Plus Therapeutics Reports First Quarter 2022 Financial Results and Business Highlights

April 21, 2022

First patient dosed in ReSPECT-LM Phase 1/2a dose escalation trial of ^{186} RNL for leptomeningeal metastases

Closed in-licensing transaction for novel targeted radioembolic technology for the treatment of solid organ tumors

Expanded ReSPECT-GBM clinical trial partnership with Medidata to design innovative registrational trial of ^{186} RNL for recurrent glioblastoma

Management to host conference call today at 5:00 p.m. ET

AUSTIN, Texas, April 21, 2022 (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 first quarter ended March 31, 2022, and provided an overview of recent business highlights.

"In the first quarter of 2022, we announced a major corporate milestone, specifically the successful enrollment of the first patient in our ReSPECT-LM Phase 1/2a dose escalation trial of ^{186}RNL in patients with leptomeningeal metastases," said Marc H. Hedrick M.D., President and Chief Executive Officer of Plus Therapeutics. "This adds a very important new clinical program to our growing drug development pipeline targeting significant unmet medical conditions."

RECENT HIGHLIGHTS

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

- Treated first patient in the ReSPECT-LM Phase 1/2a dose escalation trial of ^{186}RNL in patients with leptomeningeal metastases (LM).
- Finalized key ^{186}RNL drug product development and characterization activities for GMP manufacturing to support planned Phase 2 registrational clinical trial and commercialization of ^{186}RNL in recurrent glioblastoma (GBM).
- Expanded partnership with Medidata Solutions, Inc., a Dassault Systèmes company, utilizing Medidata's Synthetic Control Arm® (SCA) platform intended to speed enrollment, improve patient access and reduce clinical trial costs in Plus Therapeutics' planned Phase 2 registrational trial of ^{186}RNL in GBM.
- Presentation at the *American Association for Cancer Research (AACR) 2022 Annual Meeting* describing a biology-based, mathematical model to predict response of recurrent GBM to ^{186}RNL treatment (Poster).

Rhenium-188 NanoLiposome Biodegradable Alginate Microsphere (^{188} RNL-BAM), a novel radiotherapy in development for solid organ cancers

- Announced the in-licensing of a novel targeted radioembolic technology for the treatment of solid organ tumors and biodegradable alginate microspheres (BAM) technology for both diagnostic and/or therapeutic payloads.
- The Company began developing ^{188}RNL-BAM as a next-generation radioembolization therapy for rare solid organ cancers including liver cancer.

FIRST QUARTER 2022 FINANCIAL RESULTS

- The Company's cash balance was $21.2 million at March 31, 2022, compared to $18.4 million at December 31, 2021.
- Total operating expenses for the first quarter 2022 were $3.9 million, compared to total operating expenses of $2.5 million for first quarter 2021. Approximately $0.7 million of this increase is due to research and development expenses and $0.7 million to legal, intellectual property and professional fees.
- Net loss for the first quarter of 2022 was $4.1 million, or $(0.19) per share, compared to a net loss of $2.7 million, or $(0.33) per share, for the first quarter of 2021.

UPCOMING EVENTS AND MILESTONES

During the remainder of 2022, the Company expects to accomplish the following key business objectives:

- Upon U.S. Food and Drug Administration (FDA) approval, initiate a Phase 2/registrational trial in patients with recurrent GBM.
- Complete FDA CMC and clinical meetings for ^{186}RNL.
- Manufacture GMP ^{186}RNL for Phase 2 registrational trials.
- Obtain FDA approval for ReSPECT-GBM multiple dosing clinical trial arm.
- Complete initial safety cohort in ReSPECT-LM Phase 1/2a dose escalation trial.

- Obtain FDA approval for study of ^{186}RNL in patients with pediatric brain cancer (ReSPECT-PBC).
- Complete technology transfer and key CMC, FDA IND-enabling studies for ^{188}RNL-BAM.

First Quarter 2022 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 First Quarter 2022 Results Conference Call
Date:	April 21, 2022
Time:	5:00 p.m. Eastern Time
Live Call:	866-342-8591 (toll free); 203-518-9713 (Intl.); Conference ID: PSTVQ122

The webcast can be accessed live via the Investor Relations 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 focused on developing innovative, targeted radiotherapeutics for adults and children worldwide with rare and difficult-to-treat cancers. Our proprietary radiotherapeutic platform uniquely uses nanoliposomes to encapsulate and deliver the radioisotope, Rhenium, into or near a tumor via a single, direct infusion. The lead radiotherapeutic in our pipeline, Rhenium-186 NanoLiposome (^{186}RNL), is being evaluated in U.S. multi-center clinical trials for the treatment of recurrent glioblastoma and leptomeningeal metastases. 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 “designed to,” “will,” “plan,” “can,” “design,” “intend,” “potential,” “expect,” “target,” “focus,” 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, and general and administrative expenses; anticipated benefits of strategic collaborations and license agreements, intellectual property, FDA approvals and interactions and government regulation; the potential size of the market for the Company’s product candidates; the Company’s research and development efforts; results from the Company’s pre-clinical and clinical studies and implications of such results regarding the efficacy or safety of the Company's product candidates; the safety profile, pathways, and efficacy of the Company’s product candidates and formulations; anticipated advantages of the Company’s product candidates over other products available in the market and being developed; the populations that will most benefit from the Company’s product candidates and indications that will be pursued with each product candidate; anticipated progress in the Company’s current and future clinical trials; plans and strategies to create novel technologies; the Company’s IP strategy; competition; future development and/or expansion of the Company’s product candidates and therapies in its markets; sources of competition for any of the Company’s product candidates; the Company’s pipeline; the Company’s ability to generate product or development revenue and the sources of such revenue; the Company’s ability to effectively manage its gross profit margins; the Company’s ability to obtain and maintain regulatory approvals; expectations as to its future performance; portions of the “Liquidity and Capital Resources” section of its quarterly report for the period ended March 31, 2022, including its potential need for additional financing and the availability thereof; 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; the Company’s ability to transfer the drug product manufacture to a contract drug manufacturing organization; and the potential enhancement of its 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 Company’s actual results may differ, including materially, from those anticipated in these forward-looking statements as a result of various factors, including, but 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)

	March 31, 2022	December 31, 2021
Assets		
Current assets:		

Cash and cash equivalents	$ 21,239	$ 18,400
Other current assets	865	1,324
Total current assets	22,104	19,724
Property and equipment, net	1,558	1,477
Operating lease right-use-of assets	316	341
Goodwill	372	372
Intangible assets, net	150	51
Other assets	16	16
Total assets	$ 24,516	$ 21,981
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 3,203	$ 4,151
Operating lease liability	110	111
Term loan obligation, current	1,608	1,608
Total current liabilities	4,921	5,870
Noncurrent operating lease liability	235	269
Term loan obligation	4,718	5,005
Warrant liability	—	1
Total liabilities	9,874	11,145
Stockholders' equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized; 1,952 shares issued and outstanding at March 31, 2022 and December 31, 2021	—	—
Common stock, $0.001 par value; 100,000,000 shares authorized; 22,197,635 and 15,510,025 issued and outstanding at March 31, 2022 and December 31, 2021, respectively	22	16
Additional paid-in capital	465,646	457,730
Accumulated deficit	(451,026)	(446,910)
Total stockholders' equity	14,642	10,836
Total liabilities and stockholders' equity	$ 24,516	$ 21,981

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

	For the Three Months Ended March 31,	
	2022	**2021**
Operating expenses:		
Research and development	$ 1,785	$ 1,127
General and administrative	2,141	1,352
Total operating expenses	3,926	2,479
Operating loss	(3,926)	(2,479)
Other income (expense):		
Interest income	7	4
Interest expense	(198)	(247)
Change in fair value of liability instruments	1	2
Total other expense	(190)	(241)
Net loss	$ (4,116)	$ (2,720)
Net loss per share, basic and diluted	$ (0.19)	$ (0.33)
Basic and diluted weighted average shares used in calculating net loss per share attributable to common stockholders	21,507,061	8,267,901

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

	For the Three Months Ended March 31,	
	2022	**2021**
Cash flows used in operating activities:		
Net loss	$ (4,116)	$ (2,720)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	147	88
Amortization of deferred financing costs and debt discount	115	151
Change in fair value of liability instruments	(1)	(2)
Share-based compensation expense	180	107
Non-cash lease expense	(10)	1
Increases (decreases) in cash caused by changes in operating assets and liabilities:		
Other current assets	459	(170)
Accounts payable and accrued expenses	(650)	(461)
Net cash used in operating activities	(3,876)	(3,006)
Cash flows used in investing activities:		
Purchases of property and equipment	(210)	(84)
Purchase of intangible assets	(117)	—
In process research and development acquired	(250)	—
Net cash used in investing activities	(577)	(84)
Cash flows from financing activities:		
Principal payments of long-term obligations	(402)	—
Payment of financing lease liability	—	(6)
Proceeds from exercise of warrants	—	2,017
Proceeds from sale of common stock	7,694	7,180
Net cash provided by financing activities	7,292	9,191
Net increase in cash and cash equivalents	2,839	6,101
Cash and cash equivalents at beginning of period	18,400	8,346
Cash and cash equivalents at end of period	$ 21,239	$ 14,447
Supplemental disclosure of cash flows information:		
Cash paid during period for:		
Interest	$ 87	$ 96
Supplemental schedule of non-cash investing and financing activities:		
Unpaid offering cost	$ 171	$ 102

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