

**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): **February 22, 2021**

PLUS THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-34375
(Commission File Number)

33-0827593
(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 February 22, 2021, Plus Therapeutics, Inc. (the “Company”) reported financial results for the fourth quarter and year ended December 31, 2020 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 Form 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 February 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: February 22, 2021

PLUS THERAPEUTICS, INC.

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

Plus Therapeutics Reports Fourth Quarter and Full Year 2020 Financial Results and Business Highlights

- Positive interim data through cohort five for the ReSPECT™ Phase 1 clinical trial in recurrent glioblastoma, announced November 2020 –
- Completed sixth dosing cohort in ReSPECT™ December 2020 –
- Management to host conference call today, Monday, February 22nd, at 5:00 p.m. ET –

AUSTIN, Texas, February 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 fourth quarter and full year ended December 31, 2020, and provided an overview of recent business highlights.

“In the second quarter of 2020, we in-licensed a promising new radiotherapeutic platform and portfolio of investigational drugs, then made substantial clinical progress for the lead compound and also moved additional opportunities closer to clinical phase,” said Marc Hedrick M.D., President and Chief Executive Officer of Plus Therapeutics. “In 2021, we intend to make even greater progress advancing our CNS oncology portfolio through the development process and bringing it closer to a potential registrational clinical trial read out.”

Rhenium NanoLiposome (RNL™) Program - Background and 2020 Highlights

The Company’s lead investigational drug is RNL™, a radiotherapy in development for several rare cancer targets, including recurrent glioblastoma (GBM) in the U.S. multi-center ReSPECT™ Phase 1 dose-finding trial. RNL™ is designed to safely, effectively, and conveniently deliver a very high dose of radiation directly into the brain tumor compared to traditional external beam radiation therapy (EBRT). 2020 highlights for RNL™ include:

- ReSPECT™ trial of RNL™ for recurrent glioblastoma supported by a multi-phase and multi-year financial grant from the U.S. National Institutes of Health/National Cancer Institute (NIH/NCI).
 - RNL™ received Orphan Drug and Fast Track designations from the U.S. Food and Drug Administration (FDA) for the treatment of GBM.
 - Presented positive interim data from the first 15 patients, through Cohort 5, in the ReSPECT™ trial at the 2020 Society for Neuro-Oncology Annual Meeting (SNO 2020 E-poster).
 - Completed the 6th dose escalation cohort, with 18 total patients treated in ReSPECT™, with increases in both the RNL™ drug volume and radiation dose.
 - Thus far, RNL™ can be successfully delivered with up to 15 times the absorbed dose of radiation administered by standard EBRT without significant toxicity.
 - ReSPECT™ clinical trial expanded to two additional locations.
-

- Established Clinical Advisory and Scientific Advisory Boards with leading experts in the fields of neurosurgery, neuro-oncology, preclinical drug development, and nanotechnology.

Expected Upcoming Milestones and Events

In upcoming quarters, 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 with FDA for RNL™ in recurrent GBM.
- Complete pre-IND meeting with the FDA, execute IND-enabling studies, if needed, and move into clinical trials for follow-on RNL™ indications, leptomeningeal metastases and pediatric brain cancer.
- Continue development and evaluation of additional external and internal drug development candidates to expand the pipeline.
- Continue partnership discussions for three clinical-stage injectable drugs: RNL™, DocePLUS™, and generic DoxoPLUS™.

Fourth Quarter 2020 Financial Results

- As of December 31, 2020, the Company's cash balance was \$8.3 million, compared to \$17.6 million as of December 31, 2019.
- Net cash used in operating activities was \$8.4 million for the year ended December 31, 2020, compared to net cash used in operating activities of \$5.9 million during the same period in 2019.
- During the second quarter of 2020, \$5.0 million of the Oxford debt principal was paid down to a current principal balance of \$4.3 million at December 31, 2020.
- Net loss for full year 2020 was \$8.2 million, or \$(1.86) per share, compared to a net loss of \$11.4 million, or \$(8.27) per share (on a fully diluted basis including preferred stock), for full year 2019.

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 Fourth Quarter and Full Year 2020 Financial Results Conference Call and Webcast
Date: Monday, February 22, 2021
Time: 5:00 p.m. Eastern Time
Live Call: 877-402-3914 (toll free); 631-865-5294 (Intl.); Conference ID: 6206747

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 www.PlusTherapeutics.com and www.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 new, 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 greater than traditional EBRT directly into the brain tumor; and the Company's anticipated milestones and events, including with respect to 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. 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 U.S. 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 BALANCE SHEETS
(in thousands, except share and par value data)

	As of December 31,	
	2020	2019
Assets		
Current assets:		
Cash and cash equivalents	\$ 8,346	\$ 17,552
Accounts receivable	—	1,169
Restricted cash	—	40
Inventories, net	—	107
Other current assets	829	957
Total current assets	9,175	19,825
Property and equipment, net	1,820	2,179
Operating lease right-use-of assets	636	781
Goodwill	372	372
Intangible assets, net	86	—
Other assets	16	72
Total assets	\$ 12,105	\$ 23,229
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 2,081	\$ 3,279
Operating lease liability	123	147
Term loan obligation, net of discount	6,335	11,060
Total current liabilities	8,539	14,486
Noncurrent operating lease liability	528	646
Warrant liability	7	6,929
Other noncurrent liabilities	—	8
Total liabilities	9,074	22,069
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.001 par value; 5,000,000 shares authorized; 1,954 and 1,959 shares issued and outstanding in 2020 and 2019, respectively	—	—
Common stock, \$0.001 par value; 100,000,000 shares authorized; 6,749,028 and 3,880,588 shares issued and outstanding in 2020 and 2019, respectively	7	4
Additional paid-in capital	436,535	426,426
Accumulated deficit	(433,511)	(425,270)
Total stockholders' equity	3,031	1,160
Total liabilities and stockholders' equity	\$ 12,105	\$ 23,229

PLUS THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(in thousands, except share and per share data)

	For the Years Ended December 31,	
	2020	2019
Development revenue:		
Government contracts and other	\$ 303	\$ 6,998
	<u>303</u>	<u>6,998</u>
Operating expenses:		
Research and development	2,700	5,365
In process research and development acquired from NanoTx	781	—
General and administrative	6,406	5,290
Total operating expenses	<u>9,887</u>	<u>10,655</u>
Operating loss	<u>(9,584)</u>	<u>(3,657)</u>
Other income (expense):		
Interest income	50	55
Interest expense	(1,107)	(1,855)
Change in fair value of liability instruments	2,400	3,407
Issuance cost of warrants	—	(1,233)
Total other expense	<u>1,343</u>	<u>374</u>
Loss from continuing operations	\$ (8,241)	\$ (3,283)
Loss from discontinued operations	—	(7,604)
Net loss	<u>\$ (8,241)</u>	<u>\$ (10,887)</u>
Loss from continuing operations	\$ (8,241)	\$ (3,283)
Beneficial conversion feature for convertible preferred stock	—	(554)
Net loss allocable to common stockholders - continuing operations	\$ (8,241)	\$ (3,837)
Net loss allocable to common stockholders - discontinued operations	-	(7,604)
Net loss allocable to common stockholders	\$ (8,241)	\$ (11,441)
Basic and diluted net loss per share attributable to common stockholders – continuing operations	\$ (1.86)	\$ (2.77)
Basic and diluted net loss per share attributable to common stockholders - discontinued operations	-	(5.49)
Net loss per share, basic and diluted	\$ (1.86)	\$ (8.27)
Basic and diluted weighted average shares used in calculating net loss per share attributable to common stockholders	4,427,835	1,384,012

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

	For the Years Ended December 31,	
	2020	2019
Cash flows used in operating activities:		
Net loss	\$ (8,241)	\$ (10,887)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	366	896
Amortization of deferred financing costs and debt discount	584	550
In process research and development acquired from NanoTx Therapeutics	781	—
Change in fair value of liability instruments	(2,400)	(3,407)
Share-based compensation expense	247	127
Inventory write off	107	—
Noncash lease expense	3	12
Loss on sale of business	—	6,508
Allocation of issuance cost associated with warrants	—	1,233
Increases (decreases) in cash caused by changes in operating assets and liabilities:		
Accounts receivable	1,169	(1,203)
Inventories	—	259
Other current assets	126	(211)
Other assets	58	263
Accounts payable and accrued expenses	(1,234)	(28)
Deferred revenue	—	29
Other long-term liabilities	—	(47)
Net cash used in operating activities	<u>(8,434)</u>	<u>(5,906)</u>
Cash flows from (used in) investing activities:		
Purchases of property and equipment	(93)	(67)
In process research and development acquired from NanoTx Therapeutics	(400)	—
Proceeds from sale of business	—	5,637
Net cash provided by (used in) investing activities	<u>(493)</u>	<u>5,570</u>
Cash flows from financing activities:		
Principal payments of long-term obligations	(5,307)	(3,692)
Payment of financing lease liability	(117)	(131)
Proceeds from exercise of warrants	1,098	490
Proceeds from sale of common stock	4,007	15,964
Net cash (used in) provided by financing activities	<u>(319)</u>	<u>12,631</u>
Effect of exchange rate changes on cash and cash equivalents	—	(4)
Net increase (decrease) in cash and cash equivalents	(9,246)	12,291
Cash, cash equivalents, and restricted cash at beginning of period	17,592	5,301
Cash, cash equivalents, and restricted cash at end of period	<u>\$ 8,346</u>	<u>\$ 17,592</u>
Supplemental disclosure of cash flows information:		
Cash paid during period for:		
Interest	\$ 567	\$ 1,188
Supplemental schedule of non-cash investing and financing activities:		
Issuance costs paid in common stock	\$ 463	\$ —
Common stock issued in payment for in process research and development	\$ 381	\$ —
Unpaid offering cost	\$ 125	\$ —
Proceeds from sales of business, net, paid directly to lender for principal payment of long-term obligations	\$ —	\$ 3,050
Offering cost paid in warrants	\$ —	\$ 213
Reclassification of warrants upon exercise from liability to equity	\$ 4,504	\$ 794
Fair value of Convertible Preferred Stock beneficial conversion feature	\$ —	\$ 554

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