Plus Therapeutics Reports Second Quarter 2021 Financial Results and Business Highlights

July 22, 2021
Management to host conference call today at 5:00 pm ET

AUSTIN, Texas, July 22, 2021 (GLOBE NEWSWIRE) -- Plus Therapeutics, Inc. (Nasdaq: PSTV) (the "Company"), a clinical-stage pharmaceutical company developing innovative, targeted radiotherapeutics for rare and difficult-to-treat cancers, today announced financial results for the second quarter ended June 30, 2021, and provided an overview of recent business highlights.

"Our focus remains on completion of our Phase 1 dose escalation ReSPECT™-GBM trial, which is evaluating the Company's lead investigational drug, Rhenium-186 NanoLiposome (^{186}RNL) in recurrent glioblastoma (GBM), expansion of our ^{186}RNL pipeline, and GMP production of ^{186}RNL to be available in mid-2022 for a potential registrational trial," said Marc H. Hedrick M.D., President and Chief Executive Officer of Plus Therapeutics. "We believe that the evolving clinical data in ReSPECT™ shows that high doses of precisely delivered beta radiation in patients with recurrent GBM is both feasible and safe. We intend to provide a comprehensive update on the data later this year."

RECENT HIGHLIGHTS

Rhenium-186 NanoLiposome (^{186} RNL), a novel radiotherapy in development for several rare cancer targets

Recurrent Glioblastoma (GBM)

- The U.S. multi-center ReSPECT™-GBM Phase 1 dose-finding clinical trial is designed to safely and effectively deliver high doses of radiation directly to brain tumors. Thus far, 22 patients with recurrent GBM have been treated in the ReSPECT™-GBM trial across eight cohorts. Absorbed radiation doses of up to 740 Gray per tumor have been achieved without dose-limiting toxicities.
- In June 2021, the Data and Safety Monitoring Board (DSMB) recommended the Company proceed to the eighth dosing cohort of the ReSPECT™-GBM trial, which implemented a 40% increase in total radioactivity and volume. The first patient in the eighth cohort was treated in July 2021.

Leptomeningeal Metastases (LM)

- In the second quarter of 2021, the Company received a positive response to the ^{186}RNL pre-Investigational New Drug (IND) meeting briefing package that it submitted in the first quarter of 2021 to the U.S. Food and Drug Administration (FDA) for the treatment of LM.
- The Company intends to submit an IND application to the FDA and, upon approval, begin a ReSPECT™-LM Phase 1 clinical trial of ^{186}RNL for the treatment of LM by the end of 2021.

Pediatric Brain Cancer (PBC)

- In the first quarter of 2021, the Company submitted a ^{186}RNL pre-IND meeting briefing package to the FDA for treatment of various pediatric brain cancers.
- Based on the feedback from the FDA, the Company is not required to perform additional preclinical or toxicology studies and intends to submit an IND application to begin a ReSPECT™-PBC Phase 1 clinical trial of ^{186}RNL for the treatment of pediatric brain cancer in 2022.
- On June 10, 2021, a poster titled, "*A two-part, Phase I study of Rhenium-186 Nanoliposomes (^{186}RNL) delivered by convection enhanced delivery (CED) for recurrent, refractory, or progressive ependymoma and high-grade glioma (HGG)*" was presented at the 6th Biennial Pediatric Neuro-Oncology Research Conference. The data included a review of relevant preclinical research, the Company's Phase 1 ReSPECT™-GBM clinical trial and a proposed design for initiating a Phase I clinical trial in PBC.

Commercial Manufacturing and Supply Chain

- Thus far in 2021, the Company has entered into four collaboration agreements to support the Company's process development and analytical chemistry activities, as well as to strengthen its commercial supply chain in compliance with current good manufacturing practices (cGMP), for the manufacture of commercial grade ^{186}RNL.

EXPECTED UPCOMING CLINICAL MILESTONES AND EVENTS FOR 2021

During the remainder of 2021, the Company intends to focus on the following key business objectives and milestones:

- Complete enrollment of the eighth cohort in the company's ReSPECT™-GBM Phase 1 clinical trial.
- Complete pivotal trial planning in conjunction with the FDA feedback for ^{186}RNL in recurrent GBM.
- Submit IND applications to initiate clinical investigation of ^{186}RNL for LM and PBC.
- Complete planned 2021 CMC activities such that cGMP ^{186}RNL will be available in mid-2022.

SECOND QUARTER 2021 FINANCIAL RESULTS

- As of June 30, 2021, the Company's cash balance was $17.2 million, compared to $8.3 million as of December 31, 2020.
- Total operating expenses for the second quarter of 2021 were $2.6 million, compared to total operating expenses of $2.5 million for the same quarter in 2020.
- Net loss for the second quarter of 2021 was $2.8 million, or $(0.25) per share, compared to a net loss of $1.8 million, or $(0.45) per share, for the same quarter in 2020. The increase in net loss is primarily due to the gain in the fair value of warrants in the second quarter of 2020.

Second Quarter 2021 Results Conference Call

The Company will hold a conference call and live audio webcast at 5:00 p.m. Eastern Time today to discuss its financial results and provide a general business update.

Event:	Plus Therapeutics Second Quarter 2021 Results Conference Call
Date:	Thursday, July 22, 2021
Time:	5:00 p.m. Eastern Time
Live Call:	877-876-9174 (toll free); 785-424-1669 (Intl.); Conference ID: PSTVQ221

The webcast can be accessed live via the investor section of the Plus Therapeutics website at ir.plustherapeutics.com/events and will be available for replay beginning two hours after the conclusion of the conference call.

About Plus Therapeutics, Inc.

Plus Therapeutics is a clinical-stage pharmaceutical company whose radiotherapeutic portfolio is concentrated on nanoliposome-encapsulated radionuclides for several cancer targets. Central to the Company's drug development is a unique nanotechnology platform designed to reformulate, deliver and commercialize multiple drugs targeting rare cancers and other diseases. The platform is designed to facilitate new delivery approaches and/or formulations of safe and effective, injectable drugs, potentially enhancing the safety, efficacy and convenience for patients and healthcare providers. More information may be found at PlusTherapeutics.com and ReSPECT-Trials.com.

Cautionary Statement Regarding Forward-Looking Statements

This press release contains statements that may be deemed "forward-looking statements" within the meaning of U.S. securities laws. All statements in this press release other than statements of historical fact are forward-looking statements. These forward-looking statements may be identified by future verbs, as well as terms such as "will," "believe," "plan," "can," "enable," "design," "intend," "potential," "expect," "estimate," "project," "prospect," "target," "focus," "anticipate," "could," "should," and similar expressions or the negatives thereof. Such statements are based upon certain assumptions and assessments made by management in light of their experience and their perception of historical trends, current conditions, expected future developments and other factors they believe to be appropriate. These statements include, without limitation, statements regarding the following: the Company's anticipated expenditures, including research and development, sales and marketing, and general and administrative expenses; anticipated benefits of strategic collaborations and license agreements, intellectual property, FDA approval process and government regulation; the Company's ability to benefit from the NIH/NCI award for continued clinical development of ^{186}RNL for recurrent glioblastoma; the ability of ^{186}RNL to safely and effectively deliver radiation directly to the tumor at high doses; the Company's ability to expand clinical testing of ^{186}RNL to additional sites; the potential size of the market for the Company's product candidates; the Company's research and development efforts; the Company's IP strategy; competition; future development and/or expansion of its product candidates and therapies in its markets; the Company's ability to generate product or development revenue and the sources of such revenue; the amounts that the Company may be obligated to pay under license agreements; the Company's ability to effectively manage its gross profit margins; its ability to obtain and maintain regulatory approvals; expectations as to the Company's future performance; the Company's need for additional financing and the availability thereof; its ability to fully access its equity line with Lincoln Park; any changes to its interest expenses; the Company's ability to continue as a going concern; its ability to remain listed on the Nasdaq Capital Market; the Company's ability to repay or refinance some or all of its outstanding indebtedness and its ability to raise capital in the future; expectations as to the impact of recently issued or adopted accounting standards; the Company's expectations as to the impact of the COVID-19 pandemic on its business and operating results; the Company's beliefs as to the impact of any liability that may arise as a result of any legal proceedings; and the potential enhancement of the Company's cash position through development, marketing, and licensing arrangements.

The forward-looking statements included in this press release are subject to a number of risks and uncertainties that may cause actual results to differ materially from those discussed in such forward-looking statements. These risks and uncertainties include, but are not limited to the following: the early stage of the Company's product candidates and therapies, the results of the Company's research and development activities, including uncertainties relating to the clinical trials of its product candidates and therapies; the Company's liquidity and capital resources and its ability to raise additional cash, the outcome of the Company's partnering/licensing efforts, risks associated with laws or regulatory requirements applicable to it, market conditions, product performance, litigation or potential litigation, and competition within the regenerative medicine field, among others; and additional risks described under the heading "Risk Factors" in the Company's Securities and Exchange Commission filings, including in the Company's annual and quarterly reports. There may be events in the future that the Company is unable to predict, or over which it has no control, and its business, financial condition, results of operations and prospects may change in the future. The Company assumes no responsibility to update or revise any forward-looking statements to reflect events, trends or circumstances after the date they are made unless the Company has an obligation under U.S.

federal securities laws to do so.

PLUS THERAPEUTICS, INC.
CONSOLIDATED CONDENSED BALANCE SHEETS
(Unaudited)
(in thousands, except share and par value data)

	June 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 17,161	$ 8,346
Other current assets	840	829
Total current assets	18,001	9,175
Property and equipment, net	1,738	1,820
Operating lease right-of-use assets	638	636
Goodwill	372	372
Intangible assets, net	69	86
Other assets	16	16
Total assets	$ 20,834	$ 12,105
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 1,609	$ 2,081
Operating lease liability	127	123
Term loan obligations, net of discount	6,618	6,335
Total current liabilities	8,354	8,539
Noncurrent operating lease liability	530	528
Warrant liability	5	7
Total liabilities	8,889	9,074
Stockholders' equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized; 1,952 and 1,954 shares issued and outstanding at June 30, 2021 and December 31, 2020, respectively	—	—
Common stock, $0.001 par value; 100,000,000 shares authorized; 12,087,525 and 6,749,028 shares issued and outstanding at June 30, 2021 and December 31, 2020, respectively	12	7
Additional paid-in capital	450,964	436,535
Accumulated deficit	(439,031)	(433,511)
Total stockholders' equity	11,945	3,031
Total liabilities and stockholders' equity	$ 20,834	$ 12,105

PLUS THERAPEUTICS, INC.
CONSOLIDATED CONDENSED STATEMENTS OF OPERATIONS
(Unaudited)
(in thousands, except share and per share data)

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2021	2020	2021	2020
Development revenues:				
Government contracts and other	$ —	$ 185	$ —	$ 303
Operating expenses:				
Research and development	1,106	327	2,233	1,268
In process research and development acquired from NanoTx	—	781	—	781
General and administrative	1,469	1,429	2,821	3,047
Total operating expenses	2,575	2,537	5,054	5,096
Loss from operations	(2,575)	(2,352)	(5,054)	(4,793)
Other income (expense):				
Interest income	4	9	8	45
Interest expense	(229)	(252)	(476)	(601)

Change in fair value of warrants	—	756	2	2,423
Total other income (expense)	(225)	513	(466)	1,867
Net loss	$ (2,800)	$ (1,839)	$ (5,520)	$ (2,926)
Net loss per share, basic and diluted	$ (0.25)	$ (0.45)	$ (0.56)	$ (0.74)
Basic and diluted weighted average shares used in calculating net loss per share attributable to common stockholders	11,296,816	4,053,242	9,790,726	3,967,392

PLUS THERAPEUTICS, INC.
CONSOLIDATED CONDENSED STATEMENTS OF CASH FLOWS
(Unaudited)
(in thousands)

	For the Six Months Ended June 30,	
	2021	**2020**
Cash flows used in operating activities:		
Net loss	$ (5,520)	$ (2,926)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	179	188
Amortization of deferred financing costs and debt discount	283	275
In process research and development acquired from NanoTx Therapeutics	—	781
Noncash lease expenses	4	9
Change in fair value of warrants	(2)	(2,423)
Stock-based compensation expense	245	55
Increases (decreases) in cash caused by changes in operating assets and liabilities:		
Accounts receivable	—	218
Other current assets	(11)	487
Other assets	—	54
Accounts payable and accrued expenses	(583)	371
Net cash used in operating activities	(5,405)	(2,911)
Cash flows used in investing activities:		
Purchases of property and equipment	(80)	(23)
In process research and development acquired from NanoTx Therapeutics	—	(400)
Net cash used in investing activities	(80)	(423)
Cash flows provided by (used in) financing activities:		
Principal payments of long-term obligations	-	(5,307)
Payment of financing lease liability	(8)	(51)
Proceeds from exercise of warrants	2,017	366
Proceeds from sale of common stock, net	12,291	—
Net cash provided by (used in) financing activities	14,300	(4,992)
Net increase (decrease) in cash and cash equivalents	8,815	(8,326)
Cash and cash equivalents at beginning of period	8,346	17,592
Cash and cash equivalents at end of period	17,161	9,266
Supplemental disclosure of cash flows information:		
Cash paid during period for:		
Interest	$ 290	$ 372
Supplemental schedule of non-cash investing and financing activities:		
Common stock issued in payment for in process research and development	$ —	$ 381
Unpaid offering cost	$ 119	$ —
Right-of-use asset obtained in exchange for lease liabilities	$ 81	$ —

Investor Contact
Peter Vozzo
Westwicke/ICR
(443) 377-4767
Peter.Vozzo@westwicke.com

Media Contact
Terri Clevenger
Westwicke/ICR
(203) 856-4326
Terri.Clevenger@westwicke.com

Source: Plus Therapeutics Inc.