

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 12, 2020

CNS Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Nevada
(State or other jurisdiction of
incorporation or organization)

001-39126
(Commission File Number)

82-2318545
(I.R.S. Employer Identification No.)

2100 West Loop South, Suite 900
Houston, Texas 77027
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: **(800) 946-9185**

Not Applicable
(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 Instruction 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))

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.

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbols(s)	Name of each exchange on which registered
Common stock, par value \$0.001 per share	CNSP	The NASDAQ Stock Market LLC

Item 2.02 Results of Operations and Financial Condition.

On March 12, 2020, CNS Pharmaceuticals, Inc. (the “Company”) issued a press release announcing business highlights and financial results for the three months ended December 31, 2019 and fiscal year 2019.

The information contained in Item 2.01 of this Current Report on Form 8-K, including Exhibit 99.1, is being furnished and shall not be deemed to be "filed" for the purpose of the Securities Exchange Act of 1934, as amended ("Exchange Act"), nor shall it be deemed incorporated by reference in any filing under the Exchange Act or the Securities Act of 1933, as amended, unless specifically identified therein as being incorporated by reference.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Exhibit Description
99.1	<u>Press Release dated March 12, 2020</u>

Signature

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.

CNS Pharmaceuticals, Inc.

By: /s/ Chris Downs
Chris Downs
Chief Financial Officer

Dated: March 12, 2020

CNS Pharmaceuticals Announces Business Highlights and 2019 Fourth Quarter Financial Results

Company to Host Business Update Conference Call Today at 4:30 p.m. ET

HOUSTON (Mar. 12, 2020) – **CNS Pharmaceuticals, Inc. (NASDAQ: CNSP)** ("CNS" or the "Company"), a biopharmaceutical company specializing in the development of novel treatments for primary and metastatic cancers of the brain and central nervous system, today announced business highlights and financial results for the three months ended December 31, 2019 and Fiscal Year 2019.

Business highlights for the fourth quarter of 2019 and recent weeks include the following:

- **Selected a leading Polish institution for the Phase 1 pediatric trial with Berubicin in glioblastoma multiforme ("GBM").** In February 2020, CNS announced the selection of Children's Memorial Health Institute, the largest pediatric hospital in Poland as the single site for this pediatric trial which is expected to commence in the second half of 2020.
- **Completed final Good Manufacturing Practice ("GMP") reprocessing and purity validation of the existing batch of its lead drug candidate Berubicin.** In February 2020, the Company announced the final GMP reprocessing of the existing batch of Berubicin, reporting the GMP material met all specifications and analytical testing is now underway. The Company is continuing large-scale production of Berubicin and intends to utilize this supply to complete its planned Phase 2 clinical trial for patients with GBM.
- **Licensed a novel DNA-binding technology from The University of Texas MD Anderson Cancer Center to expand the clinical pipeline.** In January 2020, CNS entered into a licensing agreement with MD Anderson, granting the Company rights to develop and commercialize WP1244, a new class of DNA-binding agent designed to cross the blood-brain barrier for the potential treatment of primary and metastatic brain cancers. WP1244 has been shown in preclinical studies to be 500-times more potent than the chemotherapeutic agent daunorubicin in inhibiting tumor cell proliferation.
- **Received positive feedback from the U.S. Food and Drug Administration ("FDA") for Pre-IND (Investigational New Drug) proposal.** In its December 2019 positive response to the Company's Pre-IND request, the FDA indicated that the proposal to use a previously manufactured and currently available supply of a lyophilized drug product (i.e., Berubicin) in the Phase 2 clinical trial appears reasonable. Furthermore, the FDA noted that the requested dosage regimen for the planned Phase 2 trial with Berubicin in GBM, which will be based on the Reata Phase 1 trial, was reasonable.

Closed initial public offering (“IPO”) of common stock. The Company closed its IPO of 2,125,000 shares of common stock at an offering price of \$4.00 per share on November 13, 2019 and an additional 318,750 shares pursuant to the exercise in full of the underwriters’ over-allotment option sold at the IPO price of \$4.00 per share on November 20, 2019. Gross proceeds from the offering, including the exercise of the underwriters’ over-allotment option, were \$9.8 million and will be used to fund CNS’ clinical trials and for working capital.

"Since completing our IPO we are very pleased with the progress we have made toward initiating our Phase 2 clinical study of Berubicin to treat GBM, which represents a significant unmet medical need," stated John M. Climaco, Chief Executive Officer of CNS Pharmaceuticals. "We believe Berubicin has the ability to cross the blood-brain barrier with positive responses in these types of tumors, as demonstrated in the Phase 1 study conducted by Reata. In the second half of this year, we look forward to initiating our Phase 2 clinical study in adults in the U.S., as well as two studies conducted in Poland by our sub-license partner, WPD Pharmaceuticals, including a Phase 2 study in adults which will mirror our U.S.-based study, and a first-ever Phase 1 study in children. In addition, we plan to perform further preclinical studies for our recently licensed WP1244 drug candidate, a novel and potent DNA binding agent with high potency to inhibit tumor cell proliferation."

Fourth Quarter Financial Results

General and administrative expense was \$1.0 million for the fourth quarter of 2019, compared with \$0.2 million for the prior-year period. The increase is largely attributable to the expanded corporate infrastructure implemented in order to advance the Company’s clinical development program following its IPO.

Research and development expense for the fourth quarter of 2019 was \$1.5 million, compared with \$0 for the fourth quarter of 2018. The expense in the quarter was largely related to the cost of reprocessing and validating the existing batch of Berubicin needed for the commencement of the Phase 2 clinical trial, as well as starting the production of a new batch of the drug necessary for the contemplated clinical trials, both in the U.S. and in Poland.

The net change in cash in the fourth quarter of 2019 was \$6.3 million. As of December 31, 2019, CNS had cash and cash equivalents of \$7.2 million, which includes \$8.8 million in net proceeds from our IPO.

Conference Call

CNS senior management will provide a business update in a conference call and live audio webcast beginning at 4:30 p.m. Eastern time today, March 12, 2020. The conference call dial-in and webcast information is as follows:

DOMESTIC DIAL-IN: (844) 535-4071
INTERNATIONAL DIAL-IN: (706) 679-2458
PASSCODE: 1254059
WEBCAST: CNS Business Update Conference Call.

For those unable to participate in the live conference call or webcast, a replay will be available beginning approximately two hours after the close of the conference call. To access the replay, dial 855-859-2056 or 404-537-3406. The replay passcode is 1254059. The replay can be accessed for a period of time on the CNS website at CNS Business Update Conference Call.

About CNS Pharmaceuticals, Inc.

CNS Pharmaceuticals is developing novel treatments for primary and metastatic cancers of the brain and central nervous system. Its lead drug candidate, Berubicin, is proposed for the treatment of glioblastoma multiforme (GBM), an aggressive and incurable form of brain cancer. CNS holds a worldwide exclusive license to the Berubicin chemical compound and has acquired all data and know-how from Reata Pharmaceuticals, Inc. related to a completed Phase 1 trial with Berubicin in GBM which Reata conducted in 2006. In this trial, 44% of patients experienced a statistically significant improvement in progression-free survival. This 44% disease control rate was based on 11 patients (out of 25 evaluable patients) with stable disease, plus responders. One patient experienced a durable complete response and remains cancer-free as of February 2020. In the second half of 2020, CNS expects to commence a Phase 2 clinical trial of Berubicin for the treatment of GBM in the U.S., while a sub-licensee partner undertakes a Phase 2 trial in adults and a first-ever Phase 1 trial in pediatric GBM patients in Poland. Its second drug candidate, WP1244, is a novel DNA binding agent that has shown in preclinical studies that it is 500-times more potent than the chemotherapeutic agent daunorubicin in inhibiting tumor cell proliferation. For more information, please visit www.cnspharma.com.

Forward-Looking Statements

Some of the statements in this press release are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995, which involve risks and uncertainties. Forward-looking statements in this press release include, without limitation, the ability of the Company to further the clinical development of Berubicin in the United States and Poland. These statements relate to future events, future expectations, plans and prospects. Although CNS believes the expectations reflected in such forward-looking statements are reasonable as of the date made, expectations may prove to have been materially different from the results expressed or implied by such forward-looking statements. CNS has attempted to identify forward-looking statements by terminology including "believes," "estimates," "anticipates," "expects," "plans," "projects," "intends," "potential," "may," "could," "might," "will," "should," "approximately" or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. These statements are only predictions and involve known and unknown risks, uncertainties and other factors, including those discussed in the Company's SEC filings, including under the heading "Risk Factors" in the Form S-1 filed on October 7, 2019. Any forward-looking statements contained in this press release speak only as of its date. CNS undertakes no obligation to update any forward-looking statements contained in this press release to reflect events or circumstances occurring after its date or to reflect the occurrence of unanticipated events.

CONTACTS:**CNS Pharmaceuticals**

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CNS Pharmaceuticals, Inc.
Statements of Operations

	<u>Year Ended Dec. 31, 2019</u>	<u>Year Ended Dec. 31, 2018</u>	<u>3 Mon. Ended Dec. 31, 2019</u>	<u>3 Mon. Ended Dec. 31, 2018</u>
Operating expenses:				
General and administrative	\$ 1,978,643	\$ 860,520	\$ 1,039,337	\$ 208,583
Research and development	<u>1,854,334</u>	<u>21,267</u>	<u>1,484,394</u>	<u>–</u>
Total operating expenses	<u>3,832,977</u>	<u>881,787</u>	<u>2,523,731</u>	<u>208,583</u>
Loss from operations	<u>(3,832,977)</u>	<u>(881,787)</u>	<u>(2,523,731)</u>	<u>(208,583)</u>
Other expense:				
Loss on settlement of liabilities	–	(6,286,841)	–	(6,286,841)
Loss on change in fair value of SAFE agreements	–	(122,120)	–	(122,120)
SAFE agreement expenses	–	(54,454)	–	–
Interest expense	(26,152)	(28,615)	(3,617)	(10,632)
Amortization of debt discount	(18,082)	(18,082)	–	(3,337)
Total other expense	<u>(44,234)</u>	<u>(6,510,112)</u>	<u>(3,617)</u>	<u>(6,422,930)</u>
Net loss	<u>\$ (3,877,211)</u>	<u>\$ (7,391,899)</u>	<u>\$ (2,527,348)</u>	<u>\$ (6,631,513)</u>
Loss per share - basic and diluted	<u>\$ (0.28)</u>	<u>\$ (0.70)</u>	<u>\$ (0.17)</u>	<u>\$ (0.63)</u>
Weighted average shares outstanding - basic and diluted	<u>13,647,908</u>	<u>10,510,551</u>	<u>15,072,760</u>	<u>10,536,004</u>

CNS Pharmaceuticals, Inc.
Balance Sheets

	<u>December 31, 2019</u>	<u>December 31, 2018</u>
Assets		
Current Assets:		
Cash and cash equivalents	\$ 7,241,288	\$ 282,736
Restricted cash	–	272,397
Prepaid expenses	652,622	33,000
Total current assets	7,893,910	588,133
Fixed Assets		
Furniture and equipment, net	18,165	–
Long-Term Assets:		
Deferred issuance costs	–	95,200
Total Assets	\$ 7,912,075	\$ 683,333
Liabilities and Stockholders' Deficit		
Current Liabilities:		
Accounts payable	\$ 243,666	\$ 128,071
Accounts payable and accrued expenses - related party	45,833	794
Accrued expenses	21,500	23,599
Convertible notes payable, net of discount	–	281,918
Notes payable	–	35,000
SAFE agreements	–	763,249
Total current liabilities	310,999	1,232,631
Total Liabilities	310,999	1,232,631
Commitments and contingencies		
Stockholders' Equity (Deficit):		
Preferred stock, \$0.001 par value, 5,000,000 shares authorized and 0 shares issued and outstanding	–	–
Common stock, \$0.001 par value, 75,000,000 shares authorized and 16,450,234 and 12,694,504 shares issued and outstanding, respectively	16,450	12,695
Additional paid-in capital	19,073,098	7,049,268
Accumulated deficit	(11,488,472)	(7,611,261)
Total Stockholders' Equity (Deficit)	7,601,076	(549,298)
Total Liabilities and Stockholders' Equity (Deficit)	\$ 7,912,075	\$ 683,333

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