Prelude Therapeutics Reports Full Year 2023 Financial Results and Outlines Key Objectives for 2024

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First-in-class IV SMARCA2 degrader and potentially best-in-class CDK9 inhibitor on track to generate potential proof-of-concept data in 2024

Highly selective oral SMARCA2 degrader PRT7732 IND expected to be filed in first half and enter Phase 1 clinical trial in second half of 2024

Recently established partnership with AbCellera to jointly discover, develop, and commercialize a portfolio of next generation precision ADCs

Current cash runway into 2026 with $232.9 million in cash, cash equivalents and marketable securities as of December 31, 2023

WILMINGTON, Del., Feb. 15, 2024 (GLOBE NEWSWIRE) -- Prelude Therapeutics Incorporated (Nasdaq: PRLD), a clinical-stage precision oncology company, today reported its financial results for the fiscal year ended December 31, 2023, and outlined key objectives for 2024.

"In 2023, we prioritized and strengthened our pipeline to focus our resources on those programs that we believe have the highest likelihood of success and the greatest opportunity to deliver potentially safer and more effective therapies for patients that are currently underserved. We made significant progress with both our first-in-class IV SMARCA2 degrader compound, PRT3789, and our potentially best-in-class CDK9 inhibitor, PRT2527, which are on track to deliver meaningful initial proof-of-concept data in 2024," stated Kris Vaddi, Ph.D., Chief Executive Officer of Prelude.

Dr. Vaddi continued, "As evidence of our confidence in the potential therapeutic value of SMARCA2 to address a wide range of cancers with SMARCA4 mutations, we are also advancing our highly selective lead oral SMARCA2 degrader into Phase 1 clinical development in the second half of 2024. With both IV and oral molecules in the pipeline, we believe that we have the optionality to deliver the most appropriate treatment based on patient need and line of therapy and maintain our lead in this emerging new class of therapeutics.

"Our partnership with AbCellera represents a strategic step to expand our pipeline, based on our core competencies in medicinal chemistry, cancer biology and clinical development. The goal of the partnership is to create a portfolio of first-in-class precision ADCs that will utilize highly selective and potent small molecules and degrader payloads discovered by Prelude, coupled with highly differentiated antibodies from AbCellera. One of our first precision ADC programs utilizes a highly potent SMARCA degrader, which we expect will allow us to build on and extend the reach of our SMARCA programs."

Clinical Program Updates and Upcoming Milestones

SMARCA2 degrader PRT3789 on track to complete monotherapy dose escalation mid-year and initiate combination with docetaxel in first half of 2024; 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, currently, no effective therapies.

PRT3789 is in Phase 1 clinical development in biomarker selected SMARCA4 mutant patients. To date, PRT3789 has completed the fifth dose escalation cohort and demonstrated selective, potent and dose dependent degradation of SMARCA2 with an acceptable safety profile. Based on PK/PD and safety data today, the Company expects to conclude monotherapy dose escalation mid-2024 and identify recommended Phase 2 dose(s). In addition, enrollment of patients into back-fill cohorts enriched for NSCLC and SMARCA4 loss-of-function mutations has been initiated. 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 efficacy, pharmacokinetics and pharmacodynamics and determine a dose and potential indications for advancement into a registrational clinical trial.

CDK9 inhibitor PRT2527 on track to complete monotherapy dose escalation mid-2024; initiate 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 small molecule that has the potential to avoid off target toxicity and achieve greater clinical activity than other CDK9 programs currently in development. 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 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.

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 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, more patient-friendly dosing and may be useful in earlier therapy lines.

Partnership with AbCellera expected to advance its first precision ADC

The AbCellera partnership, announced in November 2023, continues to progress towards the goal of delivering next-generation ADCs, combining AbCellera's antibody discovery and development engine with Prelude's expertise in medicinal chemistry and drug development. The partnership includes up to five precision ADC targets. Under the terms of the agreement, Prelude and AbCellera will jointly discover, develop, and commercialize

products emerging from the collaboration. AbCellera will lead manufacturing activities and Prelude will lead clinical development and global commercialization, subject to AbCellera's option to co-promote any resulting commercial products in the United States.

Full Year 2023 Financial Results

Cash and Cash Equivalents:
Cash and cash equivalents as of December 31, 2023 were $232.9 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:
R&D expenses for the year ended December 31, 2023 increased by $10.5 million to $103.4 million from $92.9 million for the year ended December 31, 2022. Included in research and development expenses for the year ended December 31, 2023 was $12.6 million of non-cash expense related to stock-based compensation expense, including employee stock options, compared to $11.5 million for the year ended December 31, 2022. The increase in research and development expenses was due to the timing of our clinical development programs along with an increase in non-cash stock-based compensation expense.

General and Administrative (G&A) Expenses:
G&A expenses for the year ended December 31, 2023 decreased by $1.8 million to $28.9 million compared to $30.7 million for the year ended December 31, 2022. Included in the general and administrative expenses for the year ended December 31, 2023 was $13.0 million of non-cash expense related to stock-based compensation expense, including employee stock options, as compared to $13.6 million for the same period in 2022. The decrease in general and administrative expenses was primarily due to our continued management of general and administrative expenses.

Net Loss:
Net loss for the year ended December 31, 2023 was $121.8 million or $2.02 per share, compared with a net loss of $115.4 million, or $2.44 per share, for the year ended December 31, 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 three candidates currently in clinical development: an IV administered, potent and highly selective SMARCA2 degrader, PRT3789, a preclinical oral SMARCA2 selective degrader, PRT7732, a potent and highly selective CDK9 inhibitor, PRT2527, and a next generation CDK4/6 inhibitor, PRT3645.

For more information, visit our website and follow us on LinkedIn.

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, 2022, 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.

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PRELUDE THERAPEUTICS INCORPORATED
STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(in thousands, except share and per share data)	**Year ended December 31,**	
	2023	**2022**
Operating expenses:		

Research and development	$ 103,393	$ 92,889
General and administrative	28,884	30,651
Total operating expenses	132,277	123,540
Loss from operations	(132,277)	(123,540)
Other income, net	10,445	8,102
Net loss	$ (121,832)	$ (115,438)
Per share information:		
Net loss per share of common stock, basic and diluted	$ (2.02)	$ (2.44)
Weighted average common shares outstanding, basic and diluted	60,357,052	47,371,589
Comprehensive loss		
Net loss	$ (121,832)	$ (115,438)
Unrealized gain (loss) on marketable securities, net of tax	1,915	(981)
Comprehensive loss	$ (119,917)	$ (116,419)

PRELUDE THERAPEUTICS INCORPORATED
BALANCE SHEETS

	December 31,	
(in thousands, except share and per share data)	**2023**	**2022**
Assets		
Current assets:		
Cash and cash equivalents	$ 25,291	$ 30,605
Marketable securities	207,644	171,123
Prepaid expenses and other current assets	2,654	2,652
Total current assets	235,589	204,380
Restricted cash	4,044	4,044
Property and equipment, net	7,325	4,908
Right-of-use asset	30,412	1,792
Prepaid expenses and other non-current assets	295	5,376
Total assets	$ 277,665	$ 220,500
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 4,580	$ 6,777
Accrued expenses and other current liabilities	15,768	13,093
Operating lease liability	1,481	1,832
Total current liabilities	21,829	21,702
Other liabilities	3,339	3,361
Operating lease liability	15,407	—
Total liabilities	40,575	25,063
Commitments		
Stockholders' equity:		
Voting common stock, $0.0001 par value: 487,149,741 shares authorized; 42,063,995 and 36,496,994 shares issued and outstanding at December 31, 2023 and 2022, respectively	4	4
Non-voting common stock, $0.0001 par value: 12,850,259 shares authorized; 12,850,259 and 11,402,037 shares issued and outstanding at December 31, 2023 and 2022, respectively	1	1
Additional paid-in capital	693,252	531,682
Accumulated other comprehensive income (loss)	223	(1,692)
Accumulated deficit	(456,390)	(334,558)
Total stockholders' equity	237,090	195,437
Total liabilities and stockholders' equity	$ 277,665	$ 220,500