Prelude Therapeutics Announces Third Quarter 2020 Financial Results

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- Completed Initial Public Offering of Common Stock, Raising Gross Proceeds of ~$181.9M -

- Partial Response Confirmed in Glioblastoma Multiforme Patient in Phase 1 Trial of PRT811 -

- Durable Complete Response Ongoing in HRD+ High Grade Serous Ovarian Cancer Patient in Phase 1 Trial of PRT543 -

WILMINGTON, Del., Nov. 10, 2020 (GLOBE NEWSWIRE) -- Prelude Therapeutics Incorporated ("Prelude", "the Company", "we") (Nasdaq: PRLD), a clinical-stage precision oncology company, today announced its financial results for the third quarter ended September 30, 2020 and provided an update on recent developments.

"Prelude has evolved substantially to become a clinical-stage precision oncology company with multiple small molecule oral agents currently advancing through clinical trials," said Kris Vaddi, PhD, Chief Executive Officer, Prelude Therapeutics. "We continue to make great progress in advancing the clinical development of our lead PRMT5 inhibitors, PRT543 and PRT811, and believe we are well-positioned for continued success with the execution of these programs. We look forward to sharing additional data from each program in 2021."

Dr. Vaddi added, "Beyond our PRMT5 program, we recently advanced our third product candidate, MCL1 inhibitor PRT1419, into the clinic for patients with hematologic malignancies, while our discovery engine continues to generate a diverse and robust pipeline. On the heels of our recent initial public offering resulting in gross proceeds of $181.9 million, we look forward to achieving additional clinical and regulatory milestones in the coming quarters."

Clinical Program Highlights

PRT543

- **Dose Expansion Portion of Phase 1 Trial to Commence by Year-End.** The Company remains on track to commence the expansion portion of its Phase 1 trial of its lead product candidate, PRT543, which is designed to be a potent, selective, and oral inhibitor of PRMT5, in select solid tumor cohorts during the fourth quarter of 2020 and in select myeloid malignancy cohorts in early 2021. The expansion cohorts will include patients with adenoid cystic carcinoma (ACC), myelofibrosis (MF), genomically-selected myelodysplastic syndrome (MDS), and homologous recombination deficient positive (HRD+) tumors. Preliminary data from the dose escalation portion of the trial demonstrated early signs of clinical activity and tolerability, including a durable confirmed complete response (CR) in a patient with HRD+ high grade serous ovarian cancer who had received seven prior lines of therapy. The Company anticipates obtaining initial clinical data from these expansion cohorts in the first half of 2021 and presenting these data at medical meetings in 2021.

PRT811

- **Dose Escalation Ongoing in Phase 1 Trial in Patients with Advanced Solid Tumors and Recurrent High-Grade Gliomas.** The dose escalation portion of the Company's Phase 1 trial of its second clinical product candidate, PRT811, which is designed to be a potent, selective, and brain penetrant PRMT5 inhibitor, in patients with advanced solid tumors, including glioblastoma multiforme (GBM) and primary central nervous system lymphomas (PCNSL), remains ongoing. To date, the trial has demonstrated early signs of clinical activity and tolerability. The previously disclosed refractory GBM patient whose tumor had demonstrated a 66% reduction on monotherapy PRT811 has subsequently undergone a follow-up MRI at week 16 confirming a partial response (PR) per RANO (response assessment in neuro-oncology) criteria. The Company expects to commence the dose expansion portion of the trial in the first half of 2021, with data expected by the end of 2021.

PRT1419

- **Dosed First Patient in Phase 1 Trial of MCL1 Inhibitor PRT1419 for the Treatment of Relapsed/Refractory Hematologic Malignancies.** In September 2020, Prelude announced dosing of the first patient in its first-in-human Phase 1 open-label, multicenter, dose-escalation study of PRT1419 in patients with relapsed/refractory hematologic malignancies. PRT1419, the Company's third clinical candidate, is designed to be an orally available, potent, and selective MCL1 inhibitor.

Corporate Update

- **Completed Initial Public Offering (IPO).** In September 2020, Prelude closed its IPO of 9,573,750 shares of common stock, including the full exercise of the underwriters' option to purchase up to 1,248,750 additional shares of common stock, at a public offering price of $19.00 per share. Aggregate gross proceeds to Prelude were approximately $181.9 million, before deducting underwriting discounts and commissions and other offering expenses of $15.3 million.

- **Strengthened Board of Directors with Two New Appointments.** In August 2020, the Company announced the appointment of Mardi C. Dier and Victor Sandor, M.D., both highly accomplished industry veterans, to its Board of Directors.

Third Quarter 2020 Financial Results

- **Cash and cash equivalents:** Cash and cash equivalents as of September 30, 2020 were $234.8 million.

- **Research and Development (R&D) Expenses:** For the third quarter of 2020, R&D expenses increased by $9.8 million to $15.3 million compared to $5.5 million for the third quarter of 2019. The increase was mainly due to increased clinical research costs for the PRT543 and PRT811 clinical trials and increased costs associated with the initiation of the clinical trial for PRT1419, which began in the third quarter of 2020. Prelude also incurred an increase in chemistry, manufacturing, and other costs for those trials.

- **General and Administrative (G&A) Expenses:** For the third quarter of 2020, G&A expenses increased by $1.5 million to $2.9 million compared to $1.4 million for the third quarter of 2019. The increase was primarily due to an increase in personnel related expense due to increases in employee headcount and an increase in professional fees as Prelude expanded its operations to support its research and development efforts and incurred additional costs to operate as a public company.

- **Net Loss:** For the third quarter of 2020, net loss was $16.8 million, or $5.25 per share, compared to a net loss of $6.7 million, or $3.93 per share, for the third quarter of 2019.

About Prelude Therapeutics

Prelude Therapeutics is a clinical-stage precision oncology company developing innovative drug candidates targeting critical cancer cell pathways. The Company's lead product candidates are designed to be oral, potent, and selective inhibitors of PRMT5. Prelude's first clinical candidate, PRT543, is in Phase 1 development for advanced solid tumors and select myeloid malignancies. Prelude is also advancing PRT811, a second PRMT5 inhibitor optimized for high brain exposure, in a Phase 1 clinical trial including glioblastoma multiforme (GBM). The Company's diverse clinical pipeline also includes PRT1419, an orally available MCL1 inhibitor in Phase 1 development for patients with relapsed/refractory hematologic malignancies, PRT2527, a CDK9 inhibitor, and PRT-SCA2, a SMARCA2 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 and PRT811 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
(unaudited)

	Three Months Ended September 30,	
(in thousands, except share and per share data)	**2020**	**2019**
Operating expenses:		
Research and development	$ 15,293	$ 5,490
General and administrative	2,851	1,394
Total operating expenses	18,144	6,884
Loss from operations	(18,144)	(6,884)
Other income, net	1,384	150
Net loss	$ (16,760)	$ (6,734)
Per share information:		
Net loss per share of common stock, basic and diluted	$ (5.25)	$ (3.93)
Weighted average common shares outstanding, basic and diluted	3,194,471	1,713,371

Balance Sheets
(unaudited)

(in thousands, except share data)	**September 30, 2020**	**December 31, 2019**
Assets		
Current assets:		
Cash and cash equivalents	$ 234,792	$ 18,879
Prepaid expenses and other current assets	3,269	1,345
Total current assets	238,061	20,224
Property and equipment, net	1,620	1,647
Total assets	$ 239,681	$ 21,871
Liabilities, convertible preferred stock and stockholders' equity (deficit)		
Current liabilities:		
Capital lease obligation	$ —	$ 258
Accounts payable	5,074	1,974
Accrued expenses and other current liabilities	6,285	2,603
Total current liabilities	11,359	4,835
Other liabilities	15	5
Total liabilities	11,374	4,840
Convertible preferred stock, $0.0001 par value:		
Series A convertible preferred stock: No shares and 13,574,008 shares authorized at September 30, 2020 and December 31, 2019, respectively; no shares and 11,736,119 shares issued and outstanding at September 30, 2020 and December 31, 2019, respectively	—	36,595
Series B convertible preferred stock: No shares and 18,500,000 shares authorized at September 30, 2020 and December 31, 2019; No shares and 7,628,846 shares issued and outstanding at September 30, 2020 and December 31, 2019, respectively	—	29,848
Series C convertible preferred stock: no shares authorized, issued or outstanding at September 30, 2020 and December 31, 2019	—	—
Total convertible preferred stock	—	66,443
Stockholders' equity (deficit):		

Voting common stock, $0.0001 par value: 487,149,741 and 42,000,000 shares authorized at September 30, 2020 and December 31, 2019, respectively; 32,593,010 and 3,161,653 shares issued and outstanding at September 30, 2020 and December 31, 2019, respectively	3	—
Non-voting common stock, $0.0001 par value; 12,850,259 and no shares authorized at September 30, 2020 and December 31, 2019, respectively; 11,110,371 and no shares issued and outstanding at September 30, 2020 and December 31, 2019, respectively	1	—
Additional paid-in capital	316,479	1,085
Accumulated deficit	(88,176)	(50,497)
Total stockholders' equity (deficit)	228,307	(49,412)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 239,681	$ 21,871

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