

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 10, 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 7.01. Regulation FD Disclosure.

Representatives of CNS Pharmaceuticals, Inc. (the “Company”) will use the presentation set forth as Exhibit 99.1 herein in connection with various meetings from time to time with the investment community.

The information contained in Item 7.01 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>CNS Pharmaceuticals, Inc. Investor Presentation – March 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 10, 2020



CNS
PHARMACEUTICALS

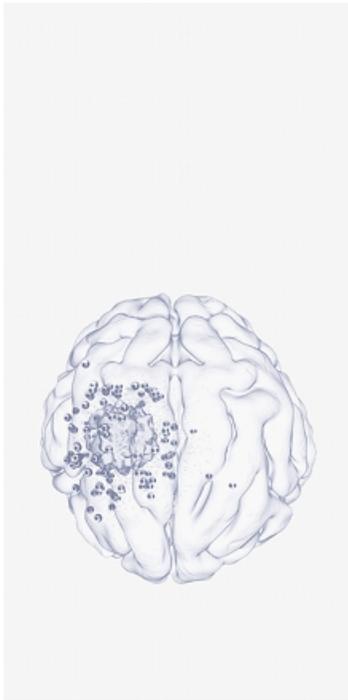
Nasdaq: CNSP

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Disclaimer.

This presentation incorporates information from materials filed with the SEC and contains forward-looking statements. All statements contained herein other than statements of historical fact, including statements regarding our future results of operations and financial position, our business strategy and plans, and our objectives for future operations, are forward-looking statements. The words "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "expect," and similar expressions are intended to identify forward looking statements. We have based these forward-looking statements largely on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, business strategy, short-term and long-term business operations and objectives, and financial needs.

These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in the "Risk Factors" section of the prospectus. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the future events and trends discussed in this presentation may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward looking statements.



About Us.

CNS IS DEVELOPING NOVEL ANTI-CANCER DRUG CANDIDATES FOR THE TREATMENT OF PRIMARY AND METASTATIC BRAIN CANCER AND CENTRAL NERVOUS SYSTEM TUMORS.

- Our lead drug candidate, Berubicin, was developed by Dr. Waldemar Priebe, Professor of Medicinal Chemistry at The University of Texas MD Anderson Cancer Center.
- Berubicin is an **Organ Targeted Therapeutic** that appeared to demonstrate **one durable Complete Response in a Phase 1** human clinical trial conducted by Reata Pharmaceuticals.*
- We have a collaboration agreement with Reata Pharmaceuticals for Phase 1 trial data and a clinical supply of Berubicin.
- Over \$25 million in private capital and grants were invested in Berubicin prior to our **\$9.8 million IPO** in November 2019.
- Licensed **second drug candidate, WP1244**, in 1Q20.
- WP1244 is a novel DNA binding agent believed to be **500x more potent than daunorubicin** in inhibiting tumor cell proliferation.

* A "complete response" to treatment means no signs of cancer are visible on MRI. This does not always mean the cancer is cured. Also called a complete remission:
www.cancer.gov/publications/dictionaries/cancer-terms/def/complete-response

Investment Highlights.

- Focusing on unmet need as glioblastoma multiforme (GBM) is an aggressive and incurable form of brain cancer
 - Orphan drug designation opportunity
 - Upside in additional cancer types
- Lead drug candidate developed Dr. Priebe, Professor of Medicinal Chemistry at The University of Texas MD Anderson Cancer Center
 - First anthracycline shown to cross the blood-brain barrier in adults
 - Positive Phase 1 results
 - Open-label Phase 2 study expected to commence in 3Q20
- Clinical development partnership enhances ability to advance drug in the clinic
 - R&D commitments for commercial rights in Eastern Europe and Central Asia
 - Received \$6 million in grants to perform to clinical studies
 - First-ever Phase 1 pediatric study to be performed
- Pipeline includes novel class of potential DNA binding therapeutics, shown to be 500x more potent than classic DNA binders in animal testing
- Collaborating with leading expert investigators

Product Development Pipeline.

PRODUCT	INDICATION	RESEARCH	PRECLINICAL	PHASE1	PHASE2 (start)	PHASE2 (complete)
Berubicin	GBM (U.S., adults)	→			2020	2022
Berubicin	GBM (Poland, 1 trial in adults + 1 trial in children)	→			2020	2022
Berubicin	Pancreatic & ovarian cancers and lymphomas	→			2021	
WP1244	CNS tumors	→			2020	

Berubicin Value Drivers.

- We have received positive pre-IND guidance from the FDA.
- Our clinical drug supply is on-hand and ready for use, per FDA guidance.
- We are preparing an IND for filing in Q2 2020.
- We plan to initiate a U.S. Phase 2 clinical trial of Berubicin for the treatment of GBM in Q3 2020.
- Potential for accelerated approval pathway due to desperate unmet clinical need.
- Berubicin was designated as an Orphan Drug when owned by Reata.
- Phase 2 trials in Poland (adults and children) to begin 2H 2020 at no cost to CNS.

About Glioblastoma Multiforme.

THERE ARE NO APPROVED CURATIVE TREATMENT OPTIONS FOR GBM.

- GBM is one of the most aggressive and common primary brain cancers in adults; it is highly invasive, malignant and virtually incurable.
- Nearly 15,000 new GBM patients are diagnosed each year in the U.S. (National Cancer Institute 2015).
- With optimal therapy (surgical resection, radiation and chemotherapy) patients have a median survival of approximately 15-23 months; nearly 100% of GBM tumors recur after first-line therapy.
- Access to the best care means nothing: U.S. Senators John McCain and Edward Kennedy, as well as Vice President Joe Biden's son Beau, all died from GBM.
- Decades of research = survival outcomes unchanged.

About Anthracyclines.

BERUBICIN IS THE FIRST ANTHRACYCLINE TO CROSS THE BLOOD-BRAIN BARRIER IN ADULTS AND REACH TUMOR CELLS IN PATIENTS WITH BRAIN CANCER.

- Anthracyclines are among the most effective anti-cancer treatments ever developed.
- According to academic literature, anthracyclines have demonstrated anti-tumor activity in a wide range of cancers including breast, stomach, uterine, ovarian, bladder, lung and hematological malignancies.
- Where effective, anthracyclines are generally considered to be preferred first-line therapeutics.
- Anthracyclines have never been shown to cross the blood-brain barrier in the adult brain and affect deadly brain cancers, until now.

About Berubicin.

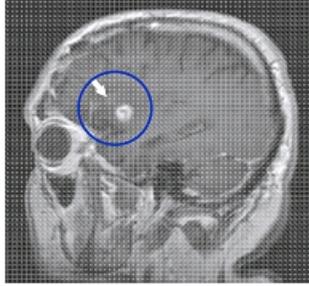
NOVEL USE FOR A PROVEN THERAPEUTIC CLASS.

- Berubicin is a novel anthracycline drug candidate for the treatment of GBM.
- **Berubicin is an Organ Targeted Therapeutic designed to concentrate in the brain *and* specifically in tumor tissue therein.**
- 44% of GBM patients enrolled in Phase 1 trial showed a clinically significant response to Berubicin.
- **One GBM patient from Phase 1 remains cancer-free over 10 years following treatment with Berubicin.**
- Berubicin has shown evidence of improved Overall Survival beyond median survival rate of only 14.6 months from diagnosis.
- **Based on limited clinical data, Berubicin is the first anthracycline that appears to cross the blood-brain barrier in the adult brain.**
- Berubicin has been in development for over 15 years.

Berubicin Phase 1 Clinical Trial.

A COMPLETE RESPONSE TO BERUBICIN MEANS NO SIGNS OF CANCER ARE VISIBLE ON MRI*

CNS pharmaceuticals



PRE-TREATMENT



6 MO. POST-TREATMENT

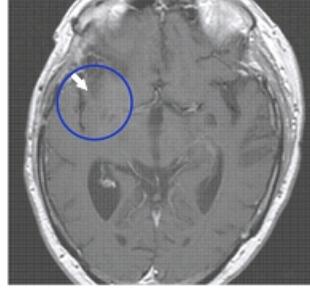
* This does not always mean the cancer is cured. Also called a complete remission: www.cancer.gov/publications/dictionaries/cancer-term/def/complete-response

Berubicin Phase 1 Clinical Trial.

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PRE-TREATMENT



6 MO. POST-TREATMENT

* This does not always mean the cancer is cured. Also called a complete remission: www.cancer.gov/publications/dictionaries/cancer-terms/def/complete-response

Planned U.S. Phase 2 Clinical Trial.

# SITES	Up to 6 (10 patients/site/year)
# PATIENTS	60 (up to 80 dependent upon screen failures)
TIMEFRAME	6 months startup + 1 year recruitment + 1 year follow-up = 2.5 years
COST/PATIENT*	\$70,000 (\$5-\$8 million)
OTHER COSTS	\$4 million (\$3-\$5 million)
TOTAL	\$8-\$13 million

Berubicin Supply Ready for U.S. Phase 2 Trial.

- CNS obtained a quantity of Berubicin from Reata (Batch 1) sufficient to conduct a majority of the planned 60-patient Phase 2 clinical trial.
- On May 1, 2019 FDA notified CNS that "its planned use of lyophilized drug product ["following reprocessing by recrystallization"] in the proposed Phase II clinical trial appears to be reasonable".
- Reprocessing by recrystallization of Batch 1 of Berubicin is complete; Batch 1 is ready to use.
- Having Berubicin available now may accelerate the clinical trial timeline and significantly de-risks CNS' operations.
- CNS has begun the process of manufacturing Batch 2 of Berubicin; Batch 2 is projected to be ready when needed.

Funding & Clinical Development Partnership.

CNS ENTERED INTO A \$6 MILLION FUNDING AND DEVELOPMENT PARTNERSHIP WITH WPD PHARMACEUTICALS, A POLISH COMPANY AFFILIATED OUR FOUNDER.

- The Company granted WPD a sub-license to Berubicin for certain Eastern European territories.
- In exchange, WPD agreed to spend a minimum of \$2 million on the development of Berubicin plus pay CNS a royalty on sales.
- In January 2019 WPD was awarded a \$6 million EU development grant to execute 2 clinical trials of Berubicin in adults (Phase 2) and children (Phase 1).

The pediatric trial will be the first to test Berubicin in children.

- **This grant significantly expands the Company's capacity to investigate Berubicin while minimizing equity dilution and spend by CNS.**

Primary & Refractory Market Opportunities.

WITH NO CURATIVE OPTIONS, WE BELIEVE BERUBICIN HAS POTENTIAL TO BECOME STANDARD-OF-CARE FOR GBM AND OTHER BRAIN CANCERS.

- Nearly all of the 40% of patients genetically predisposed to respond to temozolomide (TMZ) may become quickly become resistant; we believe **Berubicin could be used as a second-line drug treatment for these patients.**
- In the remaining 60% of patients, TMZ may be ineffective and **we believe Berubicin could be used as a primary drug treatment in these patients.**
- Berubicin may be more effective than doxorubicin via concentration in tumors that depend for their proliferation on topoisomerase II.
- This may create a unique opportunity to develop Berubicin for pancreatic and ovarian cancers and lymphomas, initiating a truly **Organ-Targeted Therapeutic.**

Additional Patient Populations.

INDICATION	PATIENT POPULATION	ESTIMATED SIZE ¹	COMMENTS
Primary Brain Tumors	Relapsed High Grade Gliomas	15,000	Existing data in this population.
Brain Metastases - Combination with Radiation Therapy	Small Cell Lung Cancer	56,500	Anthracycline sensitive, but not currently used. Patients receive prophylactic radiation to prevent mets.
	Non-Small Cell Lung Cancer	56,000	Anthracycline naïve population.
	Metastatic Breast Cancer	45,000	Anthracyclines are highly effective against breast cancer and historically used first line. Growing trend to treat Her-2+ women with Herceptin without anthracycline to minimize cardiotoxicity. Success could drive off-label use in breast cancer patients at risk of developing brain metastases.
CNS Lymphoma	2 nd Line After Methotrexate Failure	1,200	Accelerated approval opportunity (no 2 nd line therapy). Anthracycline sensitive. Small population would make trial a challenge.

Pipeline: WP1244.

A DNA-BINDING AGENT REPRESENTING A NOVEL CLASS OF POTENTIAL THERAPEUTICS.

- Licensed from The University of Texas MD Anderson Cancer Center
- Developed in the Department of Experimental Therapeutics as a collaborative effort with the Neuro-Oncology Department and Pharmaceutical Development Center.
- Designed using anthracycline and distamycin-based scaffolds to create small molecule agents binding extended DNA sequences.
- A highly potent cytotoxic agent (picomolar-level IC_{50}) against brain tumor cell lines; hundreds-fold greater than the classical DNA binders like daunorubicin or doxorubicin.
- *In vivo* testing demonstrated high uptake of WP1244 in the brain and subsequently antitumor activity in orthotopic models of brain cancer.

Key Catalysts in 2020.

- Manufacture of clinical trial Berubicin and release → 1Q20
- Submit Orphan Drug filing → April 2020
- Submit IND for Berubicin → 2Q20
- Initiate Phase 2 trial for Berubicin for GBM → 3Q20
- Initiate WP1244 preclinical studies → 4Q20
- WPD initiates clinical trials in Poland
 - Adults: Phase 2 → 2H20
 - Pediatrics: Phase 1 → 2H20

Financial Profile.

CNS Pharmaceuticals, Inc. (Nasdaq: CNSP)

Cash and Cash Equivalents
as of Sept. 30, 2019

• \$0.9 million

Initial Public Offering
Nov. 13, 2019

• \$9.8 million in gross proceeds

Shares outstanding
as of Dec. 20, 2019

• 16.5 million

Options and Warrants outstanding
as of Sept. 30, 2019

• 3.8 million warrants at a WAEP of \$3.99
• 1.6 million options at a WAEP of \$1.53

**JOHN M. CLIMACO, ESQ.**

PRESIDENT & CHIEF EXECUTIVE OFFICER OF CNS PHARMACEUTICALS, INC.

For 15 years Mr. Climaco has served in leadership roles in a variety of healthcare companies. Recently Mr. Climaco served as the Executive Vice-President of Perma-Fix Medical SA where he managed the development of a novel method to produce Technetium-99. Previously Mr. Climaco served as President and CEO of Axial Biotech, Inc., a DNA diagnostics company. In the process of taking Axial from inception to product development to commercialization, Mr. Climaco created strategic partnerships with Medtronic, Johnson & Johnson and Smith & Nephew. Mr. Climaco currently serves as a director of several public companies including MolecuLin Biotech, Inc., pharmaceutical company focused on anti-cancer drug candidates. Mr. Climaco also served as a director of PDI, Inc., a provider of outsourced commercial services to pharmaceutical companies, and InfuSystem Holdings, Inc., the largest supplier of infusion services to oncologists in the US.

**CHRISTOPHER S. DOWNS, CPA**

CHIEF FINANCIAL OFFICER OF CNS PHARMACEUTICALS, INC.

Mr. Downs will begin to serve as our chief financial officer upon the closing of this offering. From March 2016 until September 2019, Mr. Downs served as vice president of finance and treasurer of Innovative Aftermarket Systems, L.P., a privately held provider of finance and insurance solutions. Mr. Downs served as director of finance (from June 2011 to September 2013), vice president and treasurer (October 2013 to August 2015), executive vice president and interim chief financial officer (August 2015 to May 2017), and executive vice president, interim chief financial officer and member of the office of the president (May 2017 to March 2018) for InfuSystem Holdings, Inc., a supplier of infusion services to oncologists in the United States. Mr. Downs spent 10 years in investment banking with various firms including Citigroup. Mr. Downs is a graduate of the United States Military Academy at West Point where he earned his Bachelor of Science. Mr. Downs earned his MBA at Columbia Business School and his Master of Science in Accounting at the University of Houston-Clear Lake. Mr. Downs is a Certified Public Accountant in Utah and Texas.

**DR. SANDRA L. SILBERMAN, M.D., PH.D.**

CHIEF MEDICAL OFFICER OF CNS PHARMACEUTICALS, INC.

Dr. Silberman is a Hematologist/Oncologist who earned her B.A., Sc.M., and Ph.D. from the Johns Hopkins University School of Arts and Sciences, School of Public Health and School of Medicine, respectively, and her M.D. from Cornell University Medical College, and then completed both a clinical fellowship in Hematology/Oncology as well as a research fellowship in tumor immunology at the Brigham & Women's Hospital and the Dana Farber Cancer Institute in Boston, MA. Dr. Silberman has played key roles in the development of many drugs including Gleevec™, for which she led the global clinical development at Novartis. Dr. Silberman advanced several original, proprietary compounds into Phases I through III during her work with leading biopharmaceutical companies, including Bristol-Myers Squibb, AstraZeneca, Imclone and Roche.

**DR. DONALD PICKER, PH.D.**

CHIEF SCIENTIFIC OFFICER OF CNS PHARMACEUTICALS, INC.

Dr. Donald Picker, Ph.D., joined the CNS team in November, 2017 with over 35 years of drug development experience. At Johnson Matthey, Dr. Picker was responsible for the development of Carboplatin, one of the world's leading cancer drugs, acquired by Bristol-Myers Squibb and with annual sales of over \$500 million. He also oversaw the development of Satraplatin and Picoplatin, third-generation platinum drugs currently in late-stage clinical development. Dr. Picker has significant experience in dermatological pharmaceutical discovery and development as well, having led projects for topical therapies in psoriasis, atopic dermatitis and acne.

**DR. WALDEMAR PRIEBE, PH.D.**

FOUNDER, CHAIRMAN OF THE SCIENTIFIC ADVISORY BOARD

Dr. Waldemar Priebe, Ph.D., Chairman of the Scientific Advisory Board, is a world-renowned medicinal chemist and entrepreneur. Dr. Priebe is a Professor of Medicinal Chemistry in the Section of Immunobiology and Drug Carriers in the Department of Biomimunochemistry at The University of Texas MD Anderson Cancer Center. Dr. Priebe is the inventor of more than 50 patents and the author of more than 200 scientific publications. As the founder or founding scientist of 6 pharmaceutical companies, including three listed on NASDAQ, Dr. Priebe has been integral in advancing several drugs through the pipeline, five of which entered clinical development. Dr. Priebe led the research that formed basis for the development of agents with high brain uptake (BBB crossing) and is the discoverer of our lead drug candidate Berubicin.

**DR. SIGMUND HSU, M.D.**

CNS PHARMACEUTICALS INC. SCIENTIFIC ADVISOR

Dr. Sigmund Hsu, M.D. is fellowship trained and certified by the American Board of Psychiatry and Neurology, with extensive experience in the evaluation and treatment of neurological disorders in cancer patients. He specializes in primary brain tumors as well as brain and spinal cord metastases, cancer neurology and the treatment of chemotherapy neurotoxicity. Dr. Hsu has presented research at several national conferences, and his work has been published in numerous journals and textbooks. His most recent research has focused on novel therapies for recurrent primary CNS lymphoma, recurrent glioblastoma multiforme and intralumbar injections for cancer therapy, and he has several patents granted and pending for his treatments. **Most uniquely, Dr. Hsu personally treated patients with Berubicin in the Phase 1 clinical trial sponsored by Reata, including one patient with a durable complete response who is still alive today.**

**JEFF KEYES, CPA**

CHIEF FINANCIAL OFFICER OF CUSTOPHARM, INC.

Mr. Jeff Keyes joined our board on June 25, 2018. Mr. Keyes is currently the CFO of Custopharm, Inc, a private equity backed developer of generic sterile injectable pharmaceuticals, a role he has held since April 2018. From September 2012 to April 2018, Mr. Keyes was the Chief Financial Officer and Corporate Secretary of Digired Corporation, a publicly traded healthcare services and medical device company. From August 2011 until September 2012, Mr. Keyes was Corporate Controller of Sapphire Energy, Inc, a venture capital backed start-up renewable energy company. From April 2011 to August 2011, Mr. Keyes was the Corporate Controller of Advanced Bio-Healing, Inc, a venture backed provider of regenerative medicine solutions, until its sale to Shire, PLC in August 2011. Prior to April 2011, Mr. Keyes held a variety of leadership roles in healthcare and medical device companies in finance, accounting, and M&A support. Mr. Keyes earned a B.A. degree in accounting from Western Washington University and is a certified public accountant licensed. Mr. Keyes is considered a financial expert under relevant rules of the SEC, the NYSE and NASDAQ.

**DR. JERZY (GEORGE) GUMULKA, PH.D.**

RETIRED

Dr. Jerzy (George) Gumulka, Ph.D. joined our board of directors on November 8, 2017. Dr. Gumulka has been retired since 2016. From 2001 until his retirement he served as a Global Technology Manager ASC, a Technology Manager, Special Projects/New Technology Platforms, Kraton Polymers US LLC and a Technical Director of Kraton Polymers do Brasil. Dr. Gumulka served on the Board of Directors of Moleculin LLC from 2010 through 2016. Dr. Gumulka received a PhD from the University of Warsaw, Warsaw, Poland.

**CARL EVANS**

RETIRED

Mr. Evans joined our board on July 9, 2018. Mr. Evans has been retired since 2015. From 2011 until his retirement Mr. Evans was Executive Vice President – Exploration for KMD Operating Company, LLC. Prior to 2011, he managed international and domestic oil exploration and production projects for several oil companies, including British Petroleum, Texaco, and Pennzoil. Mr. Evans earned Bachelor of Science degree in Geology from the University of California, Los Angeles.

**ANDREW ANDRACZKE**

CHIEF EXECUTIVE OFFICER OF POL-TEX HOLDINGS, LLC

Mr. Andrew Andraczke joined our board on July 9, 2018. Mr. Andraczke is currently Chief Executive Officer of Pol-Tex Holdings, LLC, a role he has held since November 2012. He is also currently Chief Technology Officer of Syntech LLC (Ireland), a role he has held since November 2017. From March 2016 to April 2016 Mr. Andraczke served as an expert witness for the International Chamber of Commerce for downhole air hammer drilling of the well in volcanic rocks for a geothermal project in Slovakia. From March 2000 through November 2012 Mr. Andraczke was Vice-President of Pol-Tex Methane. Mr. Andraczke earned a M.Sc. in Engineering from Warsaw Technical University.

The image features a dark blue background with a faint, glowing anatomical illustration of a human brain and its neural pathways. The CNS logo is prominently displayed in the center. The letters 'CNS' are in a large, bold, white sans-serif font. Below them, the word 'PHARMACEUTICALS' is written in a smaller, white, all-caps sans-serif font.

CNS

PHARMACEUTICALS

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