

**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): **October 22, 2020**

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	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 October 22, 2020, Plus Therapeutics, Inc. (the “Company”) reported financial results for the quarter ended September 30, 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 October 22, 2020.

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: October 22, 2020

PLUS THERAPEUTICS, INC.

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

Plus Therapeutics Reports Third Quarter 2020 Financial Results and Business Highlights

– Received FDA Orphan Drug and Fast Track designations for novel glioblastoma radiotherapy –
– Management to host conference call today, Thursday, October 22nd, at 5:00 p.m. ET –

AUSTIN, Texas, October 22, 2020 (GLOBE NEWSWIRE) – Plus Therapeutics, Inc. (Nasdaq: PSTV) (the “Company”), today announced financial results for the third quarter ended September 30, 2020, and provided an overview of recent business highlights.

“Our lead investigational drug, RNL™ for recurrent glioblastoma, continues to progress toward its first major data readout,” said Dr. Marc Hedrick, President and Chief Executive Officer of Plus Therapeutics. “In the third quarter, we advanced RNL successfully to the sixth dosing cohort and we are now administering over 1,000% more radiation to patients in a single treatment than can be delivered with traditional external beam radiation therapy.”

Third Quarter 2020 and Recent Clinical Highlights

Plus Therapeutics has three clinical stage, nanoscale injectable oncology drugs, each designed to provide enhanced benefits versus existing therapies. The Company’s lead investigational drug is Rhenium NanoLiposome (RNL™), a radiotherapy being developed for several cancer targets. RNL is being evaluated in the U.S. NIH/NCI-supported, multi-center ReSPECT™ Phase 1 dose-finding trial and for the treatment of recurrent glioblastoma. RNL is designed to safely, effectively, and conveniently deliver a targeted and very high dose of radiation directly to brain tumors. In addition:

- The U.S. Food and Drug Administration (FDA) granted the Company Orphan Drug and Fast Track Designations for RNL for the treatment of glioblastoma patients.
- The Company established a Clinical Advisory Board of five leading experts in the fields of neurological surgery and neuro-oncology that will advise the Company as it advances its nanoscale therapeutics to treat rare brain and neurological cancers.
- The independent Data and Safety Monitoring Board (DSMB) of the ReSPECT Phase 1 trial in recurrent glioblastoma approved the Company to commence enrollment in the sixth cohort of patients.

Expected Upcoming Milestones and Events

The first nine months of 2020 marked the successful implementation of the Company’s expanded development focus, pipeline expansion and optimized costs and operational structure. In upcoming quarters, the Company intends to focus on a number of additional business objectives and potential milestones:

- Report preliminary RNL data from the ReSPECT Phase 1 dose-finding trial in recurrent glioblastoma at the Society of Neuro-Oncology Annual Meeting being held virtually November 19-22, 2020.
 - Finalize plans for the next stage of clinical development for RNL in recurrent glioblastoma.
 - Continue evaluations of additional external and internal drug development candidates.
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- Initiate IND-enabling RNL studies for additional indications.
- Explore partnership opportunities for RNL, DocePLUS™ and DoxoPLUS™ assets.

Third Quarter 2020 Financial Results

- As of September 30, 2020, the Company had cash of approximately \$7.6 million, compared to cash of approximately \$17.6 million as of December 31, 2019. During the third quarter of 2020, 317,521 series U warrants were exercised, raising \$0.7 million. Net cash used in operating activities was \$5.2 million for the nine months ended September 30, 2020, compared to net cash used of \$6.9 million during the same period in 2019. During the second quarter of 2020, \$5 million of the Oxford debt principal was paid down.
- On September 30, 2020, the Company entered into a purchase agreement and registration rights agreement with Lincoln Park Capital Fund, LLC (LPC) pursuant to which and following the filing and effectiveness of a registration statement, the Company will have the right at its sole discretion, but not the obligation, to sell to LPC up to \$25 million worth of shares over the 36-month term of the agreement, subject to various terms and conditions.
- On October 9, 2020 the Company filed a shelf registration on Form S-3 allowing for the sale of securities “at the market” of up to \$10 million.
- Loss from continuing operations for the third quarter 2020 was \$1.7 million, or \$(0.39) per share, compared to operating income of \$0.5 million, or \$(0.03) per share (on a fully diluted basis including preferred stock), for the same period in 2019.
- Net loss in the third quarter of 2020 was \$1.7 million, or \$(0.39) per share, compared to net income of \$0.5 million, or \$(0.03) per share (on a fully diluted basis including preferred stock), for the third quarter of 2019.
- Clinical expenses relating to the ReSPECT Phase 1 dose-finding trial in recurrent glioblastoma continue to be funded under a \$3 million grant with the U.S. NIH/NCI.

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 Third Quarter 2020 Financial Results Conference Call and Webcast
Date: Thursday, October 22, 2020
Time: 5:00 p.m. Eastern Time.
Live Call: 877-402-3914; 631-865-5294 (Intl.); Conference ID: 2108916

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 Company’s belief as to the platform’s capacity to leverage new delivery approaches and/or formulations to enable significant potential enhancements of safety, efficacy and convenience for patients and healthcare providers; the potential of the Company’s portfolio generally, and the potential of RNL™ to safely and effectively deliver a dose of radiation directly to the tumor up to 25 times greater than that currently being given to patients using external beam radiation therapy; the Company’s belief as to the potential of RNL™ to improve brain tumor therapy and that of other difficult to treat radiosensitive tumors; the timing, status, outcome, and anticipated expansion of clinical trials for RNL™, including the planned initiation of an additional Phase 1 study and enrollment at additional sites, and the anticipated timing thereof; the Company’s business expansion outlook for the second half of 2020, including its intended focus on certain additional business expansion milestones; the Company’s expectations regarding the progress and prospect of advancement for the Company, RNL™, and the Company’s portfolio during the second half of 2020; and the potential impact of the COVID-19 pandemic on the Company and its clinical programs, operating results, and financial condition. 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 CONDENSED BALANCE SHEETS
(UNAUDITED)
(in thousands, except share and par value data)

	As of September 30, 2020	As of December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	\$ 7,626	\$ 17,552
Accounts receivable	—	1,169
Restricted cash	—	40
Inventories, net	107	107
Other current assets	916	957
Total current assets	<u>8,649</u>	<u>19,825</u>
Property and equipment, net	1,943	2,179
Operating lease right-of-use assets	671	781
Other assets	18	72
Goodwill	372	372
Total assets	<u>\$ 11,653</u>	<u>\$ 23,229</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 2,083	\$ 3,279
Operating lease liability	140	147
Term loan obligations, net of discount	6,181	11,060
Total current liabilities	<u>8,404</u>	<u>14,486</u>
Noncurrent operating lease liability	545	646
Warrant liability	83	6,929
Other noncurrent liabilities	—	8
Total liabilities	<u>9,032</u>	<u>22,069</u>
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Preferred stock, \$0.001 par value; 5,000,000 shares authorized; 1,954 and 1,959 shares issued and outstanding at September 30, 2020 and December 31, 2019, respectively	—	—
Common stock, \$0.001 par value; 100,000,000 shares authorized; 4,591,415 and 3,880,588 shares issued and outstanding at September 30, 2020 and December 31, 2019, respectively	5	4
Additional paid-in capital	432,540	426,426
Accumulated deficit	(429,924)	(425,270)
Total stockholders' equity	<u>2,621</u>	<u>1,160</u>
Total liabilities and stockholders' equity	<u>\$ 11,653</u>	<u>\$ 23,229</u>

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

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2020	2019	2020	2019
Development revenues:				
Government contracts and other	\$ —	\$ 4,771	\$ 303	\$ 5,810
Operating expenses:				
Research and development	336	921	1,604	3,636
In process research and development acquired from NanoTx	—	—	781	—
Sales and marketing	104	94	319	305
General and administrative	956	1,076	3,788	3,313
Total operating expenses	<u>1,396</u>	<u>2,091</u>	<u>6,492</u>	<u>7,254</u>
Operating income (loss)	(1,396)	2,680	(6,189)	(1,444)
Other income (expense):				
Interest income	2	6	47	20
Interest expense	(253)	(366)	(854)	(1,477)
Change in fair value of warrants	(81)	(561)	2,342	(69)
Warrant issuance cost	—	(1,233)	—	(1,233)
Total other income (expense)	<u>(332)</u>	<u>(2,154)</u>	<u>1,535</u>	<u>(2,759)</u>
Income (Loss) from continuing operations	(1,728)	526	(4,654)	(4,203)
Loss from discontinued operations	—	—	—	(7,568)
Net income (loss)	<u>\$ (1,728)</u>	<u>\$ 526</u>	<u>\$ (4,654)</u>	<u>\$ (11,771)</u>
Income (Loss) from continuing operations	\$ (1,728)	\$ 526	\$ (4,654)	\$ (4,203)
Beneficial conversion feature for convertible preferred stock	—	(554)	—	\$ (554)
Net loss allocable to common stockholders - continuing operations	\$ (1,728)	\$ (28)	\$ (4,654)	\$ (4,757)
Net loss allocable to common stockholders - discontinued operations	\$ —	\$ —	\$ —	\$ (7,568)
Basic and diluted net loss per share attributable to common stockholders - continuing operations	\$ (0.39)	\$ (0.03)	\$ (1.13)	\$ (8.78)
Basic and diluted net loss per share attributable to common stockholders - discontinued operations	\$ —	\$ —	\$ —	\$ (13.97)
Net loss per share, basic and diluted	<u>\$ (0.39)</u>	<u>\$ (0.03)</u>	<u>\$ (1.13)</u>	<u>\$ (22.75)</u>
Basic and diluted weighted average shares used in calculating net loss per share attributable to common stockholders	4,402,221	826,548	4,113,928	541,777

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

	<u>For the Nine Months Ended September 30,</u>	
	<u>2020</u>	<u>2019</u>
Cash flows used in operating activities:		
Net loss	\$ (4,654)	\$ (11,771)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	273	778
Amortization of deferred financing costs and debt discount	428	354
In process research and development acquired from NanoTx Therapeutics	781	—
Noncash lease expenses	2	22
Change in fair value of warrants	(2,342)	69
Share-based compensation expense	149	106
Loss on sale of business	—	6,508
Allocation of issuance costs associated with warrants	—	1,233
Increases (decreases) in cash caused by changes in operating assets and liabilities:		
Accounts receivable	1,169	(4,851)
Inventories	—	274
Other current assets	516	252
Other assets	54	298
Accounts payable and accrued expenses	(1,586)	(297)
Deferred revenues	—	29
Other long-term liabilities	—	54
Net cash used in operating activities	<u>(5,210)</u>	<u>(6,942)</u>
Cash flows provided by (used in) investing activities:		
Purchases of property and equipment	(37)	(8)
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>(437)</u>	<u>5,629</u>
Cash flows used in financing activities:		
Principal payments of long-term obligations	(5,307)	(3,490)
Payment of financing lease liability	(93)	(75)
Proceeds from exercise of warrants	1,081	491
Proceeds from sale of common stock, net	—	15,964
Net cash provided by (used in) financing activities	<u>(4,319)</u>	<u>12,890</u>
Effect of exchange rate changes on cash and cash equivalents	—	(4)
Net increase (decrease) in cash and cash equivalents	<u>(9,966)</u>	<u>11,573</u>
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>7,626</u>	<u>16,874</u>
Supplemental disclosure of cash flows information:		
Cash paid during period for:		
Interest	\$ 470	\$ 1,071
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	\$ —
Offering cost paid in warrants	\$ —	\$ 213
Unpaid offering costs	\$ 12	\$ 403

Contact:

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