UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 8-K

Current Report

Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported)**: April 22, 2021**

PLUS THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-34375**	**33-0827593**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

4200 Marathon Blvd., Suite 200, Austin, Texas 78756
(Address of principal executive offices, with zip code)

(737) 255-7194
(Registrant's telephone number, including area code)

N/A
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instructions A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	PSTV	The Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).
Emerging growth company ☐
If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition.

On April 22, 2021, Plus Therapeutics, Inc. (the "Company") reported financial results for the quarter ended March 31, 2021 and other recent corporate updates. A copy of the press release is furnished as Exhibit 99.1 to this report and incorporated by reference.

The information in this Item 2.02 of this Current Report on 8-K (including Exhibit 99.1) is furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information shall not be deemed incorporated by reference into any other filing with the Securities and Exchange Commission made by the Company, whether made before or after today's date, regardless of any general incorporation language in such filing, except as shall be expressly set forth by specific references in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release Announcing Financial Results, dated April 22, 2021.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: April 22, 2021

PLUS THERAPEUTICS, INC.

By: /s/ Marc H. Hedrick, M.D.
Marc H. Hedrick, M.D.
President and Chief Executive Office

Exhibit 99.1

Plus Therapeutics Reports First Quarter 2021 Financial Results and Business Highlights

– Management to host conference call today at 5:00 pm ET –

AUSTIN, Texas, April 22, 2021 – Plus Therapeutics, Inc. (Nasdaq: PSTV) (the "Company"), a clinical-stage pharmaceutical company developing novel, targeted therapies for rare and difficult to treat cancers, today announced financial results for the first quarter ended March 31, 2021, and provided an overview of recent business highlights.

The Company's lead investigational drug is *Rhenium NanoLiposome (*RNL™), a radiotherapy in development for several rare cancer targets, including recurrent glioblastoma (GBM). RNL™, currently being evaluated in the U.S. multi-center ReSPECT™ Phase 1 dose-finding clinical trial, is designed to safely, effectively, and conveniently deliver a very high dose of radiation directly to brain tumors.

"In the first quarter of 2021, we made meaningful progress in critical areas including advancing our drug development and manufacturing activities, refining our clinical understanding of RNL™ behavior in the glioblastoma patients and in seeking FDA feedback on potential new clinical indications for RNL™," said Marc H. Hedrick M.D., President and Chief Executive Officer of Plus Therapeutics.

First Quarter 2021 Clinical Highlights

Company highlights during the first quarter of 2021 included:

- Entering into a master services agreement (MSA) with Piramal Pharma Solutions for the development, manufacture, and supply of RNL™ intermediate drug product.
- Completing the 6th dose escalation cohort, with 18 patients treated in ReSPECT™, with concomitant increases in both RNL™ drug volume and radiation dose.
- Beginning treatment in an expansion cohort at the 6th dose with higher drug flow rates and faster drug infusion times.
- Submitting 2 RNL™ pre-IND meeting briefing packages to the U.S. Food and Drug Administration (FDA) for treatment of leptomeningeal metastases and pediatric brain cancers, specifically ependymoma, high-grade glioma, and diffuse intrinsic pontine glioma.

Expected Upcoming Clinical Milestones and Events for 2021

In upcoming quarters in 2021, the Company intends to focus on a number of additional business objectives and potential milestones:

- Complete enrollment of the ReSPECT™ Phase 1 trial for RNL™ in recurrent glioblastoma.

- Complete pivotal trial planning in conjunction with FDA feedback for RNL™ in recurrent glioblastoma.
- Complete a pre-IND meeting with the FDA, execute IND-enabling studies, if needed, and move into clinical trials for new RNL™ indications.
- Continue development and evaluation of additional external and internal drug development candidates to expand the drug development pipeline.
- Continue to explore partnership opportunities for three clinical-stage investigational drugs: RNL™, DocePLUS™ and generic DoxoPLUS™.

First Quarter 2021 Financial Results

- As of March 31, 2021, the Company's cash balance was $14.4 million, compared to $8.3 million as of December 31, 2020.
- Total operating expenses for the first quarter of 2021 was $2.5 million, compared to total operating expenses of $2.56 million for the same quarter in 2020.
- Net loss for the first quarter of 2021 was $2.7 million, or $(0.33) per share, compared to a net loss of $1.1 million, or $(0.28) per share, for the same quarter in 2020. The net loss was consistent year on year when excluding the book gains on the warrants reported in Q1 2020. Remeasurement of warrant liabilities was no longer required for Series U warrants that were amended in Q2 and Q3 2020 and reclassified to equity.

First 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 First Quarter 2021 Results Conference Call
Date:	Thursday, April 22, 2021
Time:	5:00 p.m. Eastern Time
Live Call:	877-402-3914 (toll free); 631-865-5294 (Intl.); Conference ID: 3084418

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 (Nasdaq: PSTV) 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 design and potential of the Plus Therapeutics portfolio to reformulate, deliver and commercialize multiple novel, proprietary drugs targeting rare cancers and other diseases and to facilitate new delivery approaches and/or formulations of safe and effective, injectable drugs; the potential of the Company’s in-licensed portfolio of investigational drugs; the Company’s intent to advance its CNS oncology portfolio through the clinical development process; the ability of RNL to safely, effectively and conveniently deliver a very high dose of radiation directly into the brain tumor; anticipated benefits of strategic collaborations and license agreements, intellectual property, FDA approval process and government regulation; and the Company’s anticipated milestones and events, including with respect to additional sites, enrollment, pivotal trial planning, IND process, and clinical phase plans for RNL, pipeline expansion through additional drug development candidates, and partnership discussions for RNL, DocePLUS and DoxoPLUS; and future development and/or expansion of its product candidates and therapies in its markets. 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 risk that the Company is not able to successfully develop product candidates that can leverage the FDA’s accelerated regulatory pathways; the early stage of the Company’s product candidates and therapies, the results of its research and development activities, including uncertainties relating to the clinical trials of its product candidates and therapies; the Company’s history of losses; the Company’s need for, and ability to raise, additional cash or obtain other sources of funding in the immediate future; the Company’s ability to: (a) obtain and maintain regulatory approvals, (b) continue as a going concern, (c) remain listed on the Nasdaq Capital Market, (d) to obtain or maintain sufficient levels of reimbursement for its tests, and (d) to repay or refinance some or all of its outstanding indebtedness; the outcome of the Company’s partnering/licensing efforts; market and economic conditions; the impact of the COVID-19 pandemic on the Company and the effectiveness of the efforts it has taken or may take in the future in response thereto; 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, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 14,447	$ 8,346
Other current assets	999	829
Total current assets	15,446	9,175
Property and equipment, net	1,825	1,820
Operating lease right-of-use assets	600	636
Goodwill	372	372
Intangible assets, net	77	86
Other assets	16	16
Total assets	$ 18,336	$ 12,105
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 1,716	$ 2,081
Operating lease liability	113	123
Term loan obligations, net of discount	6,486	6,335
Total current liabilities	8,315	8,539
Noncurrent operating lease liability	503	528
Warrant liability	5	7
Total liabilities	8,823	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 March 31, 2021 and December 31, 2020, respectively	—	—
Common stock, $0.001 par value; 100,000,000 shares authorized; 10,180,525 and 6,749,028 shares issued and outstanding at March 31, 2021 and December 31, 2020, respectively	10	7
Additional paid-in capital	445,734	436,535
Accumulated deficit	(436,231)	(433,511)
Total stockholders' equity	9,513	3,031
Total liabilities and stockholders' equity	$ 18,336	$ 12,105

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

	For the Three Months Ended March 31,	
	2021	2020
Development revenues:		
Government contracts and other	$ —	$ 118
Operating expenses:		
Research and development	1,127	941
General and administrative	1,352	1,618
Total operating expenses	2,479	2,559
Loss from operations	(2,479)	(2,441)
Other income (expense):		
Interest income	4	36
Interest expense	(247)	(349)
Change in fair value of warrants	2	1,667
Total other income (expense)	(241)	1,354
Net loss	$ (2,720)	$ (1,087)
Net loss per share, basic and diluted	$ (0.33)	$ (0.28)
Basic and diluted weighted average shares used in calculating net loss per share attributable to common stockholders	8,267,901	3,880,588

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

	For the Three Months Ended March 31,	
	2021	2020
Cash flows used in operating activities:		
Net loss	$ (2,720)	$ (1,087)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	88	94
Amortization of deferred financing costs and debt discount	151	122
Noncash lease expenses	1	4
Change in fair value of warrants	(2)	(1,667)
Share-based compensation expense	107	12
Increases (decreases) in cash caused by changes in operating assets and liabilities:		
Accounts receivable	—	191
Other current assets	(170)	405
Other assets	—	14
Accounts payable and accrued expenses	(461)	410
Net cash used in operating activities	(3,006)	(1,502)
Cash flows provided by (used in) investing activities:		
Purchases of property and equipment	(84)	(11)
Net cash used in investing activities	(84)	(11)
Cash flows used in financing activities:		
Payment of financing lease liability	(6)	(18)
Proceeds from exercise of warrants	2,017	—
Proceeds from sale of common stock, net	7,180	—
Net cash provided by (used in) financing activities	9,191	(18)
Net increase (decrease) in cash and cash equivalents	6,101	(1,531)
Cash and cash equivalents at beginning of period	8,346	17,592
Cash and cash equivalents at end of period	14,447	16,061
Supplemental disclosure of cash flows information:		
Cash paid during period for:		
Interest	$ 96	$ 227
Supplemental schedule of non-cash investing and financing activities:		
Unpaid offering costs	$ 102	$ —

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