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): March 05, 2024

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 (Address of Principal Executive Offices)

Title of each class

Common Stock, par value \$0.001 per share

78756 (Zip Code)

Name of each exchange on which registered

The Nasdaq Capital Market

Registrant's Telephone Number, Including Area Code: (737) 255-7194

| | (Former Name or Former Address, if Changed Since Last Report) |
|--------------|---|
| theck the ap | opropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the revisions: |
| | 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: |

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

Trading

Symbol(s)

PSTV

chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company \square

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. \square

Item 2.02 Results of Operations and Financial Condition.

On March 5, 2024, Plus Therapeutics, Inc. (the "Company") reported financial results for the fourth quarter and year ended December 31, 2023 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 March 5, 2024. |
| 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.

PLUS THERAPEUTICS, INC.

Date: March 5, 2024 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 2023 Financial Results and Business Highlights

Began enrollment of the 5th of an anticipated 7 planned dosing cohorts for the ReSPECT-LM Phase 1 dose escalation trial with rhenium (¹⁸⁶Re) obisbemeda for leptomeningeal metastases (LM)

Reached agreement to expand ReSPECT-GBM Phase 2 trial and add new sites

Current financial forecast for sufficient runway to fund operations into 2H 2025

Management to Host Conference Call March 5, 2024 at 5:00 p.m. ET

AUSTIN, Texas, March 5, 2024 (GLOBE NEWSWIRE) – <u>Plus Therapeutics, Inc.</u> (Nasdaq: <u>PSTV</u>) (the "Company"), a clinical-stage pharmaceutical company developing targeted radiotherapeutics with advanced platform technologies for central nervous system cancers, today announced financial results for the fourth quarter and full year ended December 31, 2023, and provided an overview of recent and upcoming business highlights.

"Based on 2023 achievements and planned 2024 milestones, we intend to move our lead targeted radiotherapeutic into registrational trials in 2025," said Marc H. Hedrick M.D., President and Chief Executive Officer of Plus Therapeutics. "Our ReSPECT clinical trials in both LM and recurrent glioblastoma (rGBM) continue to demonstrate encouraging safety and efficacy signals for rhenium (186Re) obisbemeda and we plan U.S. Food and Drug Administration (FDA) meetings during 2024 to discuss next steps toward product approval."

UPCOMING EVENTS AND MILESTONES

In 2024 the Company plans to accomplish the following key business objectives:

Leptomeningeal Metastasis:

- Present interim safety and feasibility data from the ReSPECT-LM trial at the SNO/ASCO CNS Cancer Conference in August 2024
- Complete ReSPECT-LM Phase 1 dose escalation trial enrollment, determine the maximum tolerated dose, and recommended Phase 2 dose.
- Present complete ReSPECT-LM Phase 1 data at the SNO Annual Meeting in November 2024.
- Implement Plus' CNSide cerebral spinal fluid (CSF)-based tumor cell quantification assay as an exploratory clinical endpoint in all ReSPECT-LM trial patients in Q1 2024.
- 2024 FDA meeting to align on the design for a pivotal Phase 2/3 ReSPECT-LM trial for the treatment of breast cancer with leptomeningeal metastases, anticipated to begin in 1H 2025.
- Develop a new, multiple dosing ReSPECT-LM clinical trial in 2024.
- Complete preclinical combination studies of rhenium (¹⁸⁶Re) obisbemeda with PD-1 and PD-L1 checkpoint inhibitors.

Glioblastoma:

- Continue to advance Phase 2 ReSPECT-GBM trial and present data in the second half of 2024.
- Finalize ReSPECT-GBM pivotal design with FDA.

Pediatric Brain Cancer (PBC)

• Obtain FDA IND approval to begin enrollment of ReSPECT-PBC trial for children with high grade glioma and ependymoma.

Manufacturing:

Increase GMP manufacturing capacity of rhenium (¹⁸⁶Re) obisbemeda to support forecasted Phase 3 and commercial supply requirements.

Q4 2023 AND RECENT HIGHLIGHTS AND MILESTONE ACHIEVEMENTS Leptomeningeal Metastasis:

- <u>Completed dosing in Cohort 4</u> and initiated dosing in Cohort 5 of the ReSPECT-LM Phase 1 dose escalation trial of rhenium (¹⁸⁶Re) obisbemeda for the treatment of LM.
- Added a total of 5 new sites to the ReSPECT trials.
- <u>Partnered with K2bio</u> for implementation of the CNSide™ cerebrospinal fluid (CSF)-based tumor cell capture and enumeration assay, <u>acquired from Biocept</u>, being utilized in the ReSPECT-LM clinical trial. CNSide assay implementation is now complete.
- Orphan Drug Designation granted to rhenium (¹⁸⁶Re) obisbemeda by the FDA for the treatment of breast cancer with LM.
- <u>Presented preliminary safety and efficacy results</u> from Phase 1/Part A of the ReSPECT-LM clinical trial at the SNO/ASCO CNS Cancer Conference. Following the presentation, the Company hosted a <u>key opinion leader roundtable</u> on data presented at the conference.
- Received advance payment of grant funds of approximately \$3.3 million from CPRIT as part of its overall \$17.6 million award contract. To date, the Company has received \$7.1 million in grant funding from CPRIT.

Glioblastoma:

<u>Presented interim safety and efficacy results</u> from the ongoing ReSPECT-GBM Phase 2 clinical trial at the SNO Annual Meeting. Following the presentation, the Company hosted <u>a key opinion leader webinar</u> to discuss the data presented at the conference.

FULL YEAR 2023 FINANCIAL RESULTS

- The Company's cash balance was \$8.6 million at December 31, 2023, compared to \$18.1 million at December 31, 2022.
- The Company recognized \$4.9 million and \$0.2 million of grant revenue during the years ended December 31, 2023 and 2022, respectively, which represents CPRIT's share of the costs incurred for our rhenium (¹⁸⁶Re) obisbemeda development for the treatment of patients with LM.
- Total operating loss for the year ended December 31, 2023 was \$13.3 million compared to \$19.7 million in the same period of 2022. The decrease is primarily due to an increase in grant revenue of \$4.7 million, offset by a decrease in general and administrative expenses of \$1.7 million due to lower professional fees.

• Net loss for the year ended December 31, 2023 was \$(13.3) million, or \$(4.24) per share, compared to a net loss of \$(20.3) million, or \$(11.58) per share, for the same period the prior year.

FOURTH QUARTER AND FULL YEAR 2023 RESULTS CONFERENCE CALL

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

A live webcast will be available at ir.plustherapeutics.com/events.

Participants may also pre-register any time before the call <u>here</u>. Once registration is completed, participants will be provided a dial-in number with a personalized conference code to access the call. Please dial in 15 minutes prior to the start time.

Following the live call, a replay will be available on the Company's website under the 'For Investors' section. The webcast will be available on the Company's website for 90 days following the live call.

About Plus Therapeutics

Plus Therapeutics, Inc. is a clinical-stage pharmaceutical company developing targeted radiotherapeutics for difficult-to-treat cancers of the central nervous system with the potential to enhance clinical outcomes for patients. Combining image-guided local beta radiation and targeted drug delivery approaches, the Company is advancing a pipeline of product candidates with lead programs in recurrent glioblastoma (GBM) and leptomeningeal metastases (LM). The Company has built a supply chain through strategic partnerships that enable the development, manufacturing and future potential commercialization of its products. Plus Therapeutics is led by an experienced and dedicated leadership team and has operations in key cancer clinical development hubs including Austin and San Antonio, Texas. For more information, visit https://plustherapeutics.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, including statements regarding clinical trials, expected operations and upcoming developments. 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 "potential," "anticipating," "planning" 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 potential promise of rhenium (186Re) obisbemeda including the ability of rhenium (186Re) obisbemeda to safely and effectively deliver radiation directly to the tumor at high doses; expectations as to the Company's future performance including the next steps in developing the Company's current assets; the Company's clinical trials including statements regarding the timing and characteristics of the ReSPECT-GBM, ReSPECT-LM and ReSPECT-PBCclinical trials; possible negative effects of rhenium (186Re) obisbemeda; the continued evaluation of rhenium (186Re) obisbemeda including through evaluations in additional patient cohorts; and the intended functions of the Company's platform and expected benefits from such functions.

The forward-looking statements included in this press release could differ materially from those expressed or implied by these forward-looking statements because of risks, uncertainties, and other factors that 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 cancer diagnostics and therapeutics field, ability to develop and protect proprietary intellectual property or obtain licenses to intellectual property developed by others on commercially reasonable and competitive terms, and material security breach or cybersecurity attack

affecting the Company's operations or property. This list of risks, uncertainties, and other factors is not complete. Plus Therapeutics discusses some of these matters more fully, as well as certain risk factors that could affect Plus Therapeutics' business, financial condition, results of operations, and prospects, in its reports filed with the SEC, including Plus Therapeutics' annual report on Form 10-K for the fiscal year ended December 31, 2023, quarterly reports on Form 10-Q, and current reports on Form 8-K. These filings are available for review through the SEC's website at www.sec.gov. Any or all forward-looking statements Plus Therapeutics makes may turn out to be wrong and can be affected by inaccurate assumptions Plus Therapeutics might make or by known or unknown risks, uncertainties, and other factors, including those identified in this press release. Accordingly, you should not place undue reliance on the forward-looking statements made in this press release, which speak only as of its date. 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.

Investor Contact

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PLUS THERAPEUTICS, INC.

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

| | | As of December 31, | | |
|---|------|--------------------|------|-----------|
| | 2023 | | 2022 | |
| Assets | | | | |
| Current assets: | | | | |
| Cash and cash equivalents | \$ | 8,554 | \$ | 18,120 |
| Other current assets | | 1,280 | | 3,697 |
| Total current assets | | 9,834 | | 21,817 |
| | | | | |
| Property and equipment, net | | 906 | | 1,324 |
| Operating lease right-use-of assets | | 202 | | 248 |
| Goodwill | | 372 | | 372 |
| Intangible assets, net | | 42 | | 94 |
| Other assets | | 32 | | 12 |
| Total assets | \$ | 11,388 | \$ | 23,867 |
| Liabilities and Stockholders' Equity (Deficit) | | | | |
| Current liabilities: | | | | |
| Accounts payable and accrued expenses | \$ | 6,631 | \$ | 10,134 |
| Operating lease liability | | 120 | | 110 |
| Term loan obligation, current | | 3,976 | | 1,608 |
| Total current liabilities | | 10,727 | | 11,852 |
| | | | | |
| Noncurrent operating lease liability | | 85 | | 141 |
| Term loan obligation | | _ | | 3,786 |
| Deferred grant liability | | 1,924 | | 1,643 |
| Total liabilities | | 12,736 | , | 17,422 |
| | | | | |
| Commitments and contingencies | | | | |
| | | | | |
| Stockholders' equity (deficit): | | | | |
| Preferred stock, \$0.001 par value; 5,000,000 shares authorized; 1,952 shares issued and outstanding as of December 31, 2023 and 2022 | | _ | | |
| Common stock, \$0.001 par value; 100,000,000 shares authorized; 4,522,656 issued and 4,444,097 outstanding as of December 31, 2023, 2,240,092 shares issued and outstanding as of December 31, 2022, respectively | | | | |
| | | 5 | | 2 |
| Treasury stock (at cost, 78,559 shares as of December 31, 2023) | | (126) | | |
| Additional paid-in capital | | 479,274 | | 473,628 |
| Accumulated deficit | | (480,501) | | (467,185) |
| Total stockholders' equity (deficit) | | (1,348) | | 6,445 |
| Total liabilities and stockholders' equity (deficit) | \$ | 11,388 | \$ | 23,867 |

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

| | For the Years Ended December 31, | | ember 31, |
|--|----------------------------------|----|-----------|
| | 2023 | | 2022 |
| Grant revenue | \$ 4,913 | \$ | 224 |
| Operating expenses: | | | |
| Research and development | 9,690 | | 9,698 |
| General and administrative | 8,544 | | 10,238 |
| Total operating expenses | 18,234 | | 19,936 |
| Operating loss | (13,321) | | (19,712) |
| Other income (expense): | | | |
| Interest income | 400 | | 147 |
| Interest expense | (395) | | (711) |
| Change in fair value of liability instruments | _ | | 1 |
| Total other income/(expense) | 5 | | (563) |
| Net loss | \$ (13,316) | \$ | (20,275) |
| Net loss per share, basic and diluted | \$ (4.24) | \$ | (11.58) |
| | | | |
| Basic and diluted weighted average shares used in calculating net loss per share attributable to common stockholders | 3,140,925 | | 1,750,350 |

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

| For the Years En | ded December 31, |
|------------------|------------------|
| 2023 | 2022 |
| 2023 | 2022 |

| Cash flows used in operating activities: | | | | |
|--|---------|----------|----|----------|
| Net loss | \$ | (13,316) | \$ | (20,275) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | | | |
| Depreciation and amortization | | 628 | | 619 |
| Amortization of deferred financing costs and debt discount | | 190 | | 389 |
| Common stock issued for research and development | | 75 | | _ |
| Change in fair value of liability instruments | | _ | | (1) |
| Loss on disposal of property and equipment | | 2 | | _ |
| Share-based compensation expense | | 569 | | 606 |
| Reduction in the carrying amount of operating lease right-of-use assets | | 117 | | 93 |
| Increases (decreases) in cash caused by changes in operating assets and liabilities: | | | | |
| Other assets | | 2,397 | | (2,369) |
| Accounts payable and accrued expenses | | (3,677) | | 6,452 |
| Change in operating lease liabilities | | (117) | | (129) |
| Deferred grant liability | | 281 | | 1,643 |
| Net cash used in operating activities | | (12,851) | | (12,972) |
| | | | | |
| Cash flows used in investing activities: | | | | |
| Purchases of property and equipment and intangible assets | | (160) | | (509) |
| In process research and development acquired | | _ | | (250) |
| Net cash used in investing activities | | (160) | | (759) |
| Cash flows from financing activities: | | | | |
| Principal payments of long-term obligations | | (1,600) | | (1,608) |
| Gross proceeds from sale of common stock | | (1,608) | | |
| Payment of offering costs related to sale of common stock | | 5,527 | | 15,832 |
| Purchase of treasury stock | | (348) | | (773) |
| Net cash provided by financing activities | | (126) | | 12.451 |
| | | 3,445 | | 13,451 |
| Net decrease in cash and cash equivalents | | (9,566) | | (280) |
| Cash and cash equivalents at beginning of period | \$ | 18,120 | \$ | 18,400 |
| Cash and cash equivalents at end of period | <u></u> | 8,554 | 3 | 18,120 |
| Supplemental disclosure of cash flows information: | | | | |
| Cash paid during period for: | | | | |
| Interest | \$ | 222 | \$ | 327 |
| Supplemental schedule of non-cash investing and financing activities: | | | | |
| Unpaid offering cost | \$ | 174 | \$ | _ |
| Common stock issued in payment for in process research and development | \$ | 75 | \$ | _ |
| Right-of-use assets acquired by assuming operating lease liabilities | \$ | 71 | \$ | _ |
| | | | | |