Prelude Therapeutics Announces Third Quarter 2021 Financial Results and Operations Update

November 12, 2021 1:00 PM EST

PRT543 and PRT811 Demonstrate Favorable Safety Profile, Tolerability and Evidence of Preliminary Clinical Activity in Phase 1 Dose Escalation in Unselected Patients

Phase 1 Dose Expansion Ongoing in Biomarker-Selected Solid Tumor and Hematologic Malignancy Expansion Cohorts for PRT543; Dose Expansion Portion of Phase 1 Trial of PRT811 to Commence 4Q21 with Data Readouts Anticipated for Both Programs in 2022

PRT2527 IND Cleared by FDA; Phase 1 Clinical Trial Evaluating IV Monotherapy in Patients with Selected Solid Tumors Anticipated to Begin by Year-End

Strong Cash, Cash Equivalents and Marketable Securities Position of $320 Million to Support Clinical and Discovery Pipeline Advancement

WILMINGTON, Del., Nov. 12, 2021 (GLOBE NEWSWIRE) -- Prelude Therapeutics Inc. (Nasdaq: PRLD), a clinical-stage precision oncology company, today announced its financial results for the third quarter ended September 30, 2021 and provided an update on recent clinical and development pipeline progress.

"We continue to make significant progress advancing our novel pipeline of therapeutic candidates, most notably with the recent presentation of dose escalation data from the Phase 1 trials of our lead PRMT5 inhibitors, PRT543 and PRT811," said Kris Vaddi, PhD, Chief Executive Officer. "We were pleased by these initial data in unselected patients, which demonstrated key points of differentiation for our molecules, including good tolerability and potency, and a desirable therapeutic window. In addition, evidence of preliminary clinical activity was observed in multiple tumor types displaying preclinically validated genomic features. We look forward to leveraging learnings from these data as we execute on the dose escalation portion of the trials and evaluate PRT543 and PRT811 in biomarker-selected patient populations, with data readouts from these cohorts anticipated in 2022. Beyond our PRMT5 inhibitors, the balance of our pipeline continues to advance. During the quarter we received IND clearance from the FDA for PRT2527, our CDK9 inhibitor, positioning us to commence a Phase 1 study of this molecule before year-end."

Recent Highlights and Upcoming Milestones

PRT543

- **Phase 1 Dose Escalation Study Data Presented at the AACR-NCI-EORTC Annual Meeting; Data from Expansion Cohorts to be Presented in 2022**: In October 2021, the Company presented data from the dose escalation portion of its Phase 1 trial of PRT543, which is designed to be a potent and selective inhibitor of PRMT5, in unselected patient populations. PRT543 demonstrated target engagement and inhibition of PRMT5 functional activity, as well as preliminary clinical activity. PRT543 was generally well tolerated. Patient enrollment is ongoing in specific biomarker-selected solid tumor and hematologic malignancy expansion cohorts. The Company expects to present data from the expansion cohorts in 2022.

- **Phase 1 Dose Escalation Data for PRT543 in Patients with Myeloid Malignancies to be Presented at the 63rd American Society of Hematology (ASH) Annual Meeting**: Data from the dose escalation portion of the ongoing Phase 1 clinical trial of PRT543 in patients with myelodysplastic syndrome (MDS) and myelofibrosis (MF), including safety, pharmacokinetics, pharmacodynamics, and preliminary clinical activity, will be featured during a poster session at the 63rd ASH Annual Meeting and Exposition being held December 11-14, 2021.

PRT811

- **Phase 1 Dose Escalation Study Data Presented at the AACR-NCI-EORTC Annual Meeting; Dose Expansion Portion of Phase 1 Trial to Commence 4Q21:** In October 2021, the Company presented data from the dose escalation portion of its Phase 1 trial of PRT811, which is designed to be a potent, selective, and brain penetrant PRMT5 inhibitor, in patients with unselected advanced solid tumors. PRT811 demonstrated dose dependent inhibition of

PRMT5 activity and demonstrated signs of preliminary clinical activity. PRT811 was generally well-tolerated. Prelude will shortly commence the dose expansion portion of the Phase 1 trial in selected patients with central nervous system cancers (CNS) and non-CNS cancers. The Company expects to present data from the expansion cohorts in 2022.

PRT1419

- **Phase 1 Dose Escalation Portion of Oral and Intravenous (IV) PRT1419 Trial Ongoing**: The dose escalation portion of the Company's first-in-human Phase 1 study investigating both an oral and IV formulation of MCL-1 inhibitor, PRT1419, the Company's third clinical candidate, in patients with relapsed/refractory hematologic malignancies, including acute myeloid leukemia and high-risk myelodysplastic syndromes, and solid tumors, remains ongoing. The Company expects to add dose expansion and combination cohorts to the Phase 1 clinical trial in the first half of 2022.

PRT2527

- **Dose Escalation Phase 1 Trial of PRT2527 on Track to Begin by Year-End:** During the third quarter the Company received clearance for an Investigational New Drug (IND) application for PRT2527, which is designed to be a potent and selective CDK9 inhibitor. The Company anticipates beginning a Phase 1 trial of PRT2527 by year-end evaluating IV infusion monotherapy in patients with selected solid tumors.

- **Preclinical Data Presented at the AACR-NCI-EORTC Annual Meeting:** In October 2021, the Company presented new preclinical data demonstrating that intermittent intravenous administration of PRT2527 demonstrated strong efficacy in hematological malignancies and solid tumor models with *MYC* dysregulation.

Discovery Programs

- The Company continues to expect to initiate IND-enabling studies for PRT-SCA2, which is designed to be a SMARCA2 protein degrader, by year-end. The Company also continues to make progress in the PRT-K4 discovery program and expects to initiate IND-enabling studies by year-end.

Corporate Update

- On November 5, 2021, Brian Piper, our Chief Financial Officer, notified the Company that he will be resigning from the Company, effective November 19, 2021, to pursue other opportunities.

- The Company today announced the appointment of Laurent Chardonnet as its new Chief Financial Officer starting November 29, 2021. Mr. Chardonnet joins from Axcella Health where, since 2019, he served as Senior Vice President, CFO. Prior to Axcella, he spent 15 years at Incyte Corporation where he held roles of increasing responsibility including Vice President Finance, Treasurer and Principal Accounting Officer, Head of Finance and Administration for the company's European division, and Vice President of Alliances and Global Strategy. Mr. Chardonnet received his Master of Business Administration from Vanderbilt University and his initial business degree from the Institut Supérieur de Gestion in Paris

- The Company and Dr. David Mauro, the Company's Chief Medical Officer, mutually agreed

that Dr. Mauro would depart from the Company to pursue other opportunities. Dr. Mauro's last day with the Company was on November 9, 2021. The Company has an ongoing search for a successor. Dr. Victor Sandor, former Chief Medical Officer of Array Biopharma and current board member and chair of the Science and Technology Committee, will provide strategic and operational oversight of clinical development during this time.

Third Quarter 2021 Financial Results

- **Cash, Cash Equivalents, and Marketable Securities:** Cash, cash equivalents, and marketable securities as of September 30, 2021 were $320.9 million.

- **Research and Development (R&D) Expenses**: For the third quarter of 2021, R&D expense increased by $7.4 million to $22.7 million for the three months ended September 30, 2021 from $15.3 million for the three months ended September 30, 2020. The increase was mainly due to increased clinical research costs to support the advancement of our clinical programs as well as an increase in discovery-stage program expenses. Our chemistry, manufacturing and other costs for the clinical trials also increased.

- **General and Administrative (G&A) Expenses**: For the third quarter of 2021, G&A expense increased by $5.2 million to $8.1 million for the three months ended September 30, 2021 from $2.9 million for the three months ended September 30, 2020. The increase was primarily due to an increase in personnel related expense due to an increase in employee headcount and an increase in our professional fees as we expanded our operations to support our research and development efforts and incurred additional costs to operate as a public company.

- **Net Loss:** For the third quarter of 2021, net loss was $30.7 million, or $0.66 per share, compared with a net loss of $16.8 million, or $5.25 per share, for the same period in 2020.

- **Financial Guidance:** The Company believes that its current cash, cash equivalents and marketable securities will be sufficient to fund operating expenses and capital expenditure requirements into the second half of 2023.

About Prelude Therapeutics

Prelude Therapeutics is a clinical-stage precision oncology company developing innovative, potential best-in-class molecules targeting critical cancer cell pathways involved in cancer pathogenesis. Prelude's initial clinical candidates, PRT543 and PRT811, are potent, selective, oral PRMT5 inhibitors in Phase 1 development for the treatment of advanced solid tumors, primary and secondary CNS cancers and select myeloid malignancies. PRT1419, a potent and selective MCL1 inhibitor, is in Phase 1 development for patients with relapsed/refractory hematologic malignancies and solid tumors. PRT2527, a highly selective CDK9 inhibitor, is anticipated to begin Phase 1 clinical development by year-end as a monotherapy in patients with selected solid tumors. In addition, the Company's pipeline includes PRT-SCA2, a SMARCA2 protein degrader, PRT-K4, a highly selective kinase inhibitor, and additional discovery stage programs.

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 and the potential benefits of the Company's product candidates and platform. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. Although the Company believes that the expectations reflected in such forward-looking statements are reasonable, the Company 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 the Company's actual activities or results to differ significantly from those expressed in any forward-looking statement, including risks and uncertainties related to the Company'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 the Company's business, clinical trial sites, supply chain and manufacturing facilities, the Company's ability to maintain and recognize the benefits of certain designations received by product candidates, the timing and results of preclinical and clinical trials, the Company's ability to fund development activities and achieve development goals, the Company's ability to protect intellectual property, and other risks and uncertainties described under the heading "Risk Factors" in documents the Company 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 the Company undertakes no obligation to revise or update any forward-looking statements to reflect events or circumstances after the date hereof.

STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(UNAUDITED)

(in thousands, except share and per share data)	Three Months Ended September 30, 2021	2020
Operating expenses:		
Research and development	$ 22,721	$ 15,293
General and administrative	8,115	2,851
Total operating expenses	30,836	18,144
Loss from operations	(30,836)	(18,144)
Other income, net	149	1,384
Net loss	$ (30,687)	$ (16,760)
Per share information:		
Net loss per share of common stock, basic and diluted	$ (0.66)	$ (5.25)
Weighted average common shares outstanding, basic and diluted	46,330,794	3,194,471
Comprehensive loss		
Net loss	$ (30,687)	$ (16,760)
Unrealized gain(loss) on marketable securities, net of tax	(176)	—
Comprehensive loss	$ (30,863)	$ (16,760)

BALANCE SHEETS
(UNAUDITED)

(in thousands, except share data)	September 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 61,424	$ 218,309
Marketable securities	259,441	—
Prepaid expenses and other current assets	5,032	2,500
Total current assets	325,897	220,809
Property and equipment, net	3,213	2,480
Right-of-use asset	2,107	—
Deferred offering costs	—	301
Total assets	$ 331,217	$ 223,590
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 11,062	$ 3,920
Accrued expenses and other current liabilities	6,765	7,455
Operating lease liability	1,836	—
Total current liabilities	19,663	11,375
Other liabilities	—	32
Operating lease liability	312	—
Total liabilities	19,975	11,407
Stockholders' equity:		
Voting common stock, $ par value: 487,149,741 shares authorized; 35,789,759 and 32,595,301 shares issued and outstanding at September 30, 2021 and December 31, 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 September 30, 2021 and December 31, 2020, respectively	1	1
Additional paid-in capital	497,691	319,605
Accumulated other comprehensive income (loss)	(176)	—
Accumulated deficit	(186,278)	(107,426)
Total stockholders' equity	311,242	212,183
Total liabilities and stockholders' equity	$ 331,217	$ 223,590

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