

SECURITIES AND EXCHANGE COMMISSION  
Washington, DC 20549

FORM 10-Q

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  
For the quarterly period ended September 30, 2022

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  
For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number: **001-39126**

**CNS Pharmaceuticals, Inc.**  
(Name of registrant as specified in its charter)

**Nevada**  
(State or other jurisdiction of Incorporation or Organization)

**82-2318545**  
(I.R.S. Employer identification No.)

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

**77027**  
(Zip Code)

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

**N/A**  
(Former name or former address and former fiscal year, if changed since last report)

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

<u>Title of Each Class</u>	<u>Trading Symbol</u>	<u>Name of Each Exchange on Which Registered</u>
Common Stock	CNSP	The NASDAQ Stock Market LLC

Indicate by check mark whether the registrant (1) filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).  
Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act:

Large accelerated Filer  Accelerated Filer   
Non-accelerated Filer  Smaller reporting company   
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.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

The number of shares outstanding of the registrant's common stock, par value \$0.001 per share, as of November 10, 2022, was 40,032,481.

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PART I - FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

**CNS Pharmaceuticals, Inc.**  
**Balance Sheets**  
**(Unaudited)**

	September 30, 2022	December 31, 2021
<b>Assets</b>		
Current Assets:		
Cash and cash equivalents	\$ 7,027,470	\$ 5,004,517
Prepaid expenses	1,672,899	2,472,933
Total current assets	8,700,369	7,477,450
Noncurrent Assets:		
Prepaid expenses, net of current portion	594,898	929,688
Property and equipment, net	8,522	16,109
Deferred offering costs	334,138	334,138
Total noncurrent assets	937,558	1,279,935
Total Assets	\$ 9,637,927	\$ 8,757,385
<b>Liabilities and Stockholders' Equity</b>		
Current Liabilities:		
Accounts payable	\$ 1,005,043	\$ 1,522,823
Accrued expenses	200,000	224,949
Notes payable	39,260	387,794
Total current liabilities	1,244,303	2,135,566
Total Liabilities	1,244,303	2,135,566
Commitments and contingencies		
Stockholders' Equity:		
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 40,032,481 and 27,927,217 shares issued and outstanding, respectively	40,032	27,927
Additional paid-in capital	53,106,357	41,576,813
Accumulated deficit	(44,752,765)	(34,982,921)
Total Stockholders' Equity	8,393,624	6,621,819
Total Liabilities and Stockholders' Equity	\$ 9,637,927	\$ 8,757,385

See accompanying notes to the unaudited financial statements.

**CNS Pharmaceuticals, Inc.**  
**Statements of Operations**  
**(Unaudited)**

	Three Months Ended September 30, 2022	Three Months Ended September 30, 2021	Nine Months Ended September 30, 2022	Nine Months Ended September 30, 2021
Operating expenses:				
General and administrative	\$ 1,211,102	\$ 1,235,385	\$ 3,814,513	\$ 3,784,509
Research and development	<u>2,207,913</u>	<u>2,578,016</u>	<u>5,950,616</u>	<u>7,449,869</u>
Total operating expenses	<u>3,419,015</u>	<u>3,813,401</u>	<u>9,765,129</u>	<u>11,234,378</u>
Loss from operations	(3,419,015)	(3,813,401)	(9,765,129)	(11,234,378)
Other expenses:				
Interest expense	<u>(538)</u>	<u>(947)</u>	<u>(4,715)</u>	<u>(7,047)</u>
Total other expenses	<u>(538)</u>	<u>(947)</u>	<u>(4,715)</u>	<u>(7,047)</u>
Net loss	<u>\$ (3,419,553)</u>	<u>\$ (3,814,348)</u>	<u>\$ (9,769,844)</u>	<u>\$ (11,241,425)</u>
Loss per share - basic	<u>\$ (0.09)</u>	<u>\$ (0.14)</u>	<u>\$ (0.25)</u>	<u>\$ (0.43)</u>
Loss per share - diluted	<u>\$ (0.09)</u>	<u>\$ (0.14)</u>	<u>\$ (0.25)</u>	<u>\$ (0.43)</u>
Weighted average shares outstanding - basic	<u>40,032,481</u>	<u>27,443,771</u>	<u>39,631,939</u>	<u>25,858,221</u>
Weighted average shares outstanding - diluted	<u>40,032,481</u>	<u>27,443,771</u>	<u>39,631,939</u>	<u>25,858,221</u>

See accompanying notes to the unaudited financial statements.

**CNS Pharmaceuticals, Inc.**  
**Statements of Stockholders' Equity**  
**For the nine months ended September 30, 2022 and 2021**  
**(Unaudited)**

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance December 31, 2021	27,927,217	\$ 27,927	\$ 41,576,813	\$ (34,982,921)	\$ 6,621,819
Common stock issued for cash, net	9,489,474	9,489	10,616,297	–	10,625,786
Exercise of warrants	2,615,790	2,616	–	–	2,616
Stock-based compensation	–	–	336,685	–	336,685
Net loss	–	–	–	(2,784,339)	(2,784,339)
Balance March 31, 2022	40,032,481	40,032	52,529,795	(37,767,260)	14,802,567
Stock-based compensation	–	–	286,841	–	286,841
Net loss	–	–	–	(3,565,952)	(3,565,952)
Balance June 30, 2022	40,032,481	40,032	52,816,636	(41,333,212)	11,523,456
Stock-based compensation	–	–	289,721	–	289,721
Net loss	–	–	–	(3,419,553)	(3,419,553)
Balance September 30, 2022	<u>40,032,481</u>	<u>\$ 40,032</u>	<u>\$ 53,106,357</u>	<u>\$ (44,752,765)</u>	<u>\$ 8,393,624</u>
Balance December 31, 2020	23,856,151	\$ 23,856	\$ 34,870,471	\$ (20,946,343)	\$ 13,947,984
Common stock issued for cash, net	43,083	43	144,800	–	144,843
Exercise of warrants	1,447,325	1,447	331,303	–	332,750
Stock-based compensation	6,250	6	430,673	–	430,679
Net loss	–	–	–	(3,613,404)	(3,613,404)
Balance March 31, 2021	25,352,809	25,352	35,777,247	(24,559,747)	11,242,852
Common stock issued for cash and subscription receivable, net	2,020,426	2,020	4,506,958	–	4,508,978
Stock-based compensation	6,250	7	469,603	–	469,610
Net loss	–	–	–	(3,813,673)	(3,813,673)
Balance June 30, 2021	27,379,485	27,379	40,753,808	(28,373,420)	12,407,767
Stock-based compensation	81,250	81	506,566	–	506,647
Net loss	–	–	–	(3,814,348)	(3,814,348)
Balance September 30, 2021	<u>27,460,735</u>	<u>\$ 27,460</u>	<u>\$ 41,260,374</u>	<u>\$ (32,187,768)</u>	<u>\$ 9,100,066</u>

See accompanying notes to the unaudited financial statements.

**CNS Pharmaceuticals, Inc.**  
**Statements of Cash Flows**  
(Unaudited)

	Nine Months Ended September 30, 2022	Nine Months Ended September 30, 2021
<b>Cash Flows from Operating Activities:</b>		
Net loss	\$ (9,769,844)	\$ (11,241,425)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	913,247	1,406,936
Depreciation	9,375	9,577
Loss on disposal of fixed assets	2,635	-
Changes in operating assets and liabilities:		
Prepaid expenses	1,134,824	(1,373,257)
Accounts payable	(517,780)	515,244
Accrued expenses	(24,949)	381,418
Net cash used in operating activities	<u>(8,252,492)</u>	<u>(10,301,507)</u>
<b>Cash Flows from Investing Activities:</b>		
Purchase of property and equipment	(4,423)	(3,672)
Net cash used in investing activities	<u>(4,423)</u>	<u>(3,672)</u>
<b>Cash Flows from Financing Activities:</b>		
Payments on notes payable	(348,534)	(394,662)
Proceeds from exercise of warrants	2,616	332,750
Proceeds from sale of common stock	10,625,786	4,653,821
Net cash provided by financing activities	<u>10,279,868</u>	<u>4,591,909</u>
Net change in cash and cash equivalents	2,022,953	(5,713,270)
Cash and cash equivalents, at beginning of period	5,004,517	14,039,493
Cash and cash equivalents, at end of period	<u>\$ 7,027,470</u>	<u>\$ 8,326,223</u>
Supplemental disclosures of cash flow information:		
Cash paid for interest	\$ 5,782	\$ 7,207
Cash paid for income taxes	<u>\$ -</u>	<u>\$ -</u>
Supplemental disclosure of non-cash investing and financing activities:		
Cashless exercise of warrants	<u>\$ -</u>	<u>\$ 1,296</u>

See accompanying notes to the unaudited financial statements.

**CNS Pharmaceuticals, Inc.**  
**Notes to the Financial Statements**  
**(Unaudited)**

**Note 1 – Nature of Business**

CNS Pharmaceuticals, Inc. (“we”, “our”, the “Company”) is a clinical pharmaceutical company organized as a Nevada corporation on July 27, 2017 to focus on the development of anti-cancer drug candidates.

**Note 2 – Summary of Significant Accounting Policies**

**Basis of Presentation** - The accompanying unaudited financial statements of the Company have been prepared in accordance with accounting principles generally accepted in the United States of America (“U.S. GAAP”) for interim unaudited financial information. Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. The unaudited financial statements include all adjustments (consisting of normal recurring adjustments) which are, in the opinion of management, necessary in order to make the condensed financial statements not misleading. Operating results for the three and nine months ended September 30, 2022 are not necessarily indicative of the final results that may be expected for the year ending December 31, 2022. For more complete financial information, these unaudited financial statements should be read in conjunction with the audited financial statements for the period ended December 31, 2021 included in our Form 10-K filed with the SEC on March 3, 2022 (“Form 10-K”). Notes to the financial statements which would substantially duplicate the disclosures contained in the audited financial statements for the most recent fiscal period, as reported in the Form 10-K, have been omitted.

**Liquidity and Going Concern** - These financial statements have been prepared on a going concern basis, which assumes the Company will continue to realize its assets and discharge its liabilities in the normal course of business. The continuation of the Company as a going concern is dependent upon the ability of the Company to obtain equity financings to continue operations. The Company has a history of and expects to continue to report negative cash flows from operations and a net loss. Management believes that the cash on hand is sufficient to fund its planned operations into but not beyond the near term. These factors raise substantial doubt regarding the Company’s ability to continue as a going concern. These financial statements do not include any adjustments to the recoverability and classification of recorded asset amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern. The Company may seek additional funding through a combination of equity offerings, debt financings, government or other third-party funding, commercialization, marketing and distribution arrangements, other collaborations, strategic alliances and licensing arrangements and delay planned cash outlays or a combination thereof. Management cannot be certain that such events or a combination thereof can be achieved.

**Cash and Cash Equivalents** - The Company considers all highly liquid accounts with original maturities of three months or less at the date of acquisition to be cash equivalents. Periodically, the Company may carry cash balances at financial institutions in excess of the federally insured limit of \$250,000. The amount in excess of the FDIC insurance as of September 30, 2022 was \$6,777,470. The Company has not experienced losses on these accounts and management believes, based upon the quality of the financial institutions, that the credit risk with regard to these deposits is not significant.

**Stock-based Compensation** - Employee and non-employee share-based compensation is measured at the grant date, based on the fair value of the award, and is recognized as an expense over the requisite service period for stock options and restricted stock units.

**Restricted Stock Units (“RSUs”)** - Our RSUs vest over four years from the date of grant. The fair value of RSUs is the market price of our common stock at the date of grant.

**Performance Units (“PUs”)** - The PUs vest based on our performance against predefined share price targets and the achievement of Positive Interim, Clinical Data as defined by the Board.

**Loss Per Common Share** - Basic loss per common share is computed by dividing net loss available to common shareholders by the weighted-average number of common shares outstanding during the period. Diluted loss per common share is determined using the weighted-average number of common shares outstanding during the period, adjusted for the dilutive effect of common stock equivalents. In periods when losses are reported, the weighted-average number of common shares outstanding excludes common stock equivalents, because their inclusion would be anti-dilutive. For the nine months ended September 30, 2022 and 2021, the Company's potentially dilutive shares and options, which were not included in the calculation of net loss per share, included warrants to purchase 15,719,445 and 5,130,240 common shares, unvested restricted stock units of 285,625 and 0 common shares, unvested performance units of 856,875 and 0 common shares, and options for 2,789,736 and 2,939,736 common shares, respectively.

### **Note 3 – Note Payable**

On November 8, 2021, the Company entered into a short-term note payable for an aggregate of \$425,990, bearing interest at 3.3% per year to finance certain insurance policies. Principal and interest payments related to the note will be repaid over a 11-month period with the final payment due on September 30, 2022. As of September 30, 2022 and December 31, 2021, the Company's note payable balance was \$39,260 and \$387,794, respectively. Subsequent to September 30, 2022, the Company repaid the outstanding note balance in full.

### **Note 4 – Equity**

#### **Common Stock**

The Company engaged H.C. Wainwright & Co., LLC ("Wainwright"), to act as placement agent related to the Securities Purchase Agreement described below. The Company agreed to pay Wainwright an aggregate fee equal to 7.0% of the gross proceeds received by the Company from the sale of the securities in the transaction. The Company also issued to Wainwright or its designees warrants to purchase up to 5.0% of the aggregate number of shares of Common Stock sold in the transactions (the "Placement Agent Warrants"), or 605,263 Placement Agent Warrants. The Placement Agent Warrants have substantially the same terms as the Common Warrants, except that the Placement Agent Warrants have an exercise price equal to 125% of the offering price, or \$1.1875 per share. The Company also paid Wainwright \$50,000 for non-accountable expenses and \$10,000 for legal fees and expenses.

On January 5, 2022, the Company entered into a Securities Purchase Agreement (the "Purchase Agreement") with several institutional investors for the sale by the Company of (i) 9,489,474 shares (the "Shares") of the Company's common stock, (ii) pre-funded warrants (the "Pre-Funded Warrants") to purchase up to an aggregate of 2,615,790 shares of common stock and (iii) warrants to purchase up to an aggregate of 12,105,264 shares of common stock (the "Common Warrants" and, collectively with the Pre-Funded Warrants, the "Warrants"), in a private placement offering. The combined purchase price of one share of common stock (or one Pre-Funded Warrant) and the accompanying Common Warrant is \$0.95.

Subject to certain ownership limitations, the Warrants are exercisable upon issuance. Each Pre-Funded Warrant is exercisable into one share of common stock at a price per share of \$0.001 (as adjusted from time to time in accordance with the terms thereof). Each Common Warrant is exercisable into one share of common stock at a price per share of \$0.82 (as adjusted from time to time in accordance with the terms thereof) and will expire on the fifth anniversary of the date of issuance. The gross proceeds from the Purchase Agreement were \$11,497,385 resulting in net proceeds, after payment of commissions and expenses, received by the Company of \$10,625,786.

#### **Stock Options**

In 2017, the Board of Directors of the Company approved the CNS Pharmaceuticals, Inc. 2017 Stock Plan (the "2017 Plan"). The 2017 Plan allows for the Board of Directors to grant various forms of incentive awards for up to 2,000,000 shares of common stock. No key employee may receive more than 500,000 shares of common stock (or options to purchase more than 500,000 shares of common stock) in a single year.

In 2020, the Board of Directors of the Company approved the CNS Pharmaceuticals, Inc. 2020 Stock Plan (the "2020 Plan"). The 2020 Plan allows for the Board of Directors to grant various forms of incentive awards for up to 3,000,000 shares of common stock. No key employee may receive more than 750,000 shares of common stock (or options to purchase more than 750,000 shares of common stock) in a single year.



During the nine months ended September 30, 2022 and 2021, the Company recognized \$877,510 and \$1,228,811 of stock-based compensation, respectively, related to outstanding stock options. At September 30, 2022, the Company had \$1,583,144 of unrecognized expenses related to outstanding options.

The following table summarizes the stock option activity for the nine months ended September 30, 2022:

	<b>Options</b>	<b>Weighted-Average Exercise Price Per Share</b>
Outstanding, December 31, 2021	2,864,736	\$ 2.25
Granted	—	—
Exercised	—	—
Forfeited	—	—
Expired	(75,000)	2.35
Outstanding, September 30, 2022	<u>2,789,736</u>	\$ 2.25
Exercisable, September 30, 2022	<u>1,990,361</u>	\$ 1.93

As of September 30, 2022, the outstanding stock options have a weighted average remaining term of 6.98 years and the aggregate intrinsic value of options vested and outstanding were \$36,850. As of September 30, 2022, there were no awards remaining to be issued under the 2017 Plan and 1,067,764 awards remaining to be issued under the 2020 Plan.

#### Stock Warrants

During the nine months ended September 30, 2022, the Company received \$2,616 in cash proceeds from the exercise of 2,615,790 warrants previously issued at an exercise price of \$0.001.

The following table summarizes the stock warrant activity for the nine months ended September 30, 2022:

	<b>Warrants</b>	<b>Weighted-Average Exercise Price Per Share</b>
Outstanding, December 31, 2021	4,214,977	\$ 4.76
Granted	15,326,317	0.69
Exercised	(2,615,790)	0.001
Forfeited	—	—
Expired	(1,206,059)	11.00
Outstanding, September 30, 2022	<u>15,719,445</u>	\$ 1.11
Exercisable, September 30, 2022	<u>15,719,445</u>	\$ 1.11

As of September 30, 2022, the outstanding and exercisable warrants have a weighted average remaining term of 4.06 years and have no aggregate intrinsic value.

#### Restricted Stock Units

On April 28, 2022, the Compensation Committee approved cash bonuses totaling \$213,000 to the officers of the Company. In addition, the officers and employees were awarded a total of 285,625 Restricted Stock Units that partially vest over 4 years. The Company valued the RSUs based on the stock price at grant which total \$95,399.

During the nine months ended September 30, 2022, the Company recognized \$11,925 of stock-based compensation, related to outstanding stock RSUs. At September 30, 2022, the Company had \$83,474 of unrecognized expenses related to outstanding RSUs.

The following table summarizes the RSUs activity for the nine months ended September 30, 2022:

	RSUs	Weighted-Average Grant Date Fair Value
Non-vested, December 31, 2021	–	\$ –
Granted	285,625	0.33
Vested	–	–
Forfeited	–	–
Non-vested, September 30, 2022	<u>285,625</u>	<u>\$ 0.33</u>

#### Performance Units

On April 28, 2022, the Compensation Committee approved, the officers and employees were awarded a total of 856,875 PUs. For awards granted in 2022, they vest as follows: (i) 285,625 of the PU grant will vest if within 24 months from issuance the average the closing price of the Company’s common stock over a ten trading day period exceeds \$2.00 (subject to pro rata adjustment for stock splits or similar events), (ii) 285,625 of the PU grant will vest if within 36 months from issuance the average the closing price of the Company’s common stock over a ten trading day period exceeds \$4.00 (subject to pro rata adjustment for stock splits or similar events) and (iii) 285,625 of the PU grant will vest if within 24 months from issuance the Company achieves “Positive Interim, Clinical Data” as defined by the Board of Directors. To the extent that the market and/or “Positive Interim Clinical Data” conditions are not met, the applicable portions of the PUs will not vest and will be cancelled. The fair value at grant date of these performance units was \$169,663. Compensation expense is recognized ratably during the period the PUs are expected to vest or when “Positive Interim Clinical Data” is achieved.

The fair value of each performance unit with market conditions (vesting terms (i) and (ii)) is estimated at the date of grant using a Monte Carlo simulation with the following assumptions: underlying stock price \$0.33, hurdle prices ranging from \$2.00 - \$4.00, expected terms ranging from 2-3 years, cost of equity 18.7% and risk-free rate of 2.8%.

During the nine months ended September 30, 2022, the Company recognized \$14,619 for vesting term (i), \$9,193 for vesting term (ii) and \$0 for vesting term (iii), related to outstanding stock PUs. At September 30, 2022, the Company had \$145,853 of unrecognized expenses related to PUs.

The following table summarizes the PUs activity for the nine months ended September 30, 2022:

	PUs	Weighted-Average Grant Date Fair Value
Non-vested, December 31, 2021	–	\$ –
Granted	856,875	0.20
Vested	–	–
Forfeited	–	–
Non-vested, September 30, 2022	<u>856,875</u>	<u>\$ 0.20</u>

## **Note 5 – Commitments and Contingencies**

### ***Executive Employment Agreements***

On September 1, 2017, the Company entered into an employment agreement with Mr. John Climaco pursuant to which Mr. Climaco agreed to serve as Chief Executive Officer and Director of the Company commencing on such date for an initial term of three years. On September 1, 2020, the Company entered into an amendment to the employment agreement with Mr. Climaco. The amendment extends the term of employment under the Employment Agreement, which was originally for a three-year period, for additional twelve-month periods, unless and until either the Company or Mr. Climaco provides written notice to the other party not less than sixty days before such anniversary date that such party is electing not to extend the term. If the Company provides notice of its election not to extend the term, Mr. Climaco may terminate his employment at any time prior to the expiration of the term by giving written notice to the Company at least thirty days prior to the effective date of termination, and upon the earlier of such effective date of termination or the expiration of the term, Mr. Climaco shall be entitled to receive the same severance benefits as are provided upon a termination of employment by the Company without cause. Pursuant to the Amendment, the severance benefits shall be twelve months of Mr. Climaco's base salary. Such severance payment shall be made in a single lump sum sixty days following the termination, provided that Mr. Climaco has executed and delivered to the Company and has not revoked a general release of the Company. Pursuant to the employment agreement, the compensation committee of the board of directors reviews the base salary payable to Mr. Climaco annually during the term of the agreement. On February 6, 2021, the compensation committee of the board of directors set Mr. Climaco's 2021 annual base salary to \$525,000.

On June 28, 2019, we entered into employment letters with Drs. Silberman and Picker pursuant to which Dr. Silberman agreed to commit 50% of her time to our matters; and Dr. Picker agreed to commit 25% of his time to our matters. On February 6, 2021, the compensation committee of the board of directors set Drs. Silberman and Picker 2021 annual base salaries to \$200,000 and \$115,000, respectively.

On September 14, 2019, the Company, entered into an employment agreement with Christopher Downs to serve as its Chief Financial Officer commencing on the closing date of the Company's IPO, which occurred on November 13, 2019. The initial term of the Employment Agreement will continue for a period of three years. Pursuant to the employment agreement, the compensation committee of the board of directors reviews the base salary payable to Mr. Downs annually during the term of the agreement. On February 6, 2021, the compensation committee of the board of directors set Mr. Downs' 2021 annual base salary to \$340,000.

### ***Scientific Advisory Board***

On July 15, 2021, our Board approved the following compensation policy for the Scientific Advisory Board members. The Scientific Advisory board consisted of Dr. Waldemar Priebe, a significant shareholder and related party, and Dr. Sigmond Hsu. Each scientific advisory board member shall receive annual cash compensation of \$68,600. During the nine month months ended September 30, 2022, the Company paid \$76,087 related to the Scientific Advisory Board compensation. As of August 25, 2022, Dr. Waldemar Priebe is no longer a member of the Scientific Advisory Board. As of September 30, 2022, the Company has accrued \$82,984 related to Mr. Hsu's Scientific Advisory Board compensation.

### ***WP744 Portfolio (Berubicin)***

On November 21, 2017, the Company entered into a Collaboration and Asset Purchase Agreement with Reata Pharmaceuticals, Inc. ("Reata"). Through this agreement, the Company purchased all of Reata's rights, title, interest and previously conducted research and development results in the chemical compound commonly known as Berubicin. In exchange for these rights, the Company agreed to pay Reata an amount equal to 2.25% of the net sales of Berubicin for a period of 10 years from the Company's first commercial sale of Berubicin plus \$10,000. Reata also agreed to collaborate with the Company on the development of Berubicin, from time to time.

On December 28, 2017, the Company entered into a Technology Rights and Development Agreement with Houston Pharmaceuticals, Inc. (“HPI”). HPI is affiliated with Dr. Waldemar Priebe, our founder and significant shareholder. Pursuant to this agreement, the Company obtained a worldwide exclusive license to the chemical compound commonly known as WP744. In exchange for these rights, the Company agreed to pay consideration to HPI as follows: (i) a royalty of 2% of net sales of any product utilizing WP744 for a period of ten years after the first commercial sale of such; and (ii) \$100,000 upon beginning Phase II clinical trials (paid in 2021); and (iii) \$200,000 upon the approval by the FDA of a New Drug Application for any product utilizing WP744; and (iv) a series of quarterly development payments totaling \$750,000 beginning immediately after the Company’s raise of \$7,000,000 of investment capital. In addition, the Company issued 200,000 shares of the Company’s common stock valued at \$0.045 per share to HPI upon execution of the agreement. On November 13, 2019, the Company closed its IPO, thereby fulfilling all conditions precedent and completing the acquisition of the intellectual property discussed in the HPI agreement. During the nine months ended September 30, 2022 and 2021, the Company recognized \$262,500 related to this agreement. Unrelated to this agreement, from time to time, the Company purchases pharmaceutical products from HPI which are necessary for the manufacturing of Berubicin API and drug product in related party transactions which are reviewed and approved by the Company’s audit committee based upon the standards of providing superior pricing and time to delivery than that available from unrelated third parties. During the nine months ended September 30, 2022 and 2021, the Company expensed \$41,075 and \$385,000 respectively related to the purchase of pharmaceutical products from HPI.

On August 30, 2018, we entered into a sublicense agreement with WPD Pharmaceuticals, Inc. (“WPD”). Pursuant to the agreement, the Company granted WPD an exclusive sublicense, even as to us, for the patent rights we licensed pursuant to the HPI License within the following countries: Poland, Estonia, Latvia, Lithuania, Belarus, Ukraine, Moldova, Romania, Bulgaria, Serbia, Macedonia, Albania, Armenia, Azerbaijan, Georgia, Montenegro, Bosnia, Croatia, Slovenia, Slovakia, Czech Republic, Hungary, Chechnya, Uzbekistan, Kazakhstan, Kyrgyzstan, Tajikistan, Turkmenistan, Greece, Austria, and Russia. The sublicense agreement provides that WPD must use commercially reasonable development efforts to attempt to develop and commercialize licensed products in the above-mentioned territories, which means the expenditure of at least \$2.0 million on the development, testing, regulatory approval or commercialization of the licensed products during the three year period immediately following the date of the sublicense agreement. In consideration for the rights granted under the sublicense agreement, to the extent we are required to make any payments to HPI pursuant to the HPI License as a result of this sublicense agreement, WPD agreed to advance us such payments, and to pay us a royalty equal to 1% of such payments. WPD is a Polish corporation that is majority-owned by an entity controlled by Dr. Priebe, our founder and largest shareholder.

On February 19, 2021, CNS entered into an Investigational Medicinal Product Supply Agreement with WPD, a related party. CNS agreed to sell the Berubicin drug product to WPD at historical cost of manufacturing without markup so that WPD may conduct the clinical trials contemplated by the sublicense agreement. WPD agreed to pay CNS the following payments: (i) an upfront payment of \$131,073 upon execution of the agreement, (ii) a payment of \$262,145 upon final batch release and certification performed by WPD’s subcontractor, and (iii) a final payment of \$262,145 upon Clinical Trial Application acceptance by the relevant regulatory authority. All three milestones have been met as of December 31, 2021. In addition, as of December 31, 2021, the drug product with a cost of approximately \$655,000 has been delivered to WPD and is being held at a third party depot. As such, the full amount of approximately \$655,000 is due from WPD. As of December 31, 2021, CNS has invoiced the three amounts plus pass through cost for a total of \$656,938. As of September 30, 2022, the Company has received payments for the first and second amounts due for a total of \$393,182 and has entered into a settlement agreement whereby WPD agreed to return 168 vials (approximately 40% of the total) to us in settlement of the final amount owed. On October 24, 2022, the Company received confirmation from our third party depot service provider that the vials had been transferred into our inventory. As such, this matter is now fully resolved.

On August 31, 2018, the Company entered into a sublicense agreement with Animal Life Sciences, LLC (“ALI”), a related party, pursuant to which we granted ALI an exclusive sublicense, even as to us, for the patent rights we licensed pursuant to the HPI License solely for the treatment of cancer in non-human animals through any type of administration. In consideration for the rights granted under the sublicense agreement, ALI agreed to issue us membership interests in ALI equal to 1.52% of the outstanding ALI membership interests. As additional consideration for the rights granted, to the extent we are required to make any payments to HPI pursuant to the HPI License as a result of this sublicense agreement, ALI agreed to advance us such payments, and to pay us a royalty equal to 1% of such payments. Dr. Waldemar Priebe, our founder and largest shareholder, is also the founder and a shareholder of ALI, holds 38% of the membership interests of ALI.

On June 10, 2020, the FDA granted Orphan Drug Designation (“ODD”) for Berubicin for the treatment of malignant gliomas. ODD from the FDA is available for drugs targeting diseases with less than 200,000 cases per year. ODD may enable market exclusivity of 7 years from the date of approval of a New Drug Application (“NDA”) in the United States. During that period the FDA generally could not approve another product containing the same drug for the same designated indication. Orphan drug exclusivity will not bar approval of another product under certain circumstances, including if a subsequent product with the same active ingredient for the same indication is shown to be clinically superior to the approved product on the basis of greater efficacy or safety, or providing a major contribution to patient care, or if the company with orphan drug exclusivity is not able to meet market demand. The ODD constitutes our primary intellectual property protections although the Company is exploring if there are other patents that could be filed related to Berubicin to extend additional protections.

On July 24, 2021, the Company received Fast Track Designation from the FDA for Berubicin. Fast Track Designation is designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need.

#### ***WP1244 Portfolio***

On January 10, 2020, Company entered into a Patent and Technology License Agreement (“Agreement”) with The Board of Regents of The University of Texas System, an agency of the State of Texas, on behalf of The University of Texas M. D. Anderson Cancer Center (“UTMDACC”). Pursuant to the Agreement, the Company obtained a royalty-bearing, worldwide, exclusive license to certain intellectual property rights, including patent rights, related to the Company’s recently announced WP1244 drug technology. In consideration, the Company must make payments to UTMDACC including an up-front license fee, annual maintenance fee, milestone payments and royalty payments (including minimum annual royalties) on sales of licensed products developed under the Agreement. The term of the Agreement expires on the last to occur of: (a) the expiration of all patents subject to the Agreement, or (b) fifteen years after execution; provided that UTMDACC has the right to terminate this Agreement in the event that the Company fails to meet certain commercial diligence milestones. The commercial diligence milestones are as follows (i) initiated PC toxicology to support filing of Investigational New Drug Application (“IND”) or New Drug Application (“NDA”) for the Licensed Product within the eighteen (18) month period following the Effective Date (ii) file and IND for the Licensed Product within three (3) year period following the Effective Date and (iii) Commencement of Phase I Study within the five (5) year period following the Effective Date. During the nine months ended September 30, 2022 and 2021, the Company paid \$49,607 and \$22,902, respectively.

On May 7, 2020, pursuant to the WP1244 Portfolio license agreement described above, the Company entered into a Sponsored Research Agreement with UTMDACC to perform research relating to novel anticancer agents targeting CNS malignancies. The Company agreed to fund approximately \$1,134,000 over a two-year period. During the year ended December 31, 2020, the Company paid \$334,000 and accrued \$400,000 related to this agreement in research and development expenses in the Company’s Consolidated Statements of Operations. During the year ended December 31, 2021, the Company paid \$800,000 to UTMDACC related to this agreement. The Company has no further payment obligations as of September 30, 2022. The principal investigator for this agreement is Dr. Waldemar Priebe, a significant shareholder.

#### ***Anti-Viral Portfolio***

On March 20, 2020, the Company entered into a Development Agreement (“Agreement”) with WPD Pharmaceuticals (“WPD”), a company founded by Dr. Waldemar Priebe, the founder and largest shareholder of the Company. Pursuant to the Agreement, WPD agreed to use its commercially reasonable efforts in good faith to develop and commercialize certain products that WPD had previously sublicensed, solely in the field of pharmaceutical drug products for the treatment of any viral infection in humans, with a goal of eventual approval of in certain territories consisting of: Germany, Poland, Estonia, Latvia, Lithuania, Belarus, Ukraine, Romania, Armenia, Azerbaijan, Georgia, Slovakia, Czech Republic, Hungary, Uzbekistan, Kazakhstan, Greece, Austria, Russia, Netherlands, Turkey, Belgium, Switzerland, Sweden, Portugal, Norway, Denmark, Ireland, Finland, Luxembourg, Iceland.

Pursuant to the Agreement, the Company agreed to pay WPD the following payments: (i) an upfront payment of \$225,000 to WPD (paid in April 2020); and (ii) within thirty days of the verified achievement of the Phase II Milestone, (such verification shall be conducted by an independent third party mutually acceptable to the parties hereto), the Company will make a payment of \$775,000 to WPD. WPD agreed to pay the Company a development fee of 50% of the net sales for any products in the above territories; provided that Poland shall not be included as a territory after WPD receives marketing approval for a product in one-half of the countries included in the agreed upon territories or upon the payment by WPD to the Company of development fees of \$1.0 million. The term of the Agreement will expire on the expiration of the sublicense pursuant to which WPD has originally sublicensed the products.

### *Nasdaq Capital Markets Listing Qualifications*

On February 18, 2022, the Company received a deficiency letter from the Listing Qualifications Department of the Nasdaq Stock Market (“Nasdaq”) notifying the Company that for the last 30 consecutive business days the bid price for the Company’s common stock had closed below the minimum \$1.00 per share requirement for continued inclusion in Nasdaq Capital Market pursuant to Nasdaq Listing Rule 5550(a)(2) (the “Bid Price Rule”). The deficiency letter does not result in the immediate delisting of the Company’s common stock from Nasdaq.

The Company was initially provided an initial period of 180 calendar days, or until August 17, 2022, to regain compliance with the Bid Price Rule. The Company was granted a second 180 calendar day period, or until February 13, 2023, to regain compliance since it met the continued listing requirement for market value of publicly held shares and all other initial listing standards required by Nasdaq, except for the minimum bid price requirement.

On July 7, 2022, the Company filed a Definitive Proxy Statement on Form DEF 14A for its Annual Meeting of Stockholders to be held on July 27, 2022. The Annual Meeting of Stockholders was adjourned on July 27, 2022 until August 3, 2022, then adjourned again until August 16, 2022, and then adjourned again until August 25, 2022. In this Definitive Proxy Statement, the Company included a proposal to authorize an amendment to the Company’s amended and restated articles of incorporation to empower the Board of Directors to effect a reverse stock split of the outstanding shares of the Company’s common stock, at a split ratio of between 1-for-2 and 1-for-30 as determined by the Board of Directors in its sole discretion, prior to the one-year anniversary of this Annual Meeting. This proposal was approved by the Company’s stockholders when the Annual Meeting of Stockholders was reconvened on August 25, 2022. The Company intends to monitor the closing bid price of its common stock and, if appropriate, effect a reverse stock split of the Company’s common stock, to regain compliance with the Bid Price Rule in order to avoid being delisted from Nasdaq as well as to provide for additional shares available for issuance to continue to fund the Company’s clinical research programs. Notwithstanding the foregoing, there can be no assurance that the Company will be able to regain and maintain compliance with the Bid Price Rule if a reverse stock split is effected.

## ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

*You should read the following discussion and analysis of our financial condition and results of operations in conjunction with the financial statements and the related notes appearing elsewhere in this Form 10-Q. This discussion contains forward-looking statements reflecting our current expectations that involve risks and uncertainties. See Item 1A. "Risk Factors" of our Form 10-K for the year ended December 31, 2021, available on the Security and Exchange Commission's ("SEC") EDGAR website at [www.sec.gov](http://www.sec.gov), for a discussion of the uncertainties, risks and assumptions associated with these statements. Actual results and the timing of events could differ materially from those discussed in our forward-looking statements as a result of many factors, including those set forth under "Risk Factors" and elsewhere in this Form 10-Q.*

### CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

We make forward-looking statements under the "Management's Discussion and Analysis of Financial Condition and Results of Operations" and in other sections of this Form 10-Q. In some cases, you can identify these statements by forward-looking words such as "may," "might," "should," "would," "could," "expect," "plan," "anticipate," "intend," "believe," "estimate," "predict," "potential" or "continue," and the negative of these terms and other comparable terminology. These forward-looking statements, which are subject to known and unknown risks, uncertainties and assumptions about us, may include projections of our future financial performance based on our growth strategies and anticipated trends in our business. These statements are only predictions based on our current expectations and projections about future events. There are important factors that could cause our actual results, level of activity, performance or achievements to differ materially from the results, level of activity, performance or achievements expressed or implied by the forward-looking statements. In particular, you should consider the numerous risks and uncertainties described under Item 1A. "Risk Factors" of our Form 10-K for the year ended December 31, 2021 and in other filings made by us from time to time with the SEC.

While we believe we have identified material risks, these risks and uncertainties are not exhaustive. Other sections of this Form 10-Q may describe additional factors that could adversely impact our business and financial performance. Moreover, we operate in a very competitive and rapidly changing environment. New risks and uncertainties emerge from time to time, and it is not possible to predict all risks and uncertainties, 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.

Although we believe the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, level of activity, performance or achievements. Moreover, neither we nor any other person assumes responsibility for the accuracy or completeness of any of these forward-looking statements. You should not rely upon forward-looking statements as predictions of future events. We are under no duty to update any of these forward-looking statements after the date of this Form 10-Q to conform our prior statements to actual results or revised expectations, and we do not intend to do so.

Forward-looking statements include, but are not limited to, statements about:

- our ability to obtain additional funding to develop our product candidates;
- the need to obtain regulatory approval of our product candidates;
- the success of our clinical trials through all phases of clinical development;
- compliance with obligations under intellectual property licenses with third parties;
- any delays in regulatory review and approval of product candidates in clinical development;
- our ability to commercialize our product candidates;
- market acceptance of our product candidates;

- competition from existing products or new products that may emerge;
- potential product liability claims;
- our dependency on third-party manufacturers to supply or manufacture our products;
- our ability to establish or maintain collaborations, licensing or other arrangements;
- our ability and third parties' abilities to protect intellectual property rights;
- our ability to adequately support future growth; and
- our ability to attract and retain key personnel to manage our business effectively.

We caution you not to place undue reliance on the forward-looking statements, which speak only as of the date of this Form 10-Q in the case of forward-looking statements contained in this Form 10-Q.

You should not rely upon forward-looking statements as predictions of future events. Our actual results and financial condition may differ materially from those indicated in the forward-looking statements. We qualify all of our forward-looking statements by these cautionary statements. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. Therefore, you should not rely on any of the forward-looking statements. In addition, with respect to all of our forward-looking statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995.

## **Overview**

We are a clinical pharmaceutical company organized as a Nevada corporation in July 2017 to focus on the development of anti-cancer drug candidates for the treatment of brain and central nervous system tumors, based on intellectual property that we license under license agreements with Houston Pharmaceuticals, Inc. ("HPI") and The University of Texas M.D. Anderson Cancer Center ("UTMDACC") and own pursuant to a collaboration and asset purchase agreement with Reata Pharmaceuticals, Inc. ("Reata").

We believe our lead drug candidate, Berubicin, may be a significant development in the treatment of Glioblastoma and other CNS malignancies, and if approved by the U.S. Food and Drug Administration ("FDA"), could give Glioblastoma patients an important new therapeutic alternative to the current standard of care. Glioblastomas are tumors that arise from astrocytes, which are star-shaped cells making up the supportive tissue of the brain. These tumors are usually highly malignant (cancerous) because the cells reproduce quickly, and they are supported by a large network of blood vessels. Berubicin is an anthracycline, which is a class of drugs that are among the most powerful and extensively used chemotherapy drugs known. Based on limited clinical data, we believe Berubicin is the first anthracycline that appears to cross the blood brain barrier in significant concentrations targeting brain cancer cells. While our focus is currently on the development of Berubicin, we are also in the process of attempting to secure intellectual property rights to additional compounds that we plan to develop into drugs to treat CNS and other cancers.

Berubicin was discovered at UTMDACC by Dr. Waldemar Priebe, the founder of the Company. Through a series of transactions, Berubicin was initially licensed to Reata. Reata initiated several Phase I clinical trials with Berubicin for CNS malignancies, one of which was for malignant gliomas, but subsequently allowed their IND with the FDA to lapse for strategic reasons. This required us to obtain a new IND for Berubicin before beginning further clinical trials. On December 17, 2020, we announced that our IND application with the FDA for Berubicin for the treatment of Glioblastoma Multiforme was in effect. We initiated this trial for patient enrollment during the second quarter of 2021 with the first patient dosed during the third quarter of 2021 to investigate the efficacy of Berubicin in adults with Glioblastoma Multiforme who have failed first-line therapy. The first patient on the trial was treated during the third quarter of 2021. Correspondence between the Company and the FDA resulted in modifications to our initial trial design, including designating overall survival (OS) as the primary endpoint of the study. OS is a rigorous endpoint that the FDA has recognized as a basis for approval of oncology drugs when a statistically significant improvement can be shown relative to a randomized control arm.



The current trial being conducted will evaluate the efficacy of Berubicin in patients with Glioblastoma Multiforme who have failed primary treatment for their disease, and results will be compared to the efficacy of Lomustine, a current standard of care in this setting, with a 2 to 1 randomization of the estimated 243 patients to Berubicin or Lomustine. Patients receiving Berubicin will be administered a 2-hour IV infusion of 7.5 mg/m<sup>2</sup> berubicin hydrochloride daily for three consecutive days followed by 18 days off (a 21-day cycle). Lomustine is administered orally once every six weeks. The trial will include an interim analysis that will evaluate the comparative effectiveness of these treatments, which is an adaptive design intended to demonstrate that there are no differences in efficacy between treatments (futility analysis). Even if Berubicin is approved, there is no assurance that patients will choose an infusion treatment, as compared to the current standard of care, which requires oral administration.

We do not have manufacturing facilities and all manufacturing activities are contracted out to third parties. Additionally, we do not have a sales organization.

On November 21, 2017, we entered into a Collaboration and Asset Purchase Agreement with Reata (the “Reata Agreement”). Pursuant to the Reata Agreement we purchased all of Reata’s intellectual property and development data regarding Berubicin, including all trade secrets, knowhow, confidential information and other intellectual property rights.

On December 28, 2017, we obtained the rights to a worldwide, exclusive royalty-bearing, license to the chemical compound commonly known as Berubicin from HPI in an agreement we refer to as the HPI License. HPI is affiliated with Dr. Priebe, who controls a majority of our shares. Under the HPI License we obtained the exclusive right to develop certain chemical compounds for use in the treatment of cancer anywhere in the world. In the HPI License we agreed to pay HPI: (i) development fees of \$750,000 over a three-year period beginning November 2019; (ii) a 2% royalty on net sales; (iii) a \$50,000 per year license fee; (iv) milestone payments of \$100,000 upon the commencement of a Phase II trial and \$1.0 million upon the approval of a New Drug Application (“NDA”) for Berubicin; and (v) 200,000 shares of our common stock. The patents we licensed from HPI expired in March 2020.

On June 10, 2020, the FDA granted Orphan Drug Designation (“ODD”) for Berubicin for the treatment of malignant gliomas. ODD from the FDA is available for drugs targeting diseases with less than 200,000 cases per year. ODD may enable market exclusivity of 7 years from the date of approval of a NDA in the United States. During that period the FDA generally could not approve another product containing the same drug for the same designated indication. Orphan drug exclusivity will not bar approval of another product under certain circumstances, including if a subsequent product with the same active ingredient for the same indication is shown to be clinically superior to the approved product on the basis of greater efficacy or safety, or providing a major contribution to patient care, or if the company with orphan drug exclusivity is not able to meet market demand. The ODD now constitutes our primary intellectual property protections although the Company is exploring if there are other patents that could be filed related to Berubicin to extend additional protections.

With the Reata Agreement and the HPI License, we believe we have obtained all rights and intellectual property necessary to develop Berubicin. As stated earlier, it is our plan to obtain additional intellectual property covering other compounds which, subject to the receipt of additional financing, may be developed into drugs for brain and other cancers.

On January 10, 2020, we entered into a Patent and Technology License Agreement (the “1244 Agreement”) with The Board of Regents of The University of Texas System, an agency of the State of Texas, on behalf of the UTMDACC. Pursuant to the 1244 Agreement, we obtained a royalty-bearing, worldwide, exclusive license to certain intellectual property rights, including patent rights, related to our portfolio of WP1244 drug technology. In consideration, we must make payments to UTMDACC including an up-front license fee, annual maintenance fee, milestone payments and royalty payments (including minimum annual royalties) for sales of licensed products developed under the 1244 Agreement. The term of the 1244 Agreement expires on the last to occur of: (a) the expiration of all patents subject to the 1244 Agreement, or (b) fifteen years after execution; provided that UTMDACC has the right to terminate the 1244 Agreement in the event that we fail to meet certain commercial diligence milestones.

On May 7, 2020, pursuant to the WP1244 portfolio license agreement described above, the Company entered into a Sponsored Research Agreement with UTMDACC to perform research relating to novel anticancer agents targeting CNS malignancies. The Company agreed to fund approximately \$1,134,000 over a two-year period. The Company paid and recorded \$334,000 in 2020 related to this agreement in research and development expenses in the Company’s Statements of Operations. The remaining \$800,000 was paid in 2021. The principal investigator for this agreement is Dr. Priebe. The work conducted under this Sponsored Research Agreement has produced a new mesylate salt of WP1244 termed WP1874. We believe the enhanced solubility of this salt may increase its ability to be formulated for use in an IV infusion, while maintaining similar potency and toxicity characteristics. As such, WP1874 will be the primary focus in our development efforts of the WP1244 portfolio.

## Results of Operations for the Three Months Ended September 30, 2022 Compared to the Three Months Ended September 30, 2021

### *General and Administrative Expense*

General and administrative expense was approximately \$1,211,000 for the three months ended September 30, 2022 compared to approximately \$1,235,000 for the comparable period in 2021. The decrease in general and administrative expense was mainly attributable to decreases of approximately \$204,000 for stock-based compensation, \$46,000 in advertising and marketing, \$32,000 in insurance and \$31,000 in other expenses, which were offset by an increase of approximately \$289,000 in legal and professional expenses. Our general and administrative expenses are expected to remain approximately at these levels for the remainder of this year.

### *Research and Development Expense*

Research and development expense was approximately \$2,208,000 for the three months ended September 30, 2022 compared to approximately \$2,578,000 for the comparable period in 2021. The decrease in research and development expenses during the period were mainly attributed to the timing of drug development expenses (significant manufacturing activity occurred in the prior year period with much less occurring in the current year, and this lower level of manufacturing activity is expected to continue throughout this year), as well as a credit to research and development expense for the funds collected from WPD Pharmaceuticals related to their purchase of Berubicin drug product for their clinical trials, partially offset by an increase in contract research organization (CRO) expenses related to continued progress with our Phase II clinical trial. Our CRO expenditures are primarily for labor related to activating selected trial sites, managing patient enrollment processes, collecting and managing data from patient treatments throughout the trial, processing reimbursement to the sites for patient treatment, and assisting with necessary submissions to amend the IND. CRO expenditures are expected to remain relatively consistent with Q3 throughout the remainder of the trial as site activation efforts and the associated costs thereof transition into reimbursing clinical trial sites for patient treatment costs as site and patient enrollment increases. We expect to incur increased research and development costs in the future as we continue our Phase II clinical trial.

### *Net Loss*

The net loss for the three months ended September 30, 2022 was approximately \$3,420,000 compared to approximately \$3,814,000 for the comparable period in 2021. The change in net loss is attributable to decreases the timing of drug development expenses (significant manufacturing activity occurred in the prior year period with much less occurring in the current year), as well as a credit to research and development expense for the funds collected from WPD Pharmaceuticals related to their purchase of Berubicin drug product for their clinical trials, partially offset by an increase in CRO expenses related to continued progress with our Phase II clinical trial as well as increases in legal and professional fees and other expenses.

## Results of Operations for the Nine Months Ended September 30, 2022 Compared to the Nine Months Ended September 30, 2021

### *General and Administrative Expense*

General and administrative expense was approximately \$3,815,000 for the nine months ended September 30, 2022 compared to approximately \$3,785,000 for the comparable period in 2021. The increase in general and administrative expense was mainly attributable to increases of \$638,000 in legal and professional fees and \$6,000 in other expenses, which were offset with decreases of approximately \$109,000 for employee compensation and taxes, \$442,000 in stock-based compensation and \$63,000 in advertising and marketing. Our general and administrative expenses are expected to remain approximately at these levels for the remainder of this year.

### *Research and Development Expense*

Research and development expense was approximately \$5,951,000 for the nine months ended September 30, 2022 compared to approximately \$7,450,000 for the comparable period in 2021. The decrease in research and development expenses during the period were mainly attributed to the timing of drug development expenses (significant manufacturing activity occurred in the prior year period with much less occurring in the current year, and this lower level of manufacturing activity is expected to continue throughout this year), as well as a credit to research and development expense for the funds collected from WPD Pharmaceuticals related to their purchase of Berubicin drug product for their clinical trials, partially offset by an increase in contract research organization (CRO) expenses related to continued progress with our Phase II clinical trial. Our CRO expenditures are primarily for labor related to activating selected trial sites, managing patient enrollment processes, collecting and managing data from patient treatments throughout the trial, processing reimbursement to the sites for patient treatment, and assisting with necessary submissions to amend the IND. CRO expenditures are expected to remain relatively consistent with the year-to-date run-rate throughout the remainder of the trial as site activation efforts and the associated costs thereof transition into reimbursing clinical trial sites for patient treatment costs as site and patient enrollment increases. We expect to incur increased research and development costs in the future as we continue our Phase II clinical trial.

### *Net Loss*

The net loss for the nine months ended September 30, 2022 was approximately \$9,770,000 compared to approximately \$11,241,000 for the comparable period in 2021. The change in net loss is attributable to decreases in employee compensation and stock-based compensation, the timing of drug development expenses (significant manufacturing activity occurred in the prior year period with much less occurring in the current year), as well as a credit to research and development expense for the funds collected from WPD Pharmaceuticals related to their purchase of Berubicin drug product for their clinical trials, partially offset by an increase in CRO expenses related to continued progress with our Phase II clinical trial as well as increases in legal and professional fees and other expenses.

### **Liquidity and Capital Resources**

On September 30, 2022, we had cash of approximately \$7,027,000 and we had working capital of approximately \$7,456,000. We fund our operations from proceeds from equity sales.

In January 2022, we completed a financing with several institutional investors for the sale of (i) 9,489,474 shares of common stock, (ii) pre-funded warrants to purchase up to an aggregate of 2,615,790 shares of common stock and (iii) warrants to purchase up to an aggregate of 12,105,264 shares of common stock. The combined purchase price of one share of common stock (or one pre-funded warrant) and accompanying common warrant was \$0.95. The gross proceeds from the private placement were approximately \$11.5 million, before deducting the placement agent's fees and other offering expenses.

Our plan of operations is primarily focused on completing a Phase II clinical trial for Berubicin. We estimate that we will require additional financing of approximately \$13 - \$17 million to complete the trial (taking into account our cash on hand as of September 30, 2022 of approximately \$7.0 million), approximately \$5.0 million to support near-term WP1244/WP1874 preclinical work, plus such additional working capital to fund our operations during the pendency of the trial. Our current expectation is that our cash on hand is sufficient to fund our operations into the first quarter of 2023. The timing and costs of clinical trials are difficult to predict and trial plans may change in response to evolving circumstances and as such the foregoing estimates may prove to be inaccurate.

We will need to raise additional capital in order to meet our obligations and execute our business plan. If we are unable to raise sufficient funds, we will be required to develop and implement an alternative plan to further extend payables, reduce overhead or scale back our business plan until sufficient additional capital is raised to support further operations. There can be no assurance that such a plan will be successful.

### **Summary of Cash Flows**

#### *Cash used in operating activities*

Net cash used in operating activities was approximately \$8,252,000 and \$10,302,000 for the nine months ended September 30, 2022 and 2021, respectively, and mainly included payments made for clinical trial preparation, officer compensation, insurance, marketing and professional fees to our consultants, attorneys and accountants.

#### *Cash used in investing activities*

Net cash used by investing activities was approximately \$4,000 for the nine months ended September 30, 2022 and 2021. The amount used in 2022 and 2021 are related to the purchase of furniture and equipment.

#### *Cash provided by financing activities*

Net cash provided by financing activities was \$10,280,000 for the nine months ended September 30, 2022 related to the sale of common stock and warrants, and from the exercise of warrants, offset by the repayment of notes payable. Net cash provided by financing activities was \$4,592,000 for the nine months ended September 30, 2021 related to the sale of common stock and exercise of warrants, offset by the repayment of notes payable.

### **Off-balance Sheet Arrangements**

As of September 30, 2022, we did not have any relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes.

### **Purchase Commitments**

We do not have any material commitments for capital expenditures, although we are required to pay certain development fees to HPI and WPD as described in the section “Overview” above.

### **JOBS Act Accounting Election**

The Jumpstart Our Business Startups Act of 2012, or the JOBS Act, exempts an “emerging growth company” such as us from being required to comply with new or revised financial accounting standards until private companies are required to comply with the new or revised financial accounting standards. The JOBS Act provides that a company can elect to opt out of the extended transition period and comply with the requirements that apply to non-emerging growth companies but any such election to opt out is irrevocable. We elected not to opt out of such extended transition period which means that when a standard is issued or revised and it has different application dates for public or private companies, we, as an emerging growth company, can adopt the new or revised standard at the time private companies adopt the new or revised standard. This may make comparison of our financial statements with another public company which is neither an emerging growth company nor an emerging growth company which has opted out of using the extended transition period difficult or impossible because of the potential differences in accounting standards used.

### **Critical Accounting Policies and Estimates**

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates, assumptions and judgments that affect the amounts reported in the financial statements, including the notes thereto. As a result, management is required to routinely make judgments and estimates about the effects of matters that are inherently uncertain. Actual results may differ from these estimates under different conditions or assumptions. Management determined there were no critical accounting estimates.

### **Item 3. Quantitative and Qualitative Disclosures About Market Risk**

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information required under this item.

### **Item 4. Controls and Procedures**

#### **Evaluation of Disclosure Controls and Procedures and Changes in Internal Control over Financial Reporting**

We maintain a set of disclosure controls and procedures designed to ensure that material information required to be disclosed in our filings under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms and that material information is accumulated and communicated to our management, including our chief executive officer, who serves as our principal executive officer, and our chief financial officer, who serves as our principal financial officer, as appropriate, to allow timely decisions regarding required disclosures.

Under the supervision, and with the participation of our management, including our chief executive officer and our chief financial officer, we conducted an evaluation of the effectiveness, as of September 30, 2022, of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by an issuer in the reports that it files or submits under the Exchange Act is accumulated and communicated to the issuer's management, including its principal executive officer and principal financial officer, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

Based upon such evaluation, our chief executive officer and our chief financial officer have concluded that, as of September 30, 2022, our disclosure controls and procedures were, and continue to be, ineffective because of the material weaknesses in our internal control over financial reporting due to a lack of segregation of duties and the lack of formal documentation of our control environment.

In light of the material weakness described above, we continue to perform additional analysis and other post-closing procedures to ensure our financial statements are prepared in accordance with GAAP. Accordingly, we believe that the financial statements included in this report fairly present, in all material respects, our financial condition, results of operations and cash flows for the periods presented. Additional experienced personnel will be hired in the accounting and finance department, appropriate consultants will be retained, and our accounting system will be upgraded as soon as it becomes economically feasible and sustainable.

Other than as described above, there has been no change in our internal control over financial reporting during our most recent calendar quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

## PART II - OTHER INFORMATION

### Item 1. Legal Proceedings

From time to time in the ordinary course of our business, we may be involved in legal proceedings, the outcomes of which may not be determinable. The results of litigation are inherently unpredictable. Any claims against us, whether meritorious or not, could be time consuming, result in costly litigation, require significant amounts of management time and result in diversion of significant resources. We are not able to estimate an aggregate amount or range of reasonably possible losses for those legal matters for which losses are not probable and estimable. We have insurance policies covering potential losses where such coverage is cost effective.

We are not at this time involved in any legal proceedings.

### Item 1A. Risk Factors

In addition to the other information set forth in this report, you should carefully consider the factors discussed in the section entitled “Risk Factors” in our 2021 Annual Report on Form 10-K, filed with the SEC, which are incorporated herein by reference, as well as the additional risk factors set forth below. The risks described in such reports are not the only risks facing our Company. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition and/or operating results.

***We may be required to complete a reverse stock split to regain compliance with Nasdaq listing rules and we cannot predict the effect that any reverse stock split will have on the market price for shares of our common stock.***

On February 18, 2022, we received a deficiency letter from Nasdaq notifying us that for the last 30 consecutive business days the bid price for our common stock had closed below the minimum \$1.00 per share requirement for continued inclusion on the Nasdaq Capital Market pursuant to Nasdaq Listing Rule 5550(a)(2) (the “Bid Price Rule”). We have until February 13, 2023 to regain compliance with the Bid Price Rule.

We may complete a reverse stock split in order to regain compliance with the Bid Price Rule. We cannot predict the effect that a reverse stock split will have on the market price for shares of our common stock, and the history of similar reverse stock splits for companies in like circumstances has varied. Some investors may have a negative view of a reverse stock split. Even if a reverse stock split has a positive effect on the market price for shares of our common stock, performance of our business and financial results, general economic conditions and the market perception of our business, and other adverse factors which may not be in our control could lead to a decrease in the price of our common stock following the reverse stock split.

Furthermore, even if the reverse stock split does result in an increased market price per share of our common stock, the market price per share following the reverse stock split may not increase in proportion to the reduction of the number of shares of our common stock outstanding before the implementation of the reverse stock split. Accordingly, even with an increased market price per share, the total market capitalization of shares of our common stock after a reverse stock split could be lower than the total market capitalization before the reverse stock split. Also, even if there is an initial increase in the market price per share of our common stock after a reverse stock split, the market price may not remain at that level.

If the market price of shares of our common stock declines following a reverse stock split, the percentage decline as an absolute number and as a percentage of our overall market capitalization may be greater than would occur in the absence of the reverse stock split due to decreased liquidity in the market for our common stock. Accordingly, the total market capitalization of our common stock following the reverse stock split could be lower than the total market capitalization before the reverse stock split.

### Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

None.

**Item 3. Defaults Upon Senior Securities**

None.

**Item 4. Mine Safety Disclosures**

Not applicable.

**Item 5. Other Information**

None.

**Item 6. Exhibits**

**INDEX TO EXHIBITS**

<b>Exhibit Number</b>	<b>Description</b>
31.1*	<a href="#">Certification of the Principal Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.</a>
31.2*	<a href="#">Certification of the Principal Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.</a>
32.1*(1)	<a href="#">Certification of the Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a>
32.2*(1)	<a href="#">Certification of the Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a>
101.INS*	Inline XBRL Instance Document (the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document)
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104*	Cover Page Interactive Data File (formatted in iXBRL, and included in exhibit 101).

\* Filed herewith.

(1) The certifications on Exhibit 32 hereto are deemed not “filed” for purposes of Section 18 of the Exchange Act or otherwise subject to the liability of that Section. Such certifications will not be deemed incorporated by reference into any filing under the Securities Act or the Exchange Act.

**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 thereunto duly authorized.

**CNS PHARMACEUTICALS, INC.**

<b>SIGNATURE</b>	<b>TITLE</b>	<b>DATE</b>
<u>/s/ John Climaco</u> John Climaco	Chief Executive Officer and Director (principal executive officer)	November 10, 2022
<u>/s/ Christopher Downs</u> Christopher Downs	Chief Financial Officer (principal financial and accounting officer)	November 10, 2022



## CERTIFICATION BY CHIEF EXECUTIVE OFFICER

I, John Climaco, certify that:

1. I have reviewed this quarterly report on Form 10-Q of CNS Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and we have:

a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c. evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d. disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

November 10, 2022

By: /s/ John Climaco  
John Climaco  
Chief Executive Officer  
(Principal executive officer)

## CERTIFICATION BY CHIEF FINANCIAL OFFICER

I, Christopher Downs, certify that:

1. I have reviewed this quarterly report on Form 10-Q of CNS Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and we have:

a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c. evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d. disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

November 10, 2022

By: /s/ Christopher Downs  
Christopher Downs  
Chief Financial Officer  
(Principal financial and accounting officer)

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER**

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

(Subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code)

Pursuant to section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), the undersigned officer of CNS Pharmaceuticals, Inc., a Nevada corporation (the "Company"), does hereby certify, to such officer's knowledge, that:

The quarterly report on Form 10-Q for the quarter ended September 30, 2022 (the "Form 10-Q") of the Company fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended and information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

November 10, 2022

By: /s/ John Climaco  
John Climaco  
Chief Executive Officer  
(Principal Executive Officer)

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER**

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

(Subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code)

Pursuant to section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), the undersigned officer of CNS Pharmaceuticals, Inc., a Nevada corporation (the "Company"), does hereby certify, to such officer's knowledge, that:

The quarterly report on Form 10-Q for the quarter ended September 30, 2022 (the "Form 10-Q") of the Company fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended and information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

November 10, 2022

By: /s/ Christopher Downs  
Christopher Downs  
Chief Financial Officer  
(Principal financial and accounting officer)