

**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 24, 2022**

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 24, 2022, Plus Therapeutics, Inc. (the “Company”) reported financial results for the fourth quarter and year ended December 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 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 24, 2022.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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 24, 2022

PLUS THERAPEUTICS, INC.

By: /s/ Marc H. Hedrick, M.D.

Marc H. Hedrick, M.D.

President and Chief Executive Officer

Plus Therapeutics Reports Fourth Quarter and Full Year 2021 Financial Results and Business Highlights

Expanded pipeline with recently licensed targeted interventional radiotherapeutics platform

Announced positive interim data from ReSPECT-GBM Phase 1 clinical trial

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

AUSTIN, Texas, February 24, 2022 – 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 fourth quarter and full year ended December 31, 2021, and provided an overview of recent business highlights.

“In 2021, the Company significantly advanced its lead ¹⁸⁶RNL program and expanded its pipeline,” said Marc H. Hedrick M.D., President and Chief Executive Officer of Plus Therapeutics. “Our 2022 plan will build on our successful 2021 track record. This year we have planned an aggressive schedule of development activities in conjunction with continued strengthening of our balance sheet”.

2021 AND RECENT HIGHLIGHTS

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

- Announced positive interim data from the U.S. ReSPECT-GBM Phase 1/2 trial of ¹⁸⁶RNL in patients with recurrent glioblastoma (GBM).
- Announced plans to advance into Phase 2 development in 2022 for recurrent GBM.
- Initiated ReSPECT-LM Phase 1 dose escalation trial of ¹⁸⁶RNL in patients with leptomeningeal metastases (LM).
- Received U.S. Food and Drug Administration (FDA) Fast Track designation for ¹⁸⁶RNL for the treatment of LM.
- Entered into multiple manufacturing, analytical and supply agreements to produce Good Manufacturing Practice (cGMP) grade ¹⁸⁶RNL for use in late-stage clinical trials planned for 2022.

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

- In the fourth quarter of 2021, in-licensed a novel targeted radioembolic technology for the treatment of many solid organ tumors.
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- The in-licensed technology is intended to make and use biodegradable alginate microspheres (BAM) combined with nanoliposomes and imaging and/or therapeutic payloads.
- The Company will initially focus on developing ¹⁸⁸RNL-BAM as a next-generation radioembolization therapy for rare solid organ cancers including liver cancer.

FULL YEAR 2021 FINANCIAL RESULTS

- As of December 31, 2021, the Company's cash balance was \$18.4 million, compared to \$8.3 million as of December 31, 2020. In 2021 and in 2022 to date, the Company strengthened its balance sheet by raising \$28.5 million. As a result, at January 31, 2022, the Company's cash balance was \$23.0 million.
- Through 2021, the Company continued to utilize the \$3 million grant from the NIH/National Cancer Institute for funding of the clinical trials for the ReSPECT-GBM Phase 1/2 trial.
- Total operating expenses for full year 2021 were \$12.5 million, compared to total operating expenses of \$9.9 million for full year 2020. This increase is primarily due to increased research and development expenses in 2021.
- Net loss for full year 2021 was \$13.4 million, or \$(1.11) per share, compared to a net loss of \$8.2 million, or \$(1.86) per share, for full year 2020. The increase in net loss is primarily due to the aforementioned increase in research and development expenses.

UPCOMING EVENTS AND MILESTONES

The Company's near- and mid-term business objectives include the following:

Recurrent GBM

- Initiate a Phase 2 clinical trial in patients with recurrent GBM.
- Complete FDA CMC and clinical meetings for the ReSPECT-GBM program.
- Complete CMC activities for ¹⁸⁶RNL for GMP Phase 2 drug supply.
- Continue ReSPECT-GBM Phase 1 trial of ¹⁸⁶RNL, dose escalation and report data.
- Initiate ReSPECT-GBM retreatment protocol following FDA approval.

Other Indications

- Complete initial cohort enrollment and feasibility assessment in ReSPECT-LM Phase 1 trial.
- Obtain FDA approval of Investigational New Drug (IND) application for Phase 1 trial of ¹⁸⁶RNL in patients with pediatric brain cancer (ReSPECT-PBC).
- Complete technology transfer and key CMC, FDA IND-enabling studies for ¹⁸⁸RNL-BAM.

FOURTH QUARTER AND FULL YEAR 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 Fourth Quarter and Full Year 2021 Results Conference Call
Date:	February 24, 2022
Time:	5:00 p.m. Eastern Time
Live Call:	866-342-8591 (toll free); 203-518-9713 (Intl.); Conference ID: PSTVQ421

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 (¹⁸⁶RNL), 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 goals for the 2022 fiscal year including any milestones and accomplishments that the Company expects to achieve; the Company’s ability to expand clinical testing of ¹⁸⁶RNL to additional sites and additional indications; the Company’s clinical trials including statements regarding timing and characteristics; the Company’s research and development efforts; future development and/or expansion of its product candidates and therapies in its markets; expectations as to the Company’s future performance.

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 BALANCE SHEETS
(in thousands, except share and par value data)

	As of December 31,	
	2021	2020
Assets		
Current assets:		
Cash and cash equivalents	\$ 18,400	\$ 8,346
Other current assets	1,324	829
Total current assets	19,724	9,175
Property and equipment, net	1,477	1,820
Operating lease right-use-of assets	341	636
Goodwill	372	372
Intangible assets, net	51	86
Other assets	16	16
Total assets	<u>\$ 21,981</u>	<u>\$ 12,105</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 4,151	\$ 2,081
Operating lease liability	111	123
Term loan obligation, current	1,608	6,335
Total current liabilities	5,870	8,539
Noncurrent operating lease liability	269	528
Term loan obligation	5,005	—
Warrant liability	1	7
Total liabilities	11,145	9,074
Stockholders' equity:		
Preferred stock, \$0.001 par value; 5,000,000 shares authorized; 1,952 and 1,954 shares issued and outstanding in 2021 and 2020, respectively	—	—
Common stock, \$0.001 par value; 100,000,000 shares authorized; 15,510,025 and 6,749,028 shares issued and outstanding in 2021 and 2020, respectively	16	7
Additional paid-in capital	457,730	436,535
Accumulated deficit	(446,910)	(433,511)
Total stockholders' equity	10,836	3,031
Total liabilities and stockholders' equity	<u>\$ 21,981</u>	<u>\$ 12,105</u>

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

	For the Years Ended December 31,	
	2021	2020
Development revenue:		
Government contracts and other	\$ —	\$ 303
	<u>—</u>	<u>303</u>
Operating expenses:		
Research and development	5,323	2,700
In process research and development acquired	250	781
General and administrative	6,853	6,406
Loss on disposal of property and equipment	66	—
Total operating expenses	<u>12,492</u>	<u>9,887</u>
Operating loss	<u>(12,492)</u>	<u>(9,584)</u>
Other income (expense):		
Interest income	19	50
Interest expense	(932)	(1,107)
Change in fair value of liability instruments	6	2,400
Total other expense	<u>(907)</u>	<u>1,343</u>
Net loss	<u>\$ (13,399)</u>	<u>\$ (8,241)</u>
Net loss per share, basic and diluted	\$ (1.11)	\$ (1.86)
Basic and diluted weighted average shares used in calculating net loss per share attributable to common stockholders	12,089,186	4,427,835

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

	For the Years Ended December 31,	
	2021	2020
Cash flows used in operating activities:		
Net loss	\$ (13,399)	\$ (8,241)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	395	366
Amortization of deferred financing costs and debt discount	546	584
In process research and development acquired	250	781
Change in fair value of liability instruments	(6)	(2,400)
Loss on disposal of property and equipment	66	
Share-based compensation expense	606	247
Inventory write off	—	107
Non-cash lease expense	24	3
Increases (decreases) in cash caused by changes in operating assets and liabilities:		
Accounts receivable	—	1,169
Other current assets	(496)	126
Other assets	—	58
Accounts payable and accrued expenses	1,734	(1,234)
Other long-term liabilities	—	—
Net cash used in operating activities	<u>(10,280)</u>	<u>(8,434)</u>
Cash flows from (used in) investing activities:		
Purchases of property and equipment and intangible assets	(144)	(93)
Proceeds from sale of property and equipment	62	
In process research and development acquired from NanoTx Therapeutics	—	(400)
Net cash used in investing activities	<u>(82)</u>	<u>(493)</u>
Cash flows from financing activities:		
Principal payments of long-term obligations	(268)	(5,307)
Payment of financing lease liability	(8)	(117)
Proceeds from exercise of warrants	2,017	1,098
Proceeds from sale of common stock	18,675	4,007
Net cash provided by (used in) financing activities	<u>20,416</u>	<u>(319)</u>
Net increase (decrease) in cash and cash equivalents	10,054	(9,246)
Cash and cash equivalents at beginning of period	8,346	17,592
Cash and cash equivalents at end of period	<u>\$ 18,400</u>	<u>\$ 8,346</u>

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