of the Developmental Therapeutics Session.

Abstracts are anticipated to be available on the ESMO website on September 9th, 2024 at 12:05 AM CEST (6:05 PM EST on September 8th).

Clinical collaboration announced with Merck to evaluate PRT3789 in combination with KEYTRUDA® in patients with SMARCA4-mutated

cancers

In July 2024, Prelude announced a clinical collaboration with Merck to evaluate PRT3789 in combination with KEYTRUDA® in patients with SMARCA4-mutated cancers.

The mechanistic rationale and pre-clinical data to support the SMARCA2 and anti-PD-1 monoclonal antibody (mAb) combination was previously presented by the Company at the 2023 AACR International Conference on Molecular Targets and Cancer Therapeutics. In pre-clinical models, SMARCA2 degrader combined with an anti-PD-1 mAb in SMARCA4-mutated cancers enhanced anti-tumor immunity and demonstrated tumor regressions. Please see the Company's website under Publications - Prelude Therapeutics (preludetx.com) for more information.

Under the terms of the Agreement, Merck will provide KEYTRUDA® to Prelude. Prelude will be the sponsor of the Phase 2 clinical combination trial, anticipated to initiate in the fourth quarter of 2024. Prelude and Merck each retain all commercial rights to their respective compounds, including as monotherapy or as combination therapies.

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

PRT7732 – A potent, highly selective and orally bioavailable SMARCA2 Degrader

Prelude has identified a series of highly selective and orally bioavailable SMARCA2 degraders. The lead oral candidate, PRT7732, recently was granted IND authorization from the FDA and is expected to enter Phase 1 clinical development in the second half of 2024.

PRT2527 – A potent and highly selective CDK9 Inhibitor

PRT2527 is a potent and highly selective CDK9 inhibitor that has the potential to avoid off-target toxicities observed with other less selective CDK9 inhibitors. The Company is currently advancing PRT2527 as monotherapy in both lymphoid and myeloid hematological malignancies, and in combination with zanubrutinib in B-cell malignancies.

PRT2527 is expected to complete monotherapy dose escalation in B-cell malignancies this year. Initiation of dose escalation in myeloid malignancies occurred in the first half of 2024. Interim Phase 1 data is on track for presentation in the fourth quarter of 2024.

Second Quarter 2024 Financial Results

Cash, Cash Equivalents, and Marketable securities:
Cash, cash equivalents and marketable securities as of June 30, 2024 were $179.8 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 second quarter of 2024, R&D expense increased to $29.5 million from $25.0 million for the prior year period. Research and development expenses increased primarily due to an increase in our chemistry, manufacturing, and controls (CMC) expense to support our pre-clinical and 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 second quarter of 2024, G&A expenses increased to $7.7 million from $7.4 million for the prior year period. The increase is primarily due to 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 June 30, 2024, net loss was $34.7 million, or $0.46 per share compared to $30.4 million, or $0.54 per share, for the prior year period. Included in the net loss for the quarter ended June 30, 2024, was $6.1 million of non-cash expenses related to the impact of expensing share-based payments, including employee stock options, as compared to $6.7 million for the same period in 2023.

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 IV and oral SMARCA2 degraders, and a potentially best-in-class CDK9 inhibitor. 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. 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)

(in thousands, except share and per share data)	Three Months Ended June 30, 2024	2023
Operating expenses:		
Research and development	$ 29,509	$ 24,966
General and administrative	7,655	7,432
Total operating expenses	37,164	32,398
Loss from operations	(37,164)	(32,398)
Other income, net	2,424	1,967
Net loss	$ (34,740)	$ (30,431)
Per share information:		
Net loss per share of common stock, basic and diluted	$ (0.46)	$ (0.54)
Weighted average common shares outstanding, basic and diluted	75,762,152	56,240,491
Comprehensive loss:		
Net loss	$ (34,740)	$ (30,431)
Unrealized (loss) gain on marketable securities, net of tax	(55)	(313)
Comprehensive loss	$ (34,795)	$ (30,744)

PRELUDE THERAPEUTICS INCORPORATED

BALANCE SHEETS

(in thousands, except share data)	June 30, 2024	December 31, 2023
Assets	(unaudited)	
Current assets:		
Cash and cash equivalents	$ 27,828	$ 25,291
Marketable securities	152,016	207,644
Prepaid expenses and other current assets	2,870	2,654
Total current assets	182,714	235,589
Restricted cash	4,044	4,044
Property and equipment, net	7,554	7,325
Operating lease right-of-use asset	29,574	30,412
Other assets	405	295
Total assets	$ 224,291	$ 277,665
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 6,170	$ 4,580
Accrued expenses and other current liabilities	11,426	15,768
Deferred revenue	3,000	—
Operating lease liability	2,232	1,481
Finance lease liability	507	—
Total current liabilities	23,335	21,829
Other liabilities	3,215	3,339
Operating lease liability	15,465	15,407
Total liabilities	42,015	40,575
Commitments		
Stockholders' equity:		
Voting common stock, $0.0001 par value: 487,149,741 shares authorized; 42,158,224 and 42,063,995 shares issued and outstanding at June 30, 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 June 30, 2024 and December 31, 2023	1	1
Additional paid-in capital	705,122	693,252
Accumulated other comprehensive (loss) income	(290)	223
Accumulated deficit	(522,561)	(456,390)
Total stockholders' equity	182,276	237,090
Total liabilities and stockholders' equity	$ 224,291	$ 277,665

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