

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): May 27, 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 8.01. Other Events.

On May 27, 2020, CNS Pharmaceuticals, Inc. (the "Company") issued a press release announcing an update on its development agreement for WP1122. A copy of the press release is attached to this report as Exhibit 99.1 and is incorporated by reference herein.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

<u>Exhibit No.</u>	<u>Exhibit Description</u>
99.1	Press release dated May 27, 2020

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: May 27, 2020

CNS Provides Update on Development Agreement for WP1122

HOUSTON, May 27 2020 /PRNewswire/ -- 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 provided an update on the development of WP1122. As previously announced, CNS entered into an agreement with WPD Pharmaceuticals for the development of several preclinical drug candidates for antiviral indications, including WP1122, in certain territories. WPD Pharmaceuticals previously licensed rights to WP1122, from Moleculin Biotech, Inc. (Moleculin) for certain territories.

Today, Moleculin announced that on May 1, 2020 it submitted a request to the US Food and Drug Administration ("FDA") for a Pre-IND Meeting to seek guidance on requirements for submitting an Investigational New Drug ("IND") application to study its drug candidate, WP1122, in a clinical trial for patients with COVID-19, and that on May 6, 2020, the FDA granted Moleculin's meeting request, and indicated that its goal for providing written responses is June 30, 2020, but that it plans to act early on this meeting request, provided there are no significant deficiencies in the Pre-IND package or unexpected shifts in its work priorities. Moleculin further stated that it may be able to submit its IND application in the second half of this year. More specific timing will depend upon the guidance Moleculin receives from its Pre-IND Meeting with the FDA.

Additionally, Moleculin announced that it engaged ImQuest BioSciences ("ImQuest") and the Illinois Institute of Technology Research Institute ("IITRI"). IITRI is initially focused on preclinical toxicology testing to help determine whether WP1122 can be considered safe for testing in humans. ImQuest conducted two rounds of preclinical assessment of the potential for WP1122 to address COVID-19. The first round was to demonstrate whether or not the improved pharmacology of WP1122 gave it a greater therapeutic window than 2-DG. The second round was to demonstrate the ability of WP1122 to inhibit coronavirus production in mammalian cell culture. The testing done by ImQuest was performed on a surrogate of SARS-CoV-2 called Human coronavirus strain 229E ("HCoV-229E").

Although these in vitro results should not be considered conclusive or indicative of what will happen in vivo, the initial results, received by Moleculin on May 4, 2020, showed that both 2-DG and WP1122 have an antiviral effect on HCoV-229E. WP1122 displayed a greater therapeutic index than 2-DG, while the virus yield reduction assay demonstrated a 5 to 10-fold inhibition of coronavirus production by WP1122 and 2-DG when compared to untreated virus control. Moleculin is having ImQuest repeat its tests to provide additional confidence in its findings. In addition to having ImQuest repeat their tests, Moleculin announced that it is arranging for additional in vitro testing to include additional human cell lines and the use of a validated SARS-CoV-2 assay, as well as testing against other pathogenic viruses. The Company cautions readers that these results are initial and are not conclusive.

Under the terms of the development agreement with WPD Pharmaceuticals, CNS agreed to fund a portion of the development costs of WP1122 and other drug candidates for antiviral indications in exchange for certain economic rights. CNS made an upfront cash payment of \$225,000 and committed to a milestone payment of \$775,000 to WPD Pharmaceuticals upon the successful completion of a Phase 2 study. In return, CNS is entitled to receive 50% of the net sales, less WPD's license costs, of resulting commercial products in WPD's licensed territories, other than Poland. Those territories include 29 countries in Europe and Asia, including Russia.

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 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 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 20, 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 been shown in preclinical studies to be 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 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 include, without limitation, whether the results of Moleculin's subsequent testing will statistically support the initial ImQuest results, and Moleculin's ability to file an IND in the second half of 2020, if at all. These statements relate to future events, future expectations, plans and prospects. Although CNS believes that 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 under in our SEC filings, including under Item 1A. "Risk Factors" in our most recently filed Form 10-K filed with the Securities and Exchange Commission ("SEC") and updated from time to time in our Form 10-Q filings and in our other public filings with the SEC. Any forward-looking statements contained in this release speak only as of its date. CNS undertakes no obligation to update any forward-looking statements contained in this release to reflect events or circumstances occurring after its date or to reflect the occurrence of unanticipated events.

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