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UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 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 June 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 001-35963

**NEUBASE THERAPEUTICS, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of incorporation or organization)

**46-5622433**

(I.R.S. Employer Identification No.)

**350 Technology Drive, Pittsburgh, PA 15219**

(Address of principal executive offices and zip code)

**(412) 763-3350**

(Registrant's telephone number, including area code)

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

<b>Title of each class</b>	<b>Trading Symbol(s)</b>	<b>Name of each exchange on which registered</b>
Common Stock, \$0.0001 par value per share	NBSE	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant (1) has 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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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 Act). Yes  No

As of August 5, 2022, 32,258,657 shares of the common stock, par value \$0.0001, of the registrant were outstanding.

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## PART I.

## ITEM 1. FINANCIAL STATEMENTS

NeuBase Therapeutics, Inc. and Subsidiaries  
Condensed Consolidated Balance Sheets  
(Unaudited)

	June 30, 2022	September 30, 2021
<u>ASSETS</u>		
CURRENT ASSETS		
Cash and cash equivalents	\$ 29,846,825	\$ 52,893,387
Prepaid insurance	460,804	499,061
Other prepaid expenses and current assets	1,314,057	1,536,186
Total current assets	<u>31,621,686</u>	<u>54,928,634</u>
EQUIPMENT, net	<u>2,351,286</u>	<u>2,463,882</u>
OTHER ASSETS		
Investment	—	415,744
Right-of-use asset, operating lease asset	5,750,602	5,945,295
Security deposit	273,215	253,615
Other long-term assets	—	160,423
Total other assets	<u>6,023,817</u>	<u>6,775,077</u>
TOTAL ASSETS	<u>\$ 39,996,789</u>	<u>\$ 64,167,593</u>
<u>LIABILITIES AND STOCKHOLDERS' EQUITY</u>		
CURRENT LIABILITIES		
Accounts payable	\$ 1,655,789	\$ 1,807,885
Accrued expenses and other current liabilities	1,868,860	1,747,746
Insurance note payable	—	148,385
Operating lease liabilities	560,252	382,576
Finance lease liabilities	115,652	107,632
Total current liabilities	<u>4,200,553</u>	<u>4,194,224</u>
Long-term operating lease liability	5,463,797	5,794,096
Long-term finance lease liability	20,108	109,500
TOTAL LIABILITIES	<u>9,684,458</u>	<u>10,097,820</u>
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' EQUITY		
Preferred stock, \$0.0001 par value; 10,000,000 shares authorized; no shares issued and outstanding as of June 30, 2022 and September 30, 2021	—	—
Common stock, \$0.0001 par value; 250,000,000 shares authorized; 32,258,657 and 32,721,493 shares issued and outstanding as of June 30, 2022 and September 30, 2021, respectively	3,225	3,272
Additional paid-in capital	125,421,571	123,034,404
Accumulated deficit	(95,112,465)	(68,967,903)
Total stockholders' equity	<u>30,312,331</u>	<u>54,069,773</u>
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	<u>\$ 39,996,789</u>	<u>\$ 64,167,593</u>

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

**NeuBase Therapeutics, Inc. and Subsidiaries**  
**Condensed Consolidated Statements of Operations**  
**(Unaudited)**

	<u>Three Months ended June 30,</u>		<u>Nine Months Ended June 30,</u>	
	<u>2022</u>	<u>2021</u>	<u>2022</u>	<u>2021</u>
<b>OPERATING EXPENSES</b>				
General and administrative	\$ 3,603,999	\$ 3,470,104	\$ 9,633,422	\$ 8,833,214
Research and development	4,756,609	2,480,961	15,961,536	7,675,014
Research and development, Vera acquisition	—	2,888,029	—	2,888,029
<b>TOTAL OPERATING EXPENSES</b>	<u>8,360,608</u>	<u>8,839,094</u>	<u>25,594,958</u>	<u>19,396,257</u>
<b>LOSS FROM OPERATIONS</b>	(8,360,608)	(8,839,094)	(25,594,958)	(19,396,257)
<b>OTHER INCOME (EXPENSE)</b>				
Interest expense	(2,819)	(3,074)	(21,354)	(19,271)
Interest income	37,147	2,054	41,846	11,520
Change in fair value of warrant liabilities	—	215,547	—	936,256
Equity in losses on equity method investment	—	(37,215)	(415,744)	(98,754)
Other (expense) income, net	(165,437)	(1,087)	(154,352)	315,637
<b>Total other income (expense), net</b>	<u>(131,109)</u>	<u>176,225</u>	<u>(549,604)</u>	<u>1,145,388</u>
<b>NET LOSS</b>	<u>\$ (8,491,717)</u>	<u>\$ (8,662,869)</u>	<u>\$ (26,144,562)</u>	<u>\$ (18,250,869)</u>
<b>BASIC AND DILUTED LOSS PER SHARE</b>	<u>\$ (0.26)</u>	<u>\$ (0.29)</u>	<u>\$ (0.80)</u>	<u>\$ (0.72)</u>
<b>WEIGHTED AVERAGE SHARES OUTSTANDING:</b>				
<b>BASIC AND DILUTED</b>	<u>32,258,657</u>	<u>30,092,493</u>	<u>32,556,035</u>	<u>25,482,082</u>

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

**NeuBase Therapeutics, Inc. and Subsidiaries**  
**Condensed Consolidated Statements of Stockholders' Equity**  
**For the Three and Nine Months Ended June 30, 2022 and 2021**  
**(Unaudited)**

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
<b>Balance as of September 30, 2021</b>	<b>32,721,493</b>	<b>\$ 3,272</b>	<b>\$ 123,034,404</b>	<b>\$ (68,967,903)</b>	<b>\$ 54,069,773</b>
Stock-based compensation expense	—	—	793,204	—	793,204
Issuance of restricted stock for services	4,441	—	—	—	—
Exercise of stock options	42,250	4	38	—	42
Net loss	—	—	—	(7,728,816)	(7,728,816)
<b>Balance as of December 31, 2021</b>	<b>32,768,184</b>	<b>\$ 3,276</b>	<b>\$ 123,827,646</b>	<b>\$ (76,696,719)</b>	<b>\$ 47,134,203</b>
Stock-based compensation expense	—	—	952,828	—	952,828
Forfeiture of common stock	(509,527)	(51)	51	—	—
Net loss	—	—	—	(9,924,029)	(9,924,029)
<b>Balance as of March 31, 2022</b>	<b>32,258,657</b>	<b>\$ 3,225</b>	<b>\$ 124,780,525</b>	<b>\$ (86,620,748)</b>	<b>\$ 38,163,002</b>
Stock-based compensation expense	—	—	641,046	—	641,046
Net loss	—	—	—	(8,491,717)	(8,491,717)
<b>Balance as of June 30, 2022</b>	<b>32,258,657</b>	<b>\$ 3,225</b>	<b>\$ 125,421,571</b>	<b>\$ (95,112,465)</b>	<b>\$ 30,312,331</b>

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
<b>Balance as of September 30, 2020</b>	<b>23,154,084</b>	<b>\$ 2,315</b>	<b>\$ 74,850,935</b>	<b>\$ (43,558,602)</b>	<b>\$ 31,294,648</b>
Stock-based compensation expense	—	—	1,176,585	—	1,176,585
Issuance of restricted stock for services	1,931	—	—	—	—
Exercise of stock options	21,576	2	112,444	—	112,446
Net loss	—	—	—	(4,066,431)	(4,066,431)
<b>Balance as of December 31, 2020</b>	<b>23,177,591</b>	<b>\$ 2,317</b>	<b>\$ 76,139,964</b>	<b>\$ (47,625,033)</b>	<b>\$ 28,517,248</b>
Stock-based compensation expense	—	—	942,108	—	942,108
Issuance of restricted stock for services	2,433	—	—	—	—
Net loss	—	—	—	(5,521,569)	(5,521,569)
<b>Balance as of March 31, 2021</b>	<b>23,180,024</b>	<b>\$ 2,317</b>	<b>\$ 77,082,072</b>	<b>\$ (53,146,602)</b>	<b>\$ 23,937,787</b>
Stock-based compensation expense	—	—	625,182	—	625,182
Issuance of common stock, net of issuance costs	9,200,000	920	42,615,456	—	42,616,376
Issuance of common stock, Vera acquisition	308,635	31	1,759,189	—	1,759,220
Issuance of restricted stock for services	2,692	—	—	—	—
Exercise of stock options	25,476	3	(3)	—	—
Net loss	—	—	—	(8,662,869)	(8,662,869)
<b>Balance as of June 30, 2021</b>	<b>32,716,827</b>	<b>\$ 3,271</b>	<b>\$ 122,081,896</b>	<b>\$ (61,809,471)</b>	<b>\$ 60,275,696</b>

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

**NeuBase Therapeutics, Inc. and Subsidiaries**  
**Condensed Consolidated Statements of Cash Flows**  
**(Unaudited)**

	Nine Months Ended June 30,	
	2022	2021
<b>Cash flows from operating activities</b>		
Net loss	\$ (26,144,562)	\$ (18,250,869)
<b>Adjustments to reconcile net loss to net cash used in operating activities</b>		
Stock-based compensation	2,387,078	2,743,875
Research and development expense, Vera acquisition	—	2,888,029
Change in fair value of warrant liabilities	—	(936,256)
Depreciation and amortization	567,744	251,701
Loss on marketable securities	30	15,024
Loss on disposal of fixed assets	—	1,087
Equity in losses on equity method investment	415,744	98,754
Gain on sale of intellectual property	—	(316,724)
Amortization of right-of-use assets	359,306	69,423
<b>Changes in operating assets and liabilities</b>		
Prepaid insurance, other prepaid expenses and current assets	260,386	(166,420)
Long-term prepaid insurance	—	145,250
Security deposit	(19,600)	(253,565)
Other long-term assets	160,423	—
Accounts payable	(164,339)	(173,913)
Accrued expenses and other current liabilities	121,114	394,258
Operating lease liability	(317,236)	58,809
<b>Net cash used in operating activities</b>	<u>(22,373,912)</u>	<u>(13,431,537)</u>
<b>Cash flows from investing activities</b>		
Purchase of laboratory and office equipment	(442,905)	(1,096,781)
Purchase of marketable securities	(14,986,818)	(44,992,196)
Sale of marketable securities	14,986,788	44,977,172
Cash paid for Vera acquisition	—	(1,100,040)
<b>Net cash used in investing activities</b>	<u>(442,935)</u>	<u>(2,211,845)</u>
<b>Cash flows from financing activities</b>		
Principal payment of financed insurance	(148,385)	(235,248)
Principal payment of finance lease liability	(81,372)	—
Proceeds from issuance of stock, net of issuance costs	—	42,616,376
Proceeds from exercise of stock options	42	112,446
<b>Net cash (used in) provided by financing activities</b>	<u>(229,715)</u>	<u>42,493,574</u>
<b>Net (decrease) increase in cash and cash equivalents</b>	<u>(23,046,562)</u>	<u>26,850,192</u>
<b>Cash and cash equivalents, beginning of period</b>	<u>52,893,387</u>	<u>31,992,283</u>
<b>Cash and cash equivalents, end of period</b>	<u>\$ 29,846,825</u>	<u>\$ 58,842,475</u>
Supplemental disclosure of cash flow information:		
Cash paid for interest	\$ —	\$ 10,400
Cash paid for income taxes	\$ —	\$ —
Non-cash investing and financing activities:		
Issuance of common stock, Vera acquisition	\$ —	\$ 1,759,220
Purchases of laboratory and office equipment in accounts payable	\$ 12,243	\$ 188,452
Preferred shares in DepYmed received as consideration for sale of intellectual property	\$ —	\$ 316,724
Insurance financed through note payable	\$ —	\$ 391,625
Right-of-use asset obtained in exchange for operating lease liabilities	\$ 164,613	\$ —

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

**NeuBase Therapeutics, Inc. and Subsidiaries**  
**Notes to Condensed Consolidated Financial Statements**  
**(Unaudited)**

**1. Organization and Description of Business**

NeuBase Therapeutics, Inc. and subsidiaries (the “Company” or “NeuBase”) is developing a modular peptide-nucleic acid (“PNA”) antisense oligo (“PATrOL™”) platform to address genetic diseases, with a single, cohesive approach. The PATrOL™-enabled anti-gene therapies are designed to improve upon current genetic medicine strategies by combining the advantages of synthetic approaches with the precision of antisense technologies. NeuBase plans to use its platform to address diseases which have a genetic source, with an initial focus on Myotonic Dystrophy Type 1 (“DM1”), Huntington’s disease (“HD”) and oncology applications.

NeuBase is a preclinical-stage biopharmaceutical company and continues to develop its clinical and regulatory strategy with its internal research and development team with a view toward prioritizing market introduction as quickly as possible. NeuBase’s programs are NT-0100 in HD, NT-0200 in DM1 and NT-0300 in KRAS-driven cancers:

- The NT-0100 program is a PATrOL™-enabled therapeutic program being developed to target the mutant expansion in the HD messenger ribonucleic acid (“mRNA”). The NT-0100 program includes proprietary PNAs which have the potential to be highly selective for the mutant transcript versus the wild-type transcribed allele and the expectation to be applicable for all HD patients as it directly targets the expansion itself and has the potential to be delivered systemically. PATrOL™-enabled drugs also have the unique ability to open RNA secondary structures and bind to either the primary nucleotide sequences or the secondary and/or tertiary structures.
- The NT-0200 program is a PATrOL™-enabled therapeutic program being developed to target the mutant expansion in the DM1 disease mRNA. The NT-0200 program has the potential to be highly selective for the mutant transcript versus the wild-type transcribed allele and the expectation to be effective for nearly all DM1 patients as it directly targets the expansion itself.
- The NT-0300 program is a PATrOL™-enabled therapeutic program being developed to target the mutated *KRAS* gene. The program is comprised of candidate compounds that target two activating mutations in the *KRAS* gene: G12D and G12V. NeuBase believes these candidate compounds, and subsequent further optimized compounds, have the potential to inhibit transcription and/or translation of the oncogenic mutations and slow or stop tumor growth.

NeuBase believes its three aforementioned programs address unmet needs for diseases that currently have no effective therapeutics that target the etiologies of these conditions. NeuBase further believes there is a large opportunity in the U.S. and European markets for drugs in these areas.

**Liquidity and Going Concern**

The Company has had no revenues from product sales and has incurred operating losses since inception. As of June 30, 2022, the Company had \$29.8 million in cash and cash equivalents, and during the nine months ended June 30, 2022, incurred a loss from operations of \$25.6 million and used \$22.4 million of cash in operating activities.

The accompanying unaudited condensed consolidated financial statements have been prepared assuming the Company will continue to operate as a going concern, which contemplates the realization of assets and settlement of liabilities in the normal course of business, and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classifications of liabilities that may result from uncertainty related to its ability to continue as a going concern.

The Company’s future liquidity and capital funding requirements will depend on numerous factors, including:

- its ability to raise additional funds to finance its operations;
- its ability to maintain compliance with the listing requirements of The Nasdaq Capital Market (“Nasdaq”)
- the outcome, costs and timing of preclinical and clinical trial results for the Company’s current or future product candidates;
- the extent and amount of any indemnification claims;
- litigation expenses and the extent and amount of any indemnification claims;

**NeuBase Therapeutics, Inc. and Subsidiaries**  
**Notes to Condensed Consolidated Financial Statements**  
**(Unaudited)**

- the emergence and effect of competing or complementary products;
- its ability to maintain, expand and defend the scope of its intellectual property portfolio, including the amount and timing of any payments the Company may be required to make, or that it may receive, in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights;
- its ability to retain its current employees and the need and ability to hire additional management and scientific and medical personnel;
- the trading price of its common stock; and
- its ability to increase the number of authorized shares outstanding to facilitate future financing events.

The Company will likely need to raise substantial additional funds through issuance of equity or debt or completion of a licensing transaction for one or more of the Company's pipeline assets. If the Company is unable to maintain sufficient financial resources, its business, financial condition and results of operations will be materially and adversely affected. This could affect future development and business activities and potential future clinical studies and/or other future ventures. Failure to obtain additional equity or debt financing will have a material, adverse impact on the Company's business operations. There can be no assurance that the Company will be able to obtain the needed financing on acceptable terms or at all. Additionally, any equity financings will likely have a dilutive effect on the holdings of the Company's existing stockholders.

The Company expects to incur substantial operating losses and negative cash flows from operations for the foreseeable future. Accordingly, there are material risks and uncertainties that raise substantial doubt about the Company's ability to continue as a going concern.

## **2. Significant Accounting Policies**

### ***Basis of Presentation***

The accompanying unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto as of and for the year ended September 30, 2021 included in the Company's Annual Report on Form 10-K (the "Annual Report") filed with the U.S. Securities and Exchange Commission ("SEC") on December 23, 2021. The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. All intercompany accounts and transactions have been eliminated during the consolidation process. The Company manages its operations as a single segment for the purposes of assessing performance and making operating decisions. The accompanying unaudited condensed consolidated financial statements have been prepared by the Company in accordance with accounting principles generally accepted in the United States ("GAAP") for interim financial information and in accordance with the instructions to Form 10-Q and Article 8 of Regulation S-X. Accordingly, certain information and footnote disclosures normally included in financial statements prepared in accordance with GAAP have been condensed or omitted. In the opinion of management, the accompanying unaudited condensed consolidated financial statements for the periods presented reflect all adjustments, consisting of only normal, recurring adjustments, necessary to fairly state the Company's financial position, results of operations and cash flows. The unaudited condensed consolidated financial statements for the interim periods are not necessarily indicative of results for the full year. The preparation of these unaudited condensed consolidated financial statements requires the Company to make estimates and judgments that affect the amounts reported in the financial statements and the accompanying notes. The Company's actual results may differ from these estimates under different assumptions or conditions.

### ***Use of Estimates***

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. The most significant estimates in the Company's unaudited condensed consolidated financial statements relate to the valuation of stock-based compensation, the valuation of licenses, the fair value of warrant liabilities and the valuation allowance of deferred tax assets resulting from net operating losses. These estimates and assumptions are based on current facts, historical experience and various other factors believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities and the recording of expenses that are not readily apparent from other sources.



**NeuBase Therapeutics, Inc. and Subsidiaries**  
**Notes to Condensed Consolidated Financial Statements**  
**(Unaudited)**

The Company assesses and updates estimates each period to reflect current information, such as the economic considerations related to the impact that the novel coronavirus disease (“COVID-19”) could have on its significant accounting estimates. Actual results may differ materially and adversely from these estimates. To the extent there are material differences between the estimates and actual results, the Company’s future results of operations will be affected.

***Fair Value Measurements***

Fair value measurements are based on the premise that fair value is an exit price representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, the following three-tier fair value hierarchy has been used in determining the inputs used in measuring fair value:

Level 1 – Quoted prices in active markets for identical assets or liabilities on the reporting date.

Level 2 – Pricing inputs are based on quoted prices for similar instruments in active markets, quoted prices for identical or similar instruments in markets that are not active and model-based valuation techniques for which all significant assumptions are observable in the market or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 – Pricing inputs are generally unobservable and include situations where there is little, if any, market activity for the investment. The inputs into the determination of fair value require management’s judgment or estimation of assumptions that market participants would use in pricing the assets or liabilities. The fair values are therefore determined using factors that involve considerable judgment and interpretations, including but not limited to private and public comparables, third-party appraisals, discounted cash flow models, and fund manager estimates.

Financial instruments measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. Management’s assessment of the significance of a particular input to the fair value measurement in its entirety requires judgment and considers factors specific to the asset or liability. The use of different assumptions and/or estimation methodologies may have a material effect on estimated fair values. Accordingly, the fair value estimates disclosed, or initial amounts recorded may not be indicative of the amount that the Company or holders of the instruments could realize in a current market exchange.

***Net Loss Per Share***

Basic net loss per share is computed by dividing net loss applicable to common stockholders by the weighted average number of shares of common stock outstanding during each period. Diluted net loss per share includes the dilutive effect, if any, from the potential exercise or conversion of securities, such as convertible debt, warrants and stock options that would result in the issuance of incremental shares of common stock. In computing the basic and diluted net loss per share applicable to common stockholders, the weighted average number of shares remains the same for both calculations due to the fact that when a net loss exists, dilutive shares are not included in the calculation as the impact is anti-dilutive.

The following potentially dilutive securities outstanding as of June 30, 2022 and 2021 have been excluded from the computation of diluted weighted average shares outstanding, as they would be anti-dilutive:

	<u>As of June 30,</u>	
	<u>2022</u>	<u>2021</u>
Common stock purchase options	8,212,778	7,002,421
Restricted stock units	—	10,000
Common stock purchase warrants	180,000	820,939
	<u>8,392,778</u>	<u>7,833,360</u>

**NeuBase Therapeutics, Inc. and Subsidiaries**  
**Notes to Condensed Consolidated Financial Statements**  
**(Unaudited)**

**Recent Accounting Pronouncements**

In December 2019, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 2019-12, “Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes” (“ASU 2019-12”), which is intended to simplify various aspects related to accounting for income taxes. ASU 2019-12 removes certain exceptions to the general principles in Topic 740 and also clarifies and amends existing guidance to improve consistent application. The adoption of this standard as of October 1, 2021, did not impact the Company’s consolidated financial statements and related disclosures.

In November 2021, the FASB issued ASU No. 2021-10, “Government Assistance (Topic 832): Disclosures by Business Entities about Government Assistance”, which amends disclosures to increase transparency of government assistance, including (i) the types of assistance, (ii) accounting for the assistance and (iii) the effect of the assistance on an entity’s financial statements. The standard is effective for all business entities for annual periods beginning after December 15, 2021. The Company is currently evaluating the impact of this standard on its consolidated financial statements and related disclosures.

In June 2022, the FASB issued ASU 2022-03, “ASC Subtopic 820 Fair Value Measurement of Equity Securities Subject to Contractual Sale Restrictions” (“ASU 2022-03”). ASU 2022-03 amends ASC 820 to clarify that a contractual sales restriction is not considered in measuring an equity security at fair value and to introduce new disclosure requirements for equity securities subject to contractual sale restrictions that are measured at fair value. ASU 2022-03 applies to both holders and issuers of equity and equity-linked securities measured at fair value. The amendments in this ASU are effective for the Company in fiscal years beginning after December 15, 2023, and interim periods within those fiscal years. Early adoption is permitted for both interim and annual financial statements that have not yet been issued or made available for issuance. The Company is currently evaluating the impact of this pronouncement on its consolidated financial statements and related disclosures.

**3. Other Prepaid Expenses and Other Current Assets**

The Company’s prepaid expenses and other current assets consisted of the following:

	As of June 30, 2022	As of September 30, 2021
Prepaid research and development expense	\$ 670,420	\$ 583,267
Prepaid rent	—	172,518
Other prepaid expenses and other current assets	643,637	780,401
Total	<u>\$ 1,314,057</u>	<u>\$ 1,536,186</u>

**4. Equipment**

The Company’s equipment consisted of the following:

	As of June 30, 2022	As of September 30, 2021
Laboratory equipment	\$ 3,182,369	\$ 2,737,390
Office equipment	259,978	259,978
Leasehold improvements	10,128	—
Total	3,452,475	2,997,368
Accumulated depreciation	(1,101,189)	(533,486)
Property, plant and equipment, net	<u>\$ 2,351,286</u>	<u>\$ 2,463,882</u>

Depreciation expense for the three months ended June 30, 2022 and 2021 was approximately \$0.2 million and \$0.1 million, respectively. Depreciation expense for the nine months ended June 30, 2022 and 2021 was approximately \$0.6 million and \$0.3 million, respectively.

**NeuBase Therapeutics, Inc. and Subsidiaries**  
**Notes to Condensed Consolidated Financial Statements**  
**(Unaudited)**

**5. Accrued Expenses and Other Current Liabilities**

The Company's accrued expenses and other current liabilities consisted of the following:

	As of June 30, 2022	As of September 30, 2021
Accrued compensation and benefits	\$ 959,405	\$ 880,707
Accrued consulting settlement	75,000	200,000
Accrued professional fees	441,116	299,557
Accrued research and development	182,410	297,047
Accrued franchise tax	123,546	30,720
Other accrued expenses	87,383	39,715
<b>Total</b>	<b>\$ 1,868,860</b>	<b>\$ 1,747,746</b>

**6. Notes Payable**

***Insurance Note Payable***

As of September 30, 2021, the Company had the following insurance note payable outstanding:

	Maturity Date	Stated Interest Rate	Original Principal	Balance at June 30, 2022	Balance at September 30, 2021
<b><i>Insurance Note Payable</i></b>					
2021 Insurance Note	January 2022	4.99 %	\$ 391,625	\$ —	\$ 148,385

**7. Stockholders' Equity**

***Warrants***

Below is a summary of the Company's issued and outstanding warrants as of June 30, 2022:

Expiration date	Exercise Price	Warrants Outstanding
July 6, 2023	8.73	105,000
September 20, 2024	6.50	75,000
		<b>180,000</b>

  

	Warrants	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)
Outstanding as of September 30, 2021	895,939	\$ 18.35	
Expired	(715,939)	21.01	
Outstanding as of June 30, 2022	<b>180,000</b>	<b>7.80</b>	<b>1.5</b>
Exercisable as of June 30, 2022	<b>180,000</b>	<b>\$ 7.80</b>	<b>1.5</b>

**NeuBase Therapeutics, Inc. and Subsidiaries**  
**Notes to Condensed Consolidated Financial Statements**  
**(Unaudited)**

**8. Stock-Based Compensation**

As of June 30, 2022, an aggregate of 6,018,136 shares of common stock were authorized under the Company’s 2019 Stock Incentive Plan (the “2019 Plan”), subject to an “evergreen” provision that will automatically increase the maximum number of shares of common stock that may be issued under the term of the 2019 Plan. As of June 30, 2022, 864,396 common shares were available for future grants under the 2019 Plan. As of June 30, 2022, 291,667 shares of common stock were authorized under the Company’s 2016 Consolidated Stock Incentive Plan (the “2016 Plan”) and 147,041 common shares were available for future grants under the 2016 Plan.

The Company recorded stock-based compensation expense in the following expense categories of its unaudited condensed consolidated statements of operations for the three and nine months ended June 30, 2022 and 2021:

	Three Months ended June 30,		Nine Months Ended June 30,	
	2022	2021	2022	2021
General and administrative	\$ 507,435	\$ 574,353	\$ 1,389,227	\$ 1,865,512
Research and development	133,611	50,829	997,851	878,363
<b>Total</b>	<b>\$ 641,046</b>	<b>\$ 625,182</b>	<b>\$ 2,387,078</b>	<b>\$ 2,743,875</b>

*Stock Options*

Below is a table summarizing the options issued and outstanding as of and for the nine months ended June 30, 2022:

	Stock Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)	Total Aggregate Intrinsic Value
Outstanding at September 30, 2021	7,397,154	\$ 3.13		
Granted	1,510,366	2.14		
Exercised	(42,250)	0.00		
Forfeited	(652,492)	4.67		
Outstanding at June 30, 2022	<u>8,212,778</u>	2.84	6.9	\$ 3,430,544
Exercisable as of June 30, 2022	<u>5,628,339</u>	\$ 2.49	6.0	\$ 3,429,894

As of June 30, 2022, unrecognized compensation costs associated with the stock options of \$3.1 million will be recognized over an estimated weighted-average amortization period of 1.4 years.

The intrinsic value of options exercised during the nine months ended June 30, 2022 and 2021 was \$0.1 million and \$0.06 million, respectively.

The weighted average grant date fair value of options granted during the nine months ended June 30, 2022 and 2021 was \$1.40 and \$4.29, respectively.

Key assumptions used to estimate the fair value of the stock options granted during the nine months ended June 30, 2022 and 2021 included:

	Nine Months Ended June 30,	
	2022	2021
Expected term of options (years)	5.1 - 6.1	5.5 - 7.0
Expected common stock price volatility	73.8% - 77.2%	83% - 83.7%
Risk-free interest rate	1.1% - 3.1%	0.6% - 1.3%
Expected dividend yield	0%	0%

**NeuBase Therapeutics, Inc. and Subsidiaries**  
**Notes to Condensed Consolidated Financial Statements**  
**(Unaudited)**

*Restricted Stock*

A summary of the changes in the unvested restricted stock during the nine months ended June 30, 2022 is as follows:

	Unvested Restricted Stock	Weighted Average Grant Date Fair Value Price
Unvested as of September 30, 2021	—	\$ —
Granted	4,441	3.94
Vested	(4,441)	3.94
Unvested as of June 30, 2022	—	—
Total unrecognized expense remaining	\$ —	
Weighted-average years expected to be recognized over	—	

*Restricted Stock Units*

Below is a table summarizing the restricted stock units granted and outstanding as of and for the nine months ended June 30, 2022:

	Restricted Stock Units	Weighted Average Grant Date Fair Value Price
Unvested as of September 30, 2021	10,000	\$ 5.09
Forfeited	(10,000)	5.09
Unvested as of June 30, 2022	—	—
Total unrecognized expense remaining	\$ —	
Weighted-average years expected to be recognized over	—	

**9. Commitments and Contingencies***Litigation*

The Company has become involved in certain legal proceedings and claims which arise in the normal course of business. The Company believes that an adverse outcome is unlikely, and it cannot reasonably estimate the potential loss at this point. If an unfavorable ruling were to occur, there exists the possibility of a material adverse impact on the Company's results of operations, prospects, cash flows, financial position and brand. Costs associated with the Company's involvement in legal proceedings are expensed as incurred.

**NeuBase Therapeutics, Inc. and Subsidiaries**  
**Notes to Condensed Consolidated Financial Statements**  
**(Unaudited)**

*Securities Litigation*

On February 14, 2018, plaintiff Jeevesh Khanna, commenced an action in the Southern District of New York, against Ohr Pharmaceutical, Inc. (“Ohr”), which entered into a merger agreement with NeuBase Therapeutics, Inc. on January 2, 2019 and which merger closed on July 12, 2019, and several of its current and former officers and directors, alleging that they violated federal securities laws between June 24, 2014 and January 4, 2018. On August 7, 2018, the lead plaintiffs, now George Lehman and Insured Benefit Plans, Inc. filed an amended complaint, alleging a putative class period of April 8, 2014 through January 4, 2018. The plaintiffs did not quantify any alleged damages in their complaint, but, in addition to attorneys’ fees and costs, they seek to maintain the action as a class action and to recover damages on behalf of themselves and other persons who purchased or otherwise acquired Ohr common stock during the putative class period and purportedly suffered financial harm as a result. Ohr and the individuals dispute these claims and are defending the matter vigorously. On September 17, 2018, Ohr filed a motion to dismiss the complaint. On September 20, 2019, the district court issued an opinion and order granting the motion to dismiss. On October 23, 2019, the plaintiffs filed a notice of appeal of that order dismissing the action. After full briefing and oral argument, on October 9, 2020, the U.S. Court of Appeals for the Second Circuit issued a summary order affirming the district court’s order granting the motion to dismiss and remanding the action to the district court to make a determination on the record related to plaintiffs’ request for leave to file an amended complaint. On remand, the district court denied plaintiffs’ subsequent request to amend and dismissed with prejudice plaintiffs’ claims. On December 16, 2020, plaintiffs filed a notice of appeal of that order denying plaintiffs leave to amend. On December 16, 2021, the Second Circuit affirmed the decision and order of the district court denying plaintiffs’ motion for leave to amend, thereby dismissing the appeal and action in its entirety. Plaintiffs have neither sought reconsideration of the Second Circuit’s decision nor filed a writ of certiorari for review by the Supreme Court. This matter is now considered closed.

*Derivative Lawsuit*

On May 3, 2018, plaintiff Adele J. Barke, derivatively on behalf of Ohr, commenced an action against Michael Ferguson, Orin Hirschman, Thomas M. Riedhammer, June Almenoff and Jason Slakter in the Supreme Court, State of New York, alleging that the action was brought in the right and for the benefit of Ohr seeking to remedy their “breach of fiduciary duties, corporate waste and unjust enrichment that occurred between June 24, 2014 and the present.” It does not quantify any alleged damages. On March 30, 2022, plaintiff filed a notice of voluntary dismissal of the complaint in this action. This matter is now considered closed.

*Joint Proxy Statement Lawsuit*

Following the issuance of the preliminary joint proxy statement/prospectus related to the merger of the Company and Ohr, on March 18, 2019, the Gomez Action was filed by an individual shareholder in the United States District Court for the Southern District of New York against Ohr and its board of directors. The plaintiff in the Gomez Action alleges that the preliminary joint proxy/prospectus statement filed by Ohr with the SEC on March 8, 2019 contained false and misleading statements and omitted material information in violation of Section 14(a) of the Exchange Act and SEC Rule 14a-9 promulgated thereunder, and further that the individual defendants are liable for those alleged misstatements and omissions under Section 20(a) of the Exchange Act. On March 19, 2019, the Barke Action was filed in the United States District Court for the Southern District of New York asserting similar Section 14(a) and Section 20(a) claims against Ohr’s board of directors and additionally naming NeuBase and Ohr Acquisition Corp., but not Ohr, as defendants. On March 20, 2019, the Wheby Action was filed in the United States District Court for District of Delaware asserting similar claims under Section 14(a) and Section 20(a) and naming as defendants Ohr and its board of directors, NeuBase, and Ohr Acquisition Corp. On March 20, 2019, the Lowinger Action was filed in the Court of Chancery of the State of Delaware asserting a breach of fiduciary duty claim against Ohr’s board of directors arising out of the same facts and circumstances regarding certain alleged omissions in the preliminary joint proxy/prospectus statement. On April 4, 2019, the Garaygordobil Action was filed in the United States District Court for the Southern District of New York asserting similar Section 14(a) and Section 20(a) claims against Ohr and its board of directors. Each of the Gomez, Barke, Garaygordobil, and Lowinger Actions have been dismissed, and on July 12, 2019, the Company and Ohr consummated the Merger. On March 23, 2022, plaintiffs in the Wheby Action filed a notice of voluntary dismissal of the complaint and this case was closed.

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

### Disclosures Regarding Forward-Looking Statements

*The following should be read in conjunction with the unaudited condensed consolidated financial statements and the related notes that appear elsewhere in this report as well as in conjunction with the Risk Factors section in our Annual Report on Form 10-K for the fiscal year ended September 30, 2021, as filed with the United States Securities and Exchange Commission ("SEC") on December 23, 2021. This report and our Form 10-K include forward-looking statements made based on current management expectations pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, as amended.*

*This report includes "forward-looking statements" within the meaning of Section 21E of the Exchange Act. Those statements include statements regarding the intent, belief or current expectations of the Company and its subsidiaries and our management team. Any such forward-looking statements are not guarantees of future performance and involve risks and uncertainties, and actual results may differ materially from those projected in the forward-looking statements. These risks and uncertainties include but are not limited to those risks and uncertainties set forth in Part II, Item 1A – Risk Factors of this Quarterly Report and in Part I, Item 1A – Risk Factors of our Annual Report on Form 10-K. In light of the significant risks and uncertainties inherent in the forward-looking statements included in this Quarterly Report on Form 10-Q and in our Annual Report on Form 10-K, the inclusion of such statements should not be regarded as a representation by us or any other person that our objectives and plans will be achieved. Further, these forward-looking statements reflect our view only as of the date of this report. Except as required by law, we undertake no obligations to update any forward-looking statements and we disclaim any intent to update forward-looking statements after the date of this report to reflect subsequent developments. Accordingly, you should also carefully consider the factors set forth in other reports or documents that we file from time to time with the SEC.*

### Overview

We have designed, built, and validated a new technology platform (a peptide-nucleic acid antisense oligonucleobase platform, which we call PATrOL™) that can uniquely Drug the Genome™ to address the three disease-causing mechanisms (*i.e.*, gain-of-function, change-of-function, or loss-of-function of a gene), without the limitations of early precision genetic medicines. The technology is predicated on synthetic peptide-nucleic acid ("PNA") chemistry and can directly engage the genome in a sequence-specific manner and address root causality of diseases. These compounds operate by temporarily engaging the genome (or single and double-stranded RNA targets, if desired) and interfering with cellular machinery that processes mutant genes to halt their ability to manifest a disease. We have repeatedly demonstrated in proof-of-concept preclinical animal studies the ability to address multiple disease-causing genes, and different causal mechanisms, to resolve the disease state without the limitations of early genetic medicine technologies. As further validation of our PATrOL™ platform's capabilities, in FY2021, we described data illustrating that our first-in-class platform technology can address various types of causal insults by Drugging the Genome™ in animal models of a variety of human diseases after patient-friendly routes of administration and does so in a well-tolerated manner.

We are developing precision genetic medicines targeting rare, monogenic diseases for which there are no approved therapies, as well as more common genetic disorders, including cancers that are resistant to current therapeutic approaches. Our pipeline includes therapeutic candidates for the treatment of DM1, HD, as well as cancer-driving point mutations in *KRAS*, G12V and G12D, which are involved in many tumor types and have historically been "undruggable".

Based on compelling results from *in vitro* and *in vivo* preclinical studies, we plan to file an IND application for our DM1 investigational therapy in the middle of calendar year 2023. The HD program is currently in preclinical development, and in CY2022 we expect to present new preclinical data describing the pharmacology of a candidate compound in the brain after systemic administration and nominate a development candidate. Both are devastating systemic diseases with no effective therapies. Our oncology program was announced in FY2021, together with *in vivo* activity illustrating allele-selective engagement of mutant *KRAS* at the DNA and RNA levels, with abrogation of downstream hyperactive signaling through multiple RAS pathway members, resulting in anti-tumor activity. We continue to improve upon our platform while concurrently developing programs, resulting in next-generation compounds that continue to make their way through preclinical development in a parallel manner. We have recently finalized an analysis of the entire known mutational database and selected several additional high-value indications for screening and development.

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We were incorporated under the laws of the State of Delaware on August 4, 2009, as successor to BBM Holdings, Inc. (formerly known as Prime Resource, Inc., which was organized March 29, 2002 as a Utah corporation) pursuant to a reincorporation merger. On August 4, 2009, we reincorporated in Delaware as “Ohr Pharmaceutical, Inc.” On July 12, 2019, we completed the merger with NeuBase Corporation (formerly known as NeuBase Therapeutics, Inc.), a Delaware corporation (the “Merger”), and, upon completion of the Merger, we changed our name to “NeuBase Therapeutics, Inc.” Since the Merger, we have focused primarily on the development of our proprietary peptide-nucleic acid antisense oligo platform and preclinical-stage therapeutic candidates. Our platform technology and all of our therapeutic candidates are in the preclinical development stage. We have not initiated clinical trials for any of our product candidates, nor have any products been approved for commercial sale, and we have not generated any revenue. To date, we have not completed a clinical trial (including a pivotal clinical trial), obtained marketing approval for any product candidates, manufactured a commercial scale product or arranged for a third party to do so on our behalf, or conducted sales and marketing activities necessary for successful product commercialization. Drug development is also a highly uncertain undertaking and involves a substantial degree of risk. As a result, we have no meaningful historical operations upon which to evaluate our business and prospects and have not yet demonstrated an ability to obtain marketing approval for any of our product candidates or successfully overcome the risks and uncertainties frequently encountered by companies in the pharmaceutical industry. We also have not generated any revenues from collaboration and licensing agreements or product sales to date and continue to incur research and development and other expenses. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders’ equity and working capital, and our future success is subject to significant uncertainty.

For the foreseeable future, we expect to continue to incur losses, which we expect will increase significantly from recent historical levels as we expand our drug development activities, seek regulatory approvals for our product candidates and begin to commercialize them if they are approved by the U.S. Food and Drug Administration (the “FDA”), the European Medicines Agency (the “EMA”) or comparable foreign authorities. Even if we succeed in developing and commercializing one or more product candidates, we may never become profitable.

We expect to expend substantial funds in research and development, including preclinical studies and clinical trials for our platform technology and product candidates, and to manufacture and market any product candidates in the event they are approved for commercial sale. We will likely need additional funding to develop or acquire complementary companies, technologies and assets, as well as for working capital requirements and other operating and general corporate purposes. Moreover, an increase in our headcount would dramatically increase our costs in the near and long-term.

Such spending may not yield any commercially viable products. Due to our limited financial and managerial resources, we must focus on a limited number of research programs and product candidates and on specific indications. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities.

Because the successful development of our product candidates is uncertain, we are unable to precisely estimate the actual funds we will require to develop and potentially commercialize them. In addition, we may not be able to generate sufficient revenue, even if we are able to commercialize any of our product candidates, to become profitable.

The Company expects to incur substantial operating losses and negative cash flows from operations for the foreseeable future. Accordingly, there are material risks and uncertainties that raise substantial doubt about the Company’s ability to continue as a going concern. We will need to seek additional equity or debt financing to provide the capital required to maintain or expand our operations.

In particular, we expect that we will need to obtain additional funding to obtain clinical data from our current pipeline programs. We have based these estimates on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. Our operating plans and other demands on our cash resources may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity or debt financings or other capital sources, including potentially collaborations, licenses and other similar arrangements. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans.

There can be no assurance that we will be able to raise sufficient additional capital on acceptable terms or at all. If such additional financing is not available on satisfactory terms, or is not available in sufficient amounts, we may be required to delay, limit or eliminate the development of business opportunities, and our ability to achieve our business objectives, our competitiveness, and our business, financial condition and results of operations may be materially adversely affected. In addition, we may be required to grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.



**Critical Accounting Estimates and Policies**

The preparation of financial statements in accordance with United States generally accepted accounting principles (“U.S. GAAP”) requires management to make estimates and assumptions that affect the amounts reported in our unaudited condensed consolidated financial statements and accompanying notes. Management bases its estimates on historical experience, market and other conditions, and various other assumptions it believes to be reasonable. Although these estimates are based on management’s best knowledge of current events and actions that may impact us in the future, the estimation process is, by its nature, uncertain given that estimates depend on events over which we may not have control. If market and other conditions change from those that we anticipate, our unaudited condensed consolidated financial statements may be materially affected. In addition, if our assumptions change, we may need to revise our estimates, or take other corrective actions, either of which may also have a material effect in our unaudited condensed consolidated financial statements. We review our estimates, judgments, and assumptions used in our accounting practices periodically and reflect the effects of revisions in the period in which they are deemed to be necessary. We believe that these estimates are reasonable; however, our actual results may differ from these estimates.

Our critical accounting policies and estimates are discussed in our Annual Report on Form 10-K for the fiscal year ended September 30, 2021, and there have been no material changes to such policies or estimates during the nine months ended June 30, 2022.

**Recent Accounting Pronouncements**

Please refer to Note 2, Significant Accounting Policies—Recent Accounting Pronouncements, in Item 1, Financial Statements, for a discussion of recent accounting pronouncements.

**Results of Operations**

Results of operations for the three months ended June 30, 2022, reflect the following changes from the three months ended June 30, 2021:

	<u>Three Months ended June 30,</u>		
	<u>2022</u>	<u>2021</u>	<u>Change</u>
<b>OPERATING EXPENSES</b>			
General and administrative	\$ 3,603,999	\$ 3,470,104	\$ 133,895
Research and development	4,756,609	2,480,961	2,275,648
Research and development, Vera acquisition	—	2,888,029	(2,888,029)
<b>TOTAL OPERATING EXPENSES</b>	<u>8,360,608</u>	<u>8,839,094</u>	<u>(478,486)</u>
<b>LOSS FROM OPERATIONS</b>	<u>(8,360,608)</u>	<u>(8,839,094)</u>	<u>478,486</u>
<b>OTHER INCOME (EXPENSE)</b>			
Interest expense	(2,819)	(3,074)	255
Interest income	37,147	2,054	35,093
Change in fair value of warrant liabilities	—	215,547	(215,547)
Equity in losses on equity method investment	—	(37,215)	37,215
Other expense	(165,437)	(1,087)	(164,350)
Total other (expense) income, net	<u>(131,109)</u>	<u>176,225</u>	<u>(307,334)</u>
<b>NET LOSS</b>	<u>\$ (8,491,717)</u>	<u>\$ (8,662,869)</u>	<u>\$ 171,152</u>

During the three months ended June 30, 2022, our operating loss decreased by \$0.5 million compared to the three months ended June 30, 2021. Our net loss decreased by \$0.2 million for the three months ended June 30, 2022, as compared to the three months ended June 30, 2021. Until we are able to generate revenue from product sales, our management expects to continue to incur net losses.

**General and Administrative Expenses**

General and administrative expenses consist primarily of legal and professional fees, wages and stock-based compensation. General and administrative expenses increased by \$0.1 million for the three months ended June 30, 2022, as compared to the three months ended June 30, 2021, primarily due to increases in professional fees, settlement costs, and wage expenses.

**Research and Development Expenses**

Research and development expenses consist primarily of professional fees, research, development, manufacturing expenses, wages and stock-based compensation. Research and development expenses increased by \$2.3 million for the three months ended June 30, 2022, as compared to the three months ended June 30, 2021, primarily due to preclinical research activities, professional fees, research, development, and manufacturing expenses, and wages and stock-based compensation.

**Research and Development Expenses, Vera Acquisition**

Research and development expenses, Vera Acquisition consists of the fair value of acquired Vera assets that were determined to represent in-process research and development assets with no future alternative use. The in-process research and development assets were expensed under the guidance of ASC 730, *Research and Development*, upon the asset acquisition. No such expenses were incurred during the three months ended June 30, 2022.

**Change in Fair Value of Warrant Liabilities**

Change in fair value of warrant liabilities reflects the changes in the fair value of outstanding warrants measured at fair value on a recurring basis, which is primarily driven by changes in our stock price. We recognized a gain of \$0.2 million from the change in fair value of warrant liabilities for the three months ended June 30, 2021. Warrants measured at fair value expired unexercised during the nine months ended June 30, 2022.

**Equity in Losses on Equity Method Investment**

We account for our investment in DepYmed common shares using the equity method of accounting and record our proportionate share of DepYmed's net income and losses. As of June 30, 2022 and March 31, 2022, the carrying value of DepYmed common shares was \$0 and, as such, the Company did not record its proportionate share of losses during the three months ended June 30, 2022. Equity in losses during the three months ended June 31, 2021 was \$0.04 million.

**Other (Expense) Income, net**

We recognized other expense of \$0.2 million during the three months ended June 30, 2022 related to the correction of a payroll tax expense credit received in a prior period. Other expense recognized during the three months ended June 30, 2021 was not material.

**Results of operations for the nine months ended June 30, 2022, reflect the following changes from the nine months ended June 30, 2021:**

	Nine Months Ended June 30,		Change
	2022	2021	
<b>OPERATING EXPENSES</b>			
General and administrative	\$ 9,633,422	\$ 8,833,214	\$ 800,208
Research and development	15,961,536	7,675,014	8,286,522
Research and development, Vera acquisition	—	2,888,029	(2,888,029)
<b>TOTAL OPERATING EXPENSES</b>	<b>25,594,958</b>	<b>19,396,257</b>	<b>6,198,701</b>
<b>LOSS FROM OPERATIONS</b>	<b>(25,594,958)</b>	<b>(19,396,257)</b>	<b>(6,198,701)</b>
<b>OTHER INCOME (EXPENSE)</b>			
Interest expense	(21,354)	(19,271)	(2,083)
Interest income	41,846	11,520	30,326
Change in fair value of warrant liabilities	—	936,256	(936,256)
Equity in losses on equity method investment	(415,744)	(98,754)	(316,990)
Other (expense) income, net	(154,352)	315,637	(469,989)
<b>Total other (expense) income, net</b>	<b>(549,604)</b>	<b>1,145,388</b>	<b>(1,694,992)</b>
<b>NET LOSS</b>	<b>\$ (26,144,562)</b>	<b>\$ (18,250,869)</b>	<b>\$ (7,893,693)</b>

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During the nine months ended June 30, 2022, our operating loss increased by \$6.2 million compared to the nine months ended June 30, 2021. Our net loss increased by \$7.9 million for the nine months ended June 30, 2022, as compared to the nine months ended June 30, 2021. Until we are able to generate revenue from product sales, our management expects to continue to incur net losses.

### ***General and Administrative Expenses***

General and administrative expenses consist primarily of legal and professional fees, wages and stock-based compensation. General and administrative expenses increased by \$0.8 million for the nine months ended June 30, 2022, as compared to the nine months ended June 30, 2021, primarily due to increases in professional fees, settlement costs, and wage expenses, partially offset by a decrease in stock-based compensation expense.

### ***Research and Development Expenses***

Research and development expenses consist primarily of professional fees, research, development, manufacturing expenses, wages and stock-based compensation. Research and development expenses increased by \$8.3 million for the nine months ended June 30, 2022, as compared to the nine months ended June 30, 2021, primarily due to increases in manufacturing expenses, professional fees, employee headcount, and the ramp up of research and development activities in support of our preclinical programs.

### ***Research and Development Expenses, Vera Acquisition***

Research and development expenses, Vera Acquisition consists of the fair value of acquired Vera assets that were determined to represent in-process research and development assets with no future alternative use. The in-process research and development assets were expensed under the guidance of ASC 730, *Research and Development*, upon the asset acquisition. No such expenses were incurred during the nine months ended June 30, 2022.

### ***Change in Fair Value of Warrant Liabilities***

Change in fair value of warrant liabilities reflects the changes in the fair value of outstanding warrants measured at fair value on a reoccurring basis, which is primarily driven by changes in our stock price. The fair value of warrant liabilities was \$0 at June 30, 2022 and September 30, 2021, therefore, no change in fair value was recognized during the nine months ended June 30, 2022. During the nine months ended June 30, 2022, warrants measured at fair value expired unexercised. We recognized a gain of \$0.9 million from the change in fair value of warrant liabilities for the nine months ended June 30, 2021.

### ***Equity in Losses on Equity Method Investment***

We account for our investment in DepYmed common shares using the equity method of accounting and record our proportionate share of DepYmed's net income and losses. As of June 30, 2022 and September 30, 2021, the carrying value of our investment in DepYmed common shares was reduced to zero, therefore, during the nine months ended June 30, 2022, we recorded our share of equity losses to the extent of our investment in preferred shares of DepYmed. We will continue to monitor the operating results of DepYmed and will record equity in earnings when the equity in earnings exceeds our previously unrecognized losses. Equity in losses was \$0.4 million for the nine months ended June 30, 2022, and \$0.1 million for the nine months ended June 30, 2021.

### ***Other (Expense)Income, net***

We recognized other expense of \$0.2 million during the nine months ended June 30, 2022 related to the correction of a payroll tax expense credit received in a prior period. We recognized other income of \$0.3 million during the nine months ended June 30, 2021 related to the sale of certain intellectual property to DepYmed in exchange for shares of Series A-4 preferred stock.

### ***Liquidity, Capital Resources and Financial Condition***

We have had no revenues from product sales and have incurred operating losses since inception. As of June 30, 2022, we had cash and cash equivalents of \$29.8 million. We have historically funded our operations through the sale of common stock and the issuance of convertible notes and warrants.

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We expect to continue to incur significant operating losses for the foreseeable future and may never become profitable. As a result, we will likely need to raise additional capital through one or more of the following: the issuance of additional debt or equity or the completion of a licensing transaction for one or more of our pipeline assets.

Net working capital decreased from September 30, 2021 to June 30, 2022 by \$23.3 million (to \$27.4 million from \$50.7 million). Our quarterly cash burn has increased compared to prior periods due to increased research and development and corporate activities, and we expect it to continue to increase in future periods.

At present, we have no bank line of credit or other fixed source of capital reserves. Should we need additional capital in the future, we will be primarily reliant upon a private or public placement of our equity or debt securities, or a strategic transaction, for which there can be no warranty or assurance that we may be successful in such efforts. If we are unable to maintain sufficient financial resources, our business, financial condition and results of operations will be materially and adversely affected. This could affect future development and business activities and potential future clinical studies and/or other future ventures. Failure to obtain additional equity or debt financing will have a material adverse impact on our business operations. There can be no assurance that we will be able to obtain the financing needed to achieve our goals on acceptable terms or at all. Additionally, any equity financings will likely have a dilutive effect on the holdings of the Company's existing stockholders.

The Company expects to incur substantial operating losses and negative cash flows from operations for the foreseeable future. Accordingly, there are material risks and uncertainties that raise substantial doubt about the Company's ability to continue as a going concern.

### Cash Flow Summary

The following table summarizes selected items in our unaudited condensed consolidated statements of cash flows:

	Nine Months Ended June 30,	
	2022	2021
Net cash used in operating activities	\$ (22,373,912)	\$ (13,431,537)
Net cash used in investing activities	(442,935)	(2,211,845)
Net cash (used in) provided by financing activities	(229,715)	42,493,574
Net (decrease) increase in cash and cash equivalents	\$ (23,046,562)	\$ 26,850,192

#### Operating Activities

Net cash used in operating activities was approximately \$22.4 million for the nine months ended June 30, 2022, as compared to approximately \$13.4 million for the nine months ended June 30, 2021. Net cash used in operating activities in the nine months ended June 30, 2022, was primarily the result of our net loss, a decrease in accounts payable and operating lease liability, partially offset by stock-based compensation expense, depreciation and amortization expenses, loss on equity method investment and a decrease in prepaid expenses and current assets. Net cash used in operating activities in the nine months ended June 30, 2021, was primarily the result of our net loss, as well as the change in the fair value of warrant liabilities, gain on sale of intellectual property and cash used for the security deposit and prepayment of rent under our new operating lease for office and laboratory space, offset by the research and development costs for the Vera acquisition, stock-based compensation expense, increased accrued expenses and depreciation and amortization expenses.

#### Investing Activities

Net cash used in investing activities was approximately \$0.4 million for the nine months ended June 30, 2022, as compared to \$2.2 million for the nine months ended June 30, 2021. Net cash used in investing activities for the nine months ended June 30, 2022 was primarily due to the purchase of laboratory and office equipment, whereas for the nine months ended June 30, 2021, net cash used in investing activities was due to cash paid for the Vera acquisition and the purchase of laboratory and office equipment.

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*Financing Activities*

Net cash used in financing activities was approximately \$0.2 million for the nine months ended June 30, 2022, as compared to net cash provided by financing activities of \$42.5 million for the nine months ended June 30, 2021. Net cash used in financing activities for the nine months ended June 30, 2022 primarily reflects the principal payments of financed insurance and a finance lease liability, partially offset by the proceeds received from the exercise of stock options. Net cash provided by financing activities for the nine months ended June 30, 2021 primarily reflects the proceeds from the issuance of common stock of \$42.6 million, net of issuance costs, partially offset by the principal payments of financed insurance.

**ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

We are a smaller reporting company, as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended, and are not required to provide the information required under this item.

**ITEM 4. CONTROLS AND PROCEDURES**

*Evaluation of Disclosure Controls and Procedures*

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of June 30, 2022. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that as of June 30, 2022, our disclosure controls and procedures were effective to provide reasonable assurance that the information required to be disclosed in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to management as appropriate to allow timely decisions regarding required disclosure.

*Changes in Internal Control over Financial Reporting*

There have been no changes in our internal control over financial reporting that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting during the quarterly period ended June 30, 2022.

## PART II.

### ITEM 1. LEGAL PROCEEDINGS

We have become involved in certain legal proceedings and claims which arise in the normal course of business. If an unfavorable ruling were to occur, there exists the possibility of a material adverse impact on our results of operations, prospects, cash flows, financial position and brand. Costs associated with the Company's involvement in legal proceedings are expensed as incurred.

#### *Securities Class Action Lawsuit*

On February 14, 2018, plaintiff Jeevesh Khanna, commenced an action in the Southern District of New York, against Ohr Pharmaceutical, Inc. ("Ohr"), which entered into a merger agreement with NeuBase Therapeutics, Inc. on January 2, 2019 and which merger closed on July 12, 2019, and several of its current and former officers and directors, alleging that they violated federal securities laws between June 24, 2014 and January 4, 2018. On August 7, 2018, the lead plaintiffs, now George Lehman and Insured Benefit Plans, Inc. filed an amended complaint, alleging a putative class period of April 8, 2014 through January 4, 2018. The plaintiffs did not quantify any alleged damages in their complaint, but, in addition to attorneys' fees and costs, they seek to maintain the action as a class action and to recover damages on behalf of themselves and other persons who purchased or otherwise acquired Ohr common stock during the putative class period and purportedly suffered financial harm as a result. Ohr and the individuals dispute these claims and are defending the matter vigorously. On September 17, 2018, Ohr filed a motion to dismiss the complaint. On September 20, 2019, the district court issued an opinion and order granting the motion to dismiss. On October 23, 2019, the plaintiffs filed a notice of appeal of that order dismissing the action. After full briefing and oral argument, on October 9, 2020, the U.S. Court of Appeals for the Second Circuit issued a summary order affirming the district court's order granting the motion to dismiss and remanding the action to the district court to make a determination on the record related to plaintiffs' request for leave to file an amended complaint. On remand, the district court denied plaintiffs' subsequent request to amend and dismissed with prejudice plaintiffs' claims. On December 16, 2020, plaintiffs filed a notice of appeal of that order denying plaintiffs leave to amend. On December 16, 2021, the Second Circuit affirmed the decision and order of the district court denying plaintiffs' motion for leave to amend, thereby dismissing the appeal and action in its entirety. Plaintiffs have neither sought reconsideration of the Second Circuit's decision nor filed a writ of *certiorari* for review by the Supreme Court. This matter is now considered closed.

#### *Derivative Lawsuit*

On May 3, 2018, plaintiff Adele J. Barke, derivatively on behalf of Ohr, commenced an action against Michael Ferguson, Orin Hirschman, Thomas M. Riedhammer, June Almenoff and Jason Slakter in the Supreme Court, State of New York, alleging that the action was brought in the right and for the benefit of Ohr seeking to remedy their "breach of fiduciary duties, corporate waste and unjust enrichment that occurred between June 24, 2014 and the present." It does not quantify any alleged damages. On March 30, 2022, plaintiff filed a notice of voluntary dismissal of the complaint in this action. This matter is now considered closed.

*Joint Proxy Statement Lawsuit*

Following the issuance of the preliminary joint proxy statement/prospectus related to the merger of the Company and Ohr, on March 18, 2019, the Gomez Action was filed by an individual shareholder in the United States District Court for the Southern District of New York against Ohr and its board of directors. The plaintiff in the Gomez Action alleges that the preliminary joint proxy/prospectus statement filed by Ohr with the SEC on March 8, 2019 contained false and misleading statements and omitted material information in violation of Section 14(a) of the Exchange Act and SEC Rule 14a-9 promulgated thereunder, and further that the individual defendants are liable for those alleged misstatements and omissions under Section 20(a) of the Exchange Act. On March 19, 2019, the Barke Action was filed in the United States District Court for the Southern District of New York asserting similar Section 14(a) and Section 20(a) claims against Ohr's board of directors and additionally naming NeuBase and Ohr Acquisition Corp., but not Ohr, as defendants. On March 20, 2019, the Wheby Action was filed in the United States District Court for District of Delaware asserting similar claims under Section 14(a) and Section 20(a) and naming as defendants Ohr and its board of directors, NeuBase, and Ohr Acquisition Corp. On March 20, 2019, the Lowinger Action was filed in the Court of Chancery of the State of Delaware asserting a breach of fiduciary duty claim against Ohr's board of directors arising out of the same facts and circumstances regarding certain alleged omissions in the preliminary joint proxy/prospectus statement. On April 4, 2019, the Garaygordobil Action was filed in the United States District Court for the Southern District of New York asserting similar Section 14(a) and Section 20(a) claims against Ohr and its board of directors. Each of the Gomez, Barke, Garaygordobil, and Lowinger Actions have been dismissed, and on July 12, 2019, the Company and Ohr consummated the Merger. On March 23, 2022, plaintiffs in the Wheby Action filed a notice of voluntary dismissal of the complaint and this case was closed.

**ITEM 1A. RISK FACTORS**

We operate in a dynamic and rapidly changing environment that involves numerous risks and uncertainties. Certain factors may have a material adverse effect on our business, prospects, financial condition and results of operations, and you should carefully consider them. Accordingly, in evaluating our business, in addition to other information contained in this Quarterly Report on Form 10-Q, you should carefully consider the factors discussed under the caption "Risk Factors" that appear in Item 1A of our Annual Report on Form 10-K for the year ended September 30, 2021, filed with the U.S. Securities and Exchange Commission ("SEC") on December 23, 2021. Other events that we do not currently anticipate or that we currently deem immaterial may also affect our business, prospects, financial condition and results of operations. Other than the following disclosed risk factors, there have been no material changes from the risk factors previously disclosed in our Annual Report on Form 10-K for the year ended September 30, 2021.

**Risks Related to the Company**

*Management has determined that there are factors that raise substantial doubt about our ability to continue as a going concern.*

The accompanying unaudited condensed consolidated financial statements have been prepared assuming we will continue to operate as a going concern, which contemplates the realization of assets and settlement of liabilities in the normal course of business, and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classifications of liabilities that may result from uncertainty related to our ability to continue as a going concern. We have had no revenues from product sales and have incurred operating losses since inception. As of June 30, 2022, we had \$29.8 million in cash and cash equivalents and during the nine months ended June 30, 2022, we incurred a loss from operations of \$25.6 million and used \$22.4 million of cash in operating activities. Our existing balance of cash and cash equivalents may not be sufficient to enable us to fund our operations for at least the next twelve months from the date that this Quarterly Report is filed with the SEC. These factors raise substantial doubt about our ability to continue as a going concern within one year from the issuance date of this filing. Our ability to continue as a going concern is dependent on our ability to raise the required additional equity or debt financing to meet short and long-term operating requirements. We may also encounter business endeavors that require significant cash commitments or unanticipated problems or expenses that could result in a requirement for additional cash, including as a result of COVID-19 and its impacts. If we raise additional funds through the issuance of equity or convertible debt securities in the future, the percentage ownership of our current stockholders could be reduced, and such securities might have rights, preferences or privileges senior to our common stock. Additional financing may not be available upon acceptable terms, or at all. If adequate funds are not available or are not available on acceptable terms, we may not be able to take advantage of prospective business endeavors or opportunities, which could significantly and materially restrict our operations.

*If development of our candidates does not produce favorable results, we and our collaborators, if any, may be unable to commercialize these products.*

To receive regulatory approval for the commercialization of the PATrOL™ platform, or any product candidates that we may develop, adequate and well-controlled clinical trials must be conducted to demonstrate safety and efficacy in humans to the satisfaction of the FDA, the EMA and comparable foreign authorities. In order to support marketing approval, these agencies typically require successful results in one or more Phase III clinical trials, which our current product candidates have not yet reached and may never reach. The development process is expensive, can take many years and has an uncertain outcome. Failure can occur at any stage of the process. We may experience numerous unforeseen events during, or as a result of, the development process that could delay or prevent commercialization of our current or future product candidates, including the following:

- preclinical studies conducted with product candidates for potential clinical development to evaluate their toxicology, carcinogenicity and pharmacokinetics and optimize their formulation, among other things, may produce unfavorable results;
- patient recruitment and enrollment in clinical trials may be slower than we anticipate;
- clinical trials may produce negative or inconclusive results;
- costs of development may be greater than we anticipate;
- the potential advantages of the PATrOL™-enabled anti-gene drug candidates may not materialize and thus would confer no benefits to patients over other parties' products that may emerge;
- our product candidates or our PATrOL™ platform may cause undesirable side effects that delay or preclude regulatory approval or limit their commercial use or market acceptance, if approved;
- collaborators who may be responsible for the development of our product candidates may not devote sufficient resources to these clinical trials or other preclinical studies of these candidates or conduct them in a timely manner; or
- we may face delays in obtaining regulatory approvals to commence one or more clinical trials.

Additionally, because our technology potentially involves mutation silencing via genome binding and/or editing across multiple cell and tissue types, we are subject to many of the challenges and risks that advanced therapies, such as gene therapies, face, including:

- regulatory requirements governing gene and cell therapy products have changed frequently and may continue to change in the future;
- improper modification of a gene sequence in a patient's genome could lead to lymphoma, leukemia or other cancers, or other aberrantly functioning cells; and
- the FDA recommends a follow-up observation period of 15 years or longer for all patients who receive treatment using gene therapies, and we may need to adopt and support such an observation period for our product candidates.

Success in early development does not mean that later development will be successful because, for example, product candidates in later-stage clinical trials may fail to demonstrate sufficient safety and efficacy despite having progressed through initial clinical trials.

We may license or acquire intellectual property related to our product candidates from universities. Some of our preclinical studies and other analyses with respect to our product candidates may be performed by their original owners or collaborators. As a company, we have limited experience in conducting research on our platform technology and preclinical trials for our product candidates. Since our experience with our platform technology and product candidates is limited, we will need to train our existing personnel or hire additional personnel in order to successfully administer and manage our preclinical studies and clinical trials as anticipated, which may result in delays in completing such anticipated preclinical trials and clinical studies.



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We currently do not have strategic collaborations in place for clinical development of our platform technology and any of our current product candidates. Therefore, in the future, we or any potential future collaborative partner will be responsible for establishing the targeted endpoints and goals for development of our product candidates. These targeted endpoints and goals may be inadequate to demonstrate the safety and efficacy levels required for regulatory approvals. Even if we believe data collected during the development of our product candidates are promising, such data may not be sufficient to support marketing approval by the FDA, the EMA or comparable foreign authorities.

Further, data generated during development can be interpreted in different ways, and the FDA, the EMA or comparable foreign authorities may interpret such data in different ways than we or our collaborators. Our failure to adequately demonstrate the safety and efficacy of our platform technology and any of our product candidates would prevent our receipt of regulatory approval, and such failure would ultimately prevent the potential commercialization of these product candidates.

Since we do not currently possess the resources necessary to independently develop and commercialize our product candidates or any other product candidates that we may develop, we may seek to enter into collaborative agreements to assist in the development and potential future commercialization of some or all of these assets as a component of our strategic plan. Our discussions with potential collaborators, however, may not lead to the establishment of collaborations on acceptable terms, if at all, or it may take longer than expected to establish new collaborations, leading to development and potential commercialization delays, which would adversely affect our business, financial condition and results of operations.

***If we fail to comply with our obligations in the agreements under which we in-license intellectual property and other rights from third parties or otherwise experiences disruptions to our business relationships with our licensors, we could lose intellectual property rights that are important to our business.***

We may enter into license agreements with universities. A license agreement may impose various royalties, sublicensing fees and other obligations on us. If we fail to comply with our obligations under these agreements, or if we file for bankruptcy, we may be required to make certain payments to the Licensor, we may lose the exclusivity of our license, or the Licensor may have the right to terminate the license, in which event we would not be able to develop or market products covered by the license. Additionally, the royalties and other payments associated with these licenses could materially and adversely affect our business, financial condition and results of operations.

Pursuant to the terms of our license agreement with CMU (the “CMU License Agreement”), the Licensor has the right to terminate the CMU License Agreement with respect to the program licensed under certain circumstances, including, but not limited to: (i) if we do not pay amounts when due and within the applicable cure periods or (ii) if we file or have filed against us a petition in bankruptcy or make an assignment for the benefit of creditors. In the event the CMU License Agreement is terminated by the Licensor, all licenses (or, in the determination of the Licensor, the exclusivity of such licenses) granted to us by the Licensor will terminate immediately.

In some cases, patent prosecution of our licensed technology may be controlled solely by the licensor. If our licensor fails to obtain and maintain patent or other protection for the proprietary intellectual property we in-license, then we could lose our rights to the intellectual property or our exclusivity with respect to those rights, and our competitors could market competing products using the intellectual property. In certain cases, we may control the prosecution of patents resulting from licensed technology. In the event we breach any of our obligations related to such prosecution, we may incur significant liability to our licensing partners. Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues. Disputes may arise regarding intellectual property subject to a licensing agreement, including, but not limited to:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our collaborators; and

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- the priority of invention of patented technology.

If disputes over intellectual property and other rights that we have in-licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates. If we fail to comply with any such obligations to our licensor, such licensor may terminate their licenses to us, in which case we would not be able to market products covered by these licenses. The loss of our licenses would have a material adverse effect on our business, financial condition and results of operations.

***We may be required to pay royalties and sublicensing fees pursuant to university licensing agreements, which could adversely affect the overall profitability for us of any product candidates that we may seek to commercialize.***

If our sales are covered by a licensing agreement with a university, then we may be required to pay royalties on future worldwide net product sales and a percentage of sublicensing fees that we may earn. These royalty payments and sublicensing fees could adversely affect the overall profitability for us of any product candidates that we may seek to commercialize.

***We may infringe the intellectual property rights of others, which may prevent or delay our drug development efforts and prevent us from commercializing or increase the costs of commercializing our product candidates.***

Our commercial success depends significantly on our ability to operate without infringing the patents and other intellectual property rights of third parties. For example, there could be issued patents of which we are not aware that our current or potential future product candidates infringe.

As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that others may assert our product candidates infringe the patent rights of others. Moreover, it is not always clear to industry participants, including us, which patents cover various types of drugs, products or their methods of use or manufacture. Thus, because of the large number of patents issued and patent applications filed in our fields, there may be a risk that third parties may allege they have patent rights encompassing our product candidates, technologies or methods. Furthermore, because the nucleic acid therapeutics intellectual property landscape is still evolving and our product candidates have not been through clinical trials or commercialized, it is difficult to conclusively assess our freedom to operate without infringing third party rights. There are numerous companies that have pending patent applications and issued patents directed to certain aspects of nucleic acid therapeutics. We are aware of third-party competitors in the oligonucleotide therapeutics space, whose patent filings and/or issued patents may include claims directed to targets and/or products related to some of our programs. It is possible that at the time that we commercialize our products these third-party patent portfolios may include issued patent claims that cover our product candidates or critical features of their production or use. Our competitive position may suffer if patents issued to third parties or other third-party intellectual property rights cover, or may be alleged to cover, our product candidates or elements thereof, or methods of manufacture or use relevant to our development plans. In such cases, we may not be in a position to develop or commercialize product candidates unless we successfully pursue litigation to nullify or invalidate the third-party intellectual property right concerned or enter into a license agreement with the intellectual property right holder, if available on commercially reasonable terms.

Moreover, patent applications are in some cases maintained in secrecy until patents are issued. The publication of discoveries in the scientific or patent literature frequently occurs substantially later than the date on which the underlying discoveries were made and patent applications were filed. Because patents can take many years to issue, there may be currently pending applications of which we are unaware that may later result in issued patents that our product candidates or potential products infringe. For example, pending applications may exist that claim or can be amended to claim subject matter that our product candidates or potential products infringe. Competitors may file continuing patent applications claiming priority to already issued patents in the form of continuation, divisional, or continuation-in-part applications, in order to maintain the pendency of a patent family and attempt to cover our product candidates. We cannot be certain that others have not filed patent applications for technology covered by our issued patents or our pending applications, or that we were the first to invent the technology. Our competitors may have filed, and may in the future file, patent applications covering our products or technology similar to ours. Any such patent application may have priority over our patent applications or patents, which could require us to obtain rights to issued patents covering such technologies.

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Third parties may assert that we are employing their proprietary technology without authorization and may sue us for patent or other intellectual property infringement. These lawsuits are costly and could adversely affect our business, financial condition and results of operations and divert the attention of managerial and scientific personnel. If we are sued for patent infringement, we would need to demonstrate that our product candidates, potential products or methods either do not infringe the claims of the relevant patent or that the patent claims are invalid, and we may not be able to do this. Proving invalidity is difficult. For example, in the U.S., proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could have a material adverse effect on us. In addition, we may not have sufficient resources to bring these actions to a successful conclusion. If a court holds that any third-party patents are valid, enforceable and cover our products or their use, the holders of any of these patents may be able to block our ability to commercialize our products unless it acquires or obtains a license under the applicable patents or until the patents expire.

If a third party claims that we infringe its intellectual property rights, we may face a number of issues, including, but not limited to: infringement and other intellectual property claims which, regardless of merit, may be expensive and time-consuming to litigate and may divert our management's attention from our core business; substantial damages for infringement, which we may have to pay if a court decides that the product candidate or technology at issue infringes on or violates the third party's rights, and, if the court finds that the infringement was willful, we could be ordered to pay treble damages and the patent owner's attorneys' fees; a court prohibiting us from developing, manufacturing, marketing or selling our product candidates, or from using our proprietary technologies, unless the third party licenses its product rights to us, which it is not required to do; if a license is available from a third party, we may have to pay substantial royalties, upfront fees and other amounts, and/or grant cross-licenses to intellectual property rights for our products; and redesigning our product candidates or processes so they do not infringe, which may not be possible or may require substantial monetary expenditures and time.

We may choose to challenge the patentability of claims in a third party's U.S. patent by requesting that the USPTO review the patent claims in an *ex-parte* re-exam, *inter partes* review or post-grant review proceedings. These proceedings are expensive and may consume our time or other resources. We may choose to challenge a third party's patent in patent opposition proceedings in the EPO, or other foreign patent office. The costs of these opposition proceedings could be substantial and may consume our time or other resources. If we fail to obtain a favorable result at the USPTO, EPO or other patent office then we may be exposed to litigation by a third party alleging that the patent may be infringed by our product candidates or proprietary technologies.

We may not be able to enter into licensing arrangements or make other arrangements at a reasonable cost or on reasonable terms. Any inability to secure licenses or alternative technology could result in delays in the introduction of our product candidates or lead to prohibition of the manufacture or sale of products by us. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology or product candidate. In addition, in any such proceeding or litigation, we could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially and adversely affect our business, financial condition and results of operations. Any claims by third parties that we have misappropriated their confidential information or trade secrets could have a similar material and adverse effect on our business, financial condition and results of operations. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations.

Our product candidates may also require specific formulations to work effectively and efficiently. These formulations may be covered by intellectual property rights held by others. We may develop products containing our compounds and pre-existing pharmaceutical compounds. These pharmaceutical compounds may be covered by intellectual property rights held by others. We may be required by the FDA or comparable foreign regulatory authorities to provide a companion diagnostic test or tests with our product candidates. These diagnostic test or tests may be covered by intellectual property rights held by others. We may be unable to acquire or in-license any relevant third-party intellectual property rights that we identify as necessary or important to our business operations.

We, or our licensors, may not be able to detect infringement against our owned or in-licensed patents, as the case may be, which may be especially difficult for manufacturing processes or formulation patents. Even if we or our licensors detect infringement by a third party of our owned or in-licensed patents, we or our licensors, as the case may be, may choose not to pursue litigation against or settlement with the third party. If we, or our licensors, later sue such third party for patent infringement, the third party may have certain legal defenses available to it, which otherwise would not be available except for the delay between when the infringement was first detected and when the suit was brought. Such legal defenses may make it impossible for us or our licensors to enforce our owned or in-licensed patents, as the case may be, against such third party.

#### **Risks Related to Government Regulation**

***Preclinical and clinical trials are expensive, time-consuming and difficult to design and implement, and involve uncertain outcomes. Furthermore, results of earlier preclinical studies and clinical trials may not be predictive of results of future preclinical studies or clinical trials.***

All of our product candidates are still in the preclinical stage, and their risk of failure is high. Before we can commence clinical trials for a product candidate, we must complete extensive preclinical testing and studies that support our planned INDs in the U.S., or similar applications in other jurisdictions. We cannot be certain of the timely completion or outcome of our preclinical testing and studies and cannot predict if the FDA or other regulatory authorities will accept our proposed clinical programs or if the outcome of our preclinical testing and studies will ultimately support the further development of our programs. It is also possible that the FDA may require changes to our proposed clinical development programs. For example, our nonclinical studies for our DM1 program are using a proposed formulation of the NT-0200 development candidate that contains an excipient in quantities in excess of current FDA guidance. We believe that no additional nonclinical studies or modifications to the planned nonclinical toxicology studies related to the concentration of the excipient in the formulation will be needed to support clinical development. We cannot assure you that this will be the case, however. It is also impossible to predict when or if any of our product candidates will complete clinical trials evaluating their safety and effectiveness in humans or will receive regulatory approval. To obtain the requisite regulatory approvals to market and sell any of our product candidates, we must demonstrate through extensive preclinical studies and clinical trials that our PATrOL™ platform and product candidates are safe and effective in humans for use in each target indication. To date, we have never advanced a product candidate into a clinical trial. Preclinical and clinical testing is expensive and can take many years to complete, and the outcome is inherently uncertain. Failure can occur at any time during the preclinical or clinical trial process. Our preclinical programs may experience delays or may never advance to clinical trials, which would adversely affect our ability to obtain regulatory approvals or commercialize these programs on a timely basis or at all, which would have an adverse effect on our business, financial condition and results of operations.

Additionally, the results of preclinical studies and future clinical trials of product candidates may not be predictive of the results of later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy results despite having progressed through preclinical studies and initial clinical trials. Many companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials due to adverse safety profiles or lack of efficacy, notwithstanding promising results in earlier studies. Similarly, our future clinical trial results may not be successful for these or other reasons.

This product candidate development risk is heightened by any changes in the anticipated clinical trials compared to the completed clinical trials. As product candidates are developed from preclinical through early to late stage clinical trials towards approval and commercialization, it is customary that various aspects of the development program, such as manufacturing and methods of administration, are altered along the way in an effort to optimize processes and results. While these types of changes are common and are intended to optimize the product candidates for late stage clinical trials, approval and commercialization, such changes carry the risk that they will not achieve these intended objectives.

Any of these changes could make the results of our anticipated clinical trials or other future clinical trials we may initiate less predictable and could cause our product candidates to perform differently, including causing toxicities, which could delay completion of our clinical trials, delay approval of our product candidates, and/or jeopardize our ability to commence product sales and generate revenues.

**Risks Related to our Common Stock**

*If we are unable to continue to meet the standards for continued listing on the Nasdaq Capital Market, our common stock could potentially be delisted which could negatively impact the price of our common stock, liquidity and our ability to access the capital markets.*

The listing standards of the Nasdaq Capital Market provide that a company, in order to qualify for continued listing, must maintain a minimum stock price of \$1.00 and satisfy standards relative to minimum stockholders' equity, minimum market value of publicly held shares and various additional requirements. If we fail to comply with all listing standards applicable to issuers listed on the Nasdaq Capital Market, our common stock may be delisted. If our common stock is delisted, it could reduce the price of our common stock and the levels of liquidity available to our stockholders. In addition, the delisting of our common stock could materially adversely affect our access to the capital markets, and any limitation on liquidity or reduction in the price of our common stock could materially adversely affect our ability to raise capital. Delisting from the Nasdaq Capital Market could also result in other negative consequences, including the potential loss of confidence by suppliers, customers and employees, the loss of institutional investor interest and fewer business development opportunities.

**ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS**

Not applicable.

**ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

Not applicable.

**ITEM 4. MINE SAFETY DISCLOSURES**

Not applicable.

**ITEM 5. OTHER INFORMATION**

Not applicable.

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**ITEM 6. EXHIBITS**

Exhibit Number	Description	Incorporated by Reference			
		Form	File Number	Filing Date	Exhibit
2.1+	<a href="#">Agreement and Plan of Merger and Reorganization, dated as of January 2, 2019, by and among Ohr Pharmaceutical, Inc., Ohr Acquisition Corp. and NeuBase Therapeutics, Inc.</a>	8-K	001-35963	1/3/2019	2.1
2.2	<a href="#">First Amendment to the Agreement and Plan of Merger and Reorganization, dated as of June 27, 2019, by and among Ohr Pharmaceutical, Inc., Ohr Acquisition Corp. and NeuBase Therapeutics, Inc.</a>	8-K	001-35963	7/3/2019	2.1
3.1	<a href="#">Amended and Restated Certificate of Incorporation of the Company.</a>	8-K	001-35963	7/12/2019	3.1
3.2	<a href="#">Amended and Restated Bylaws of the Company.</a>	8-K	001-35963	9/23/2019	3.1
4.1	<a href="#">Form of Series A Warrant issued to investors pursuant to the Securities Purchase Agreement, dated December 7, 2016, by and among Ohr Pharmaceutical, Inc. and the purchasers listed therein.</a>	8-K	001-35963	12/8/2016	4.1
4.2	<a href="#">Form of Warrant issued to investors pursuant to the Securities Purchase Agreement, dated as of April 5, 2017, by and among Ohr Pharmaceutical, Inc. and the purchasers listed therein.</a>	8-K	001-35963	4/6/2017	4.1
4.3	<a href="#">Form of Common Stock Certificate.</a>	S-8	333-233346	8/16/2019	4.17
31.1*	<a href="#">Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a>				
31.2*	<a href="#">Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a>				
32.1**	<a href="#">Certification of Chief Executive Officer and Chief 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*	XBRL Instance Document.				
101.SCH*	XBRL Taxonomy Extension Schema Document.				
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document.				
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document.				
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document.				
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document.				

\* Filed herewith.

\*\* Furnished herewith.

+ All schedules and exhibits to the agreement have been omitted pursuant to Item 601(b)(2) of Regulation S-K. A copy of any omitted schedule and/or exhibit will be furnished to the SEC upon request.

**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.

Date: August 11, 2022

NeuBase Therapeutics, Inc.

/s/ Todd Branning

Todd Branning  
Chief Financial Officer

*(Principal Financial and Accounting Officer)*





**CERTIFICATION PURSUANT TO  
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,  
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Todd Branning, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of NeuBase Therapeutics, 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(s) 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 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; and
5. The registrant's other certifying officer(s) 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.

Date: August 11, 2022

By: \_\_\_\_\_  
/s/ Todd Branning  
Todd Branning  
Chief Financial Officer  
(Principal Financial and Accounting Officer)

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