Prelude Therapeutics Reports Full Year 2021 Financial Results

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Significant progress achieved in 2021: Pipeline now includes six internally discovered small molecule compounds targeting clinically validated pathways in cancers with underserved patients

Objectives for 2022: Focused on demonstrating proof-of-concept clinical data for lead pipeline compounds and continued advancement of Prelude's diverse precision oncology pipeline

Cash runway guidance extended to 2H/2024

WILMINGTON, Del., March 16, 2022 (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, 2021.

"With Prelude's core competencies in cancer biology and medicinal chemistry, in approximately five years we have successfully created a highly differentiated diverse pipeline that includes five distinct targets and six proprietary small molecule compounds, each with best-in-class potential aimed at addressing clinically validated pathways for cancers with selectable underserved patients," stated Kris Vaddi, Ph.D., Chief Executive Officer of Prelude. "Given the clinical progress we made in 2021, we have made important strategic portfolio prioritization and resource allocation decisions focusing on select molecules and indications where we see the greatest need and most efficient path to establishing proof-of-concept. This includes selecting PRT811 as the lead candidate in our PRMT5 program and prioritizing development of the intravenous formulation of our MCL1 candidate, PRT1419, and rapidly selecting a Phase 2 dose for PRT2527, our CKD9 inhibitor, in selected patients with cancers dependent on CKD9."

"Our discovery team continued to exceed expectations by bringing two new candidates into our pipeline, a differentiated SMARCA2/BRM protein degrader and most recently, PRT3645, a differentiated, selective and highly brain penetrant CDK4/6 inhibitor. We remain on track to file Investigational New Drug applications for each of these molecules in 2022."

Dr. Vaddi added, "Dr. Jane Huang's appointment as President and Chief Medical Officer strengthens our leadership team. Dr. Huang's extensive experience in oncology drug development, strong associations within the oncology community and success in building high-performing clinical development and operational teams supports our commitment to discover and deliver safe and effective precision oncology medicines to patients with underserved cancers."

Program Highlights and 2022 Objectives

- **PRMT5:** Prelude is prioritizing PRT811 for continued clinical development focusing on splicing mutated myeloid malignancies and solid tumors, including uveal melanoma, and IDH1 mutated high grade gliomas. Prelude intends to complete the data analyses of the ongoing expansion cohorts for PRT543, including adenoid cystic carcinoma (ACC). Prelude expects to report data for the PRMT5 program in 2H/2022.

- **MCL1:** Prelude is prioritizing development of the intravenous (IV) formulation of PRT1419 which demonstrated a desirable pharmacokinetic, pharmacodynamic and safety profile with potential for differentiation from competitor compounds. Prelude plans to initiate a combination trial with venetoclax by mid-year and report data by year-end 2022.

- **CKD9**: Prelude intends to complete enrollment in the Phase 1 dose escalation study and identify a recommended Phase 2 dose by 2H/2022.

- **CDK4/6**: Prelude intends to file an Investigational New Drug (IND) application mid-year and initiate a Phase 1 trial in 2H/2022.

- **SMARCA2/BRM**: Prelude plans to complete IND-enabling studies and submit an IND application by year-end 2022.

Corporate Update

- On March 9, 2022, Prelude announced the appointment of Jane Huang, M.D., to the newly created position of President and Chief Medical Officer. Dr. Huang joins Prelude from BeiGene Ltd., where she served as Chief Medical Officer, Hematology. Currently, Dr. Huang serves as an Adjunct Clinical Assistant Professor in Thoracic Oncology at Stanford University.

Full Year 2021 Financial Results

- **Cash and Cash Equivalents:** Cash and cash equivalents as of December 31, 2021 were $291.2 million. Following Prelude's recently announced program prioritization initiatives, the Company has extended its cash guidance and anticipates that its existing cash, cash equivalents and marketable securities will fund Prelude's operations into the second half of 2024.

- **Research and Development (R&D) Expenses**: R&D expenses for the year ended December 31, 2021 increased $38.6 million to $86.8 million compared to $48.2 million for the year ended December 31, 2020. The increase year-over-year was primarily due to increased clinical research costs to support the advancement of Prelude's clinical programs and related chemistry, manufacturing and other costs for the clinical trials, in addition to an increase in discovery-stage program expenses.

- **General and Administrative (G&A) Expenses**: G&A expenses for the year ended December 31, 2021 increased by $16.4 million to $27.0 million compared to $10.6 million for the year ended December 31, 2020. The increase was primarily due to increased employee headcount and an increase in professional fees as Prelude expanded its operations to support R&D efforts and incurred additional costs associated with operating as a public company.

- **Net Loss:** Net loss for the year ended December 31, 2021 was $111.7 million or $2.43 per share, compared with a net loss of $56.9 million, or $4.56 per share for the year ended December 31, 2020.

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: PRT811 and PRT543, highly selective, potent, orally bioavailable PRMT5 inhibitors; PRT1419, a potent, selective inhibitor of MCL1; and PRT2527, a potent and highly selective CDK9 inhibitor. Additionally, the Company is progressing two novel preclinical candidates, PRT3645, a brain penetrant CDK4/6 inhibitor; and a potential first-in-class SMARCA2/BRM protein degrader.

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, timing of availability and announcements of clinical results, the timing of the expansion portion for its Phase 1 clinical trial for PRT543, PRT811 and PRT1419, the timing of IND-related activities for PRT2527 and PRT-SCA2, 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 second half 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

(in thousands, except share and per share data)	Year ended December 31, 2021	2020
Operating expenses:		
Research and development	$ 86,778	$ 48,177
General and administrative	26,957	10,586
Total operating expenses	113,735	58,763
Loss from operations	(113,735)	(58,763)
Other income, net	2,041	1,834
Net loss	$ (111,694)	$ (56,929)
Per share information:		
Net loss per share of common stock, basic and diluted	$ (2.43)	$ (4.56)
Weighted average common shares outstanding, basic and diluted	46,049,763	12,478,463
Comprehensive loss		
Net loss	$ (111,694)	$ (56,929)
Unrealized gain (loss) on marketable securities, net of tax	(711)	—
Comprehensive loss	$ (112,405)	$ (56,929)

PRELUDE THERAPEUTICS INCORPORATED
BALANCE SHEETS

(in thousands, except share and per share data)	December 31, 2021	2020
Assets		
Current assets:		
Cash and cash equivalents	$ 31,828	$ 218,309
Marketable securities	259,405	—
Prepaid expenses and other current assets	3,882	2,500
Total current assets	295,115	220,809
Restricted cash	4,044	—
Property and equipment, net	3,929	2,480
Right-of-use asset	1,707	—
Other assets	303	301
Total assets	$ 305,098	$ 223,590
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 7,840	$ 3,920
Accrued expenses and other current liabilities	9,621	7,455
Operating lease liability	1,740	—
Total current liabilities	19,201	11,375
Other liabilities	—	32
Total liabilities	19,201	11,407
Commitments (note 8)		
Stockholders' equity:		
Voting common stock, $0.0001 par value: 487,149,741 shares authorized; 36,200,299 and 32,595,301 shares issued and outstanding at December 31, 2021 and 2020, respectively	4	3
Non-voting common stock, $0.0001 par value: 12,850,259 shares authorized; 11,402,037 and 11,110,371 shares issued and outstanding at December 31, 2021 and 2020, respectively	1	1
Additional paid-in capital	505,723	319,605
Accumulated other comprehensive income (loss)	(711)	—
Accumulated deficit	(219,120)	(107,426)
Total stockholders' equity	285,897	212,183
Total liabilities and stockholders' equity	$ 305,098	$ 223,590

Investor Contacts:
Stacey Jurchison
Executive Director, Corporate Affairs
410-474-8200
sjurchison@preludetx.com

Melissa Forst
Argot Partners
212.600.1902
prelude@argotpartners.com

Media Contact:

Paige Donnelly
Argot Partners
212.600.1902
prelude@argotpartners.com