

**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): **July 21, 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 July 21, 2022, Plus Therapeutics, Inc. (the “Company”) reported financial results for the quarter ended June 30, 2022 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.**

<b>Exhibit Number</b>	<b>Description</b>
99.1	<a href="#">Press Release Announcing Financial Results, dated July 21, 2022.</a>
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: July 21, 2022

**PLUS THERAPEUTICS, INC.**

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

**Plus Therapeutics Reports Second Quarter 2022 Financial Results and Business Highlights**

*Completed enrollment of Cohort 1 in ReSPECT-LM Phase 1/2a dose escalation trial of <sup>186</sup>RNL for Leptomeningeal Metastases*

*On track to complete key manufacturing objectives for cGMP <sup>186</sup>RNL to support ongoing and planned clinical trials in 2022 and beyond*

*Multiple planned data presentations for glioblastoma and leptomeningeal metastasis indications planned for the second half of 2022*

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

AUSTIN, Texas, July 21, 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 second quarter ended June 30, 2022, and provided an overview of recent business highlights.

“During the second quarter, we maintained the momentum to successfully complete our key corporate goals for 2022,” said Marc H. Hedrick M.D., President and Chief Executive Officer of Plus Therapeutics. “Clinical data from our glioblastoma and leptomeningeal metastasis trials, though early in development, continue to show promise and we remain on track to complete key CMC and regulatory objectives.”

**RECENT HIGHLIGHTS****Rhenium-186 NanoLiposome (<sup>186</sup>RNL), a novel radiotherapy in development for several rare cancer targets**

- In July 2022, the Company completed the technology transfer and initiation of cGMP manufacturing of the <sup>186</sup>RNL drug intermediate with Piramal Pharma Solutions. Additionally, the intermediate drug product is in stability testing and compliant with the U.S. Food and Drug Administration (FDA) guidance for manufacture of nanoliposomal drug products for use in late-stage clinical trials and commercialization. The Company expects to have GMP drug availability in the second half of 2022 for ongoing and planned clinical trials in adults with recurrent glioblastoma, leptomeningeal metastasis and future disease targets.
  - In July 2022, at the Society of Nuclear Medicine and Molecular Imaging (SNMMI) 2022 Annual Meeting, the Company presented positive interim data on the lead investigational drug, <sup>186</sup>RNL, from the Phase 1/2a ReSPECT-GBM dose escalation clinical trial in patients with recurrent glioblastoma (GBM). During the presentation, the Company noted that the trial has evaluated 23 adult patients with recurrent GBM across 7 cohorts of increasing dose. To date, there have been no dose limiting toxicities and promising efficacy signals have been observed in patients receiving average absorbed doses of radiation > 100 Gy.
-

- The Company's principal investigator will provide a full data update on the Phase 1/2a ReSPECT-GBM dose escalation clinical trial at the European Society of Medical Oncology Meeting in Paris France, September 9-13, 2022.
- In the second quarter of 2022, the Company completed enrollment of Cohort 1 of the ReSPECT-LM Phase 1/2a dose escalation trial of <sup>186</sup>RNL in patients with leptomeningeal metastases (LM). <sup>186</sup>RNL was successfully delivered without dose limiting toxicities in this initial cohort and the independent ReSPECT-LM trial Data Safety & Monitoring board has approved the plan to move ahead with the Cohort 2.
- The Company submitted two briefing packages to the FDA to seek their opinion on the recurrent GBM clinical program and CMC development plans.
- The Company entered into a multi-year agreement with Biocept, Inc. to employ its cerebrospinal fluid assay in the ReSPECT-LM Phase 1/2a dose-escalation clinical trial. Biocept's assay provides a highly sensitive method to assess and quantify tumor cell burden in LM of the central nervous system. Assay results will be used to evaluate biologic response to treatment and treatment efficacy for patients enrolling in the ReSPECT-LM trial.
- The Company obtained FDA approval for the ReSPECT-GBM multiple dose extension trial.

#### **Rhenium-188 NanoLiposome Biodegradable Alginate Microsphere (<sup>188</sup>RNL-BAM), a novel radiotherapy in development for solid organ cancers**

- The Company has completed key technology transfer activities from UT Health Science Center at San Antonio and is on track to complete key CMC feasibility and IND enabling preclinical studies in the fourth quarter of 2022.

#### **SECOND QUARTER 2022 FINANCIAL RESULTS**

- The Company's cash balance was \$18.1 million at June 30, 2022, compared to \$18.4 million at December 31, 2021.
- Total operating expenses for the second quarter of 2022 were \$5.1 million, compared to total operating expenses of \$2.6 million for second quarter of 2021. The increase is due primarily to incremental CMC spend relating to the development of GMP <sup>186</sup>RNL drug and key regulatory consulting activities, both of which are on track to be completed in the third quarter of 2022. In addition, to a lesser extent, the Company had a forecasted increase in legal, professional fees and other general corporate expenses.
- Net loss for the second quarter of 2022 was \$5.3 million, or \$(0.24) per share, compared to a net loss of \$2.8 million, or \$(0.25) per share, for the second quarter of 2021.

#### **UPCOMING EVENTS AND MILESTONES**

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

---

- Present updated data from the ReSPECT-GBM and ReSPECT-LM at European Society of Medical Oncology and Society of Neuro-Oncology scientific conferences.
- Receive FDA feedback from CMC and clinical Type C meetings for the recurrent GBM program.
- Complete GMP manufacturing milestones for <sup>186</sup>RNL.
- Submit a protocol for the study of <sup>186</sup>RNL in patients with pediatric brain cancer (ReSPECT-PBC).
- Complete key CMC & IND-enabling studies for <sup>188</sup>RNL-BAM.

### **Second 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.

A live webcast will be available at [ir.plustherapeutics.com/events](http://ir.plustherapeutics.com/events).

Participants may also pre-register any time before the call. 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 Investor](#)' 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 focused on the development, manufacture, and commercialization of complex and innovative treatments for patients battling cancer and other life-threatening diseases. Our proprietary nanotechnology platform is currently centered around the enhanced delivery of a variety of drugs using novel liposomal encapsulation technology. Liposomal encapsulation has been extensively explored and undergone significant technical and commercial advances since it was first developed. Our 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](http://PlusTherapeutics.com) and [ReSPECT-Trials.com](http://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," "can," "potential," "focus," "preparing," "next steps," "possibly," 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 about the Company's anticipated expenditures, including research and development, and general and administrative

---

expenses; the Company's strategic collaborations and license agreements, intellectual property, FDA approvals and interactions and government regulation; the potential size of the market for its product candidates; the Company's research and development efforts; results from the Company's pre-clinical and clinical studies and the implications of such results regarding the efficacy or safety of its product candidates; the safety profile, pathways, and efficacy of its 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 its product candidates and therapies in its markets; sources of competition for any of the Company's product candidates; the Company's pipeline; its 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 June 30, 2022, including the Company's 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 our 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)**

	<u>June 30, 2022</u>	<u>December 31, 2021</u>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 18,090	\$ 18,400
Other current assets	799	1,324
Total current assets	<u>18,889</u>	<u>19,724</u>
Property and equipment, net	1,560	1,477
Operating lease right-use-of assets	303	341
Goodwill	372	372
Intangible assets, net	131	51
Other assets	16	16
Total assets	<u>\$ 21,271</u>	<u>\$ 21,981</u>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 5,259	\$ 4,151
Operating lease liability	104	111
Term loan obligation, current	1,608	1,608
Total current liabilities	<u>6,971</u>	<u>5,870</u>
Noncurrent operating lease liability	202	269
Term loan obligation	4,419	5,005
Warrant liability	—	1
Total liabilities	<u>11,592</u>	<u>11,145</u>
Stockholders' equity:		
Preferred stock, \$0.001 par value; 5,000,000 shares authorized; 1,952 shares issued and outstanding at June 30, 2022 and December 31, 2021	—	—
Common stock, \$0.001 par value; 100,000,000 shares authorized; 22,468,682 and 15,510,025 issued and outstanding at June 30, 2022 and December 31, 2021, respectively	22	16
Additional paid-in capital	465,965	457,730
Accumulated deficit	<u>(456,308)</u>	<u>(446,910)</u>
Total stockholders' equity	<u>9,679</u>	<u>10,836</u>
Total liabilities and stockholders' equity	<u>\$ 21,271</u>	<u>\$ 21,981</u>



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

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2022	2021	2022	2021
<b>Operating expenses:</b>				
Research and development	2,831	1,106	4,615	2,233
General and administrative	2,289	1,469	4,431	2,821
Total operating expenses	5,120	2,575	9,046	5,054
Operating loss	(5,120)	(2,575)	(9,046)	(5,054)
<b>Other income (expense):</b>				
Interest income	19	4	26	8
Interest expense	(181)	(229)	(379)	(476)
Change in fair value of liability instruments	—	—	1	2
Total other expense	(162)	(225)	(352)	(466)
Net loss	\$ (5,282)	\$ (2,800)	\$ (9,398)	\$ (5,520)
Net loss per share, basic and diluted	\$ (0.24)	\$ (0.25)	\$ (0.43)	\$ (0.56)
Basic and diluted weighted average shares used in calculating net loss per share attributable to common stockholders	22,254,823	11,296,816	21,919,956	9,790,726

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

	<b>For the Six Months Ended June 30,</b>	
	<b>2022</b>	<b>2021</b>
<b>Cash flows used in operating activities:</b>		
Net loss	\$ (9,398)	\$ (5,520)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	302	179
Amortization of deferred financing costs and debt discount	218	283
Change in fair value of liability instruments	(1)	(2)
Stock-based compensation expense	347	245
Change of operating lease assets and liabilities	(36)	—
Non-cash lease expense	—	4
Increases (decreases) in cash caused by changes in operating assets and liabilities:		
Other current assets	525	(11)
Accounts payable and accrued expenses	1,527	(583)
Net cash used in operating activities	<u>(6,516)</u>	<u>(5,405)</u>
<b>Cash flows (used in) investing activities:</b>		
Purchases of property and equipment	(348)	(80)
Purchases of intangible assets	(117)	—
In process research and development acquired	(250)	—
Net cash used in investing activities	<u>(715)</u>	<u>(80)</u>
<b>Cash flows from financing activities:</b>		
Principal payments of long-term obligations	(804)	—
Payment of financing lease liability	—	(8)
Proceeds from exercise of warrants	—	2,017
Proceeds from sale of common stock, net	7,725	12,291
Net cash provided by financing activities	<u>6,921</u>	<u>14,300</u>
Net increase (decrease) in cash and cash equivalents	<u>(310)</u>	<u>8,815</u>
Cash and cash equivalents at beginning of period	18,400	8,346
Cash and cash equivalents at end of period	<u>\$ 18,090</u>	<u>\$ 17,161</u>

**Investor Contact**

Peter Vozzo  
ICR Westwicke  
(443) 377-4767  
Peter.Vozzo@westwicke.com

**Media Contact**

Terri Clevenger  
ICR Westwicke  
(203) 856-4326  
Terri.Clevenger@westwicke.com