#### UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington, DC 20549

#### Form 10-Q

#### (Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
 For the Quarterly Period Ended September 30, 2022

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from \_\_\_\_\_ to \_\_\_\_

Commission file number 001-37809

#### NeuroBo Pharmaceuticals, Inc.

(Exact name of Registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or organization)

200 Berkeley Street, Office 19<sup>th</sup> Floor Boston, Massachusetts

(Address of principal executive offices)

(IRS Employer Identification No.)

47-2389984

**02116** (Zip Code)

(857) 702-9600

(Registrant's telephone number, including area code)

Not Applicable

(Former name, former address and former fiscal year, if changed since last report)

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

Title of Each Class	Trading Symbol(s)	Name of Each Exchange On Which Registered
Common stock, \$0.001 par value	NRBO	The Nasdag 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  $\boxtimes$  No  $\square$ 

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  $\boxtimes$  No  $\square$ 

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  $\Box$ 

Non-accelerated filer  $\boxtimes$ 

Accelerated filer  $\square$ 

Smaller reporting company  $extsf{ }$ 

Emerging growth company  $\Box$ 

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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

The number of outstanding shares of the registrant's common stock, \$0.001 par value, as of November 11, 2022 was 6,503,528

#### NeuroBo Pharmaceuticals, Inc. FORM 10-Q INDEX

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#### PART I – FINANCIAL INFORMATION ITEM 1 – FINANCIAL STATEMENTS

#### NeuroBo Pharmaceuticals, Inc. Condensed Consolidated Balance Sheets (in thousands, except share amounts and par value)

	September 30, 2022 (unaudited)		D	ecember 31, 2021
Assets				
Current assets:				
Cash	\$	6,356	\$	16,387
Prepaid expenses		859		197
Deferred offering costs		339		—
Total current assets		7,554		16,584
Right-of-use assets and other				105
Property and equipment, net		3		110
Total assets	\$	7,557	\$	16,799
Liabilities and stockholders' equity			-	
Current liabilities:				
Accounts payable	\$	1,075	\$	830
Accrued liabilities		544		1,301
Lease liability, short-term				26
Total current liabilities		1,619		2,157
Lease liability, long-term				45
Total liabilities		1,619		2,202
Commitments and contingencies (Notes 4, 5, and 10)				
Stockholders' equity				
Preferred stock, \$0.001 par value per share; 10,000,000 shares authorized as of				
September 30, 2022 and December 31, 2021; no shares issued or outstanding				
as of September 30, 2022 and December 31, 2021.				
Common stock, \$0.001 par value per share, 100,000,000 shares authorized as				
of September 30, 2022 and December 31, 2021; 888,693 shares issued				
and outstanding as of September 30, 2022 and December 31, 2021.		1		1
Additional paid–in capital		97,056		96,420
Accumulated other comprehensive income		_		4
Accumulated deficit		(91,119)		(81,828)
Total stockholders' equity		5,938		14,597
Total liabilities and stockholders' equity	\$	7,557	\$	16,799

See accompanying notes to condensed consolidated financial statements.

#### NeuroBo Pharmaceuticals, Inc. Condensed Consolidated Statements of Operations and Comprehensive Loss (in thousands, except share and per share amounts) (unaudited)

	For the Three Months Ended September 30,			Fo	or the Nine I Septem	Months Ended ber 30.		
		2022		2021	2022			2021
Operating expenses:								<u> </u>
Research and development	\$	571	\$	1,394	\$	2,473	\$	4,549
General and administrative		2,533		2,070		6,725		6,171
Total operating expenses		3,104		3,464		9,198	_	10,720
Loss from operations		(3,104)		(3,464)		(9,198)		(10,720)
Interest income		_		3		_		14
Other expense		(9)				(93)		—
Loss before income taxes		(3,113)		(3,461)		(9,291)	_	(10,706)
Provision for income taxes		_		_		_		_
Net loss		(3,113)		(3,461)		(9,291)	_	(10,706)
Other comprehensive income (loss), net of tax				1		(4)		(10)
Comprehensive loss	\$	(3,113)	\$	(3,460)	\$	(9,295)	\$	(10,716)
Loss per share:					_		_	
Net loss per share, basic and diluted	\$	(3.50)	\$	(4.66)	\$	(10.45)	\$	(14.58)
Weighted average shares of common stock outstanding:								
Basic and diluted	8	388,693		742,810		888,693		734,500
			-		_		_	

See accompanying notes to condensed consolidated financial statements.

#### NeuroBo Pharmaceuticals, Inc. Condensed Consolidated Statements of Changes in Stockholders' Equity (in thousands, except share amounts) (unaudited)

	Common Stock		Additional Accumulated Paid–In Comprehensive			cumulated	Total	
	Shares		ount	Capital	Income		Deficit	Equity
Balance at December 31, 2020	655,662	\$	1	\$ 73,732 \$	14	\$	(66,544)	\$ 7,203
Issuance of common stock and warrants in connection								
with equity financing	83,338		—	10,000	_		_	10,000
Transaction costs in connection with equity financing	—		—	(908)	_		—	(908)
Stock–based compensation	_		—	187	_		_	187
Foreign currency translation adjustment	—		—	—	(7)			(7)
Net loss			_				(3,324)	(3,324)
Balance at March 31, 2021	739,000		1	83,011	7		(69,868)	13,151
Stock-based compensation	_		—	180	_		_	180
Exercise of stock options	3,810		—	72	_			72
Foreign currency translation adjustment	_		—	_	(4)		_	(4)
Net loss							(3,921)	(3,921)
Balance at June 30, 2021	742,810		1	83,263	3		(73,789)	9,478
Stock-based compensation			—	107	—			107
Foreign currency translation adjustment	_		—	—	1		_	1
Net loss							(3,461)	(3,461)
Balance at September 30, 2021	742,810	\$	1	\$ 83,370 \$	4	\$	(77,250)	\$ 6,125
Balance at December 31, 2021	888,693	\$	1	\$ 96,420 \$	4	\$	(81,828)	\$ 14,597
Stock–based compensation				207	_			207
Foreign currency translation adjustment	_		—	_	(1)			(1)
Net loss	_		—	—	_		(2,875)	(2,875)
Balance at March 31, 2022	888,693		1	96,627	3		(84,703)	11,928
Stock–based compensation			_	211	_			211
Foreign currency translation adjustment			_		(3)		_	(3)
Net loss	_		—	_	_		(3,303)	(3,303)
Balance at June 30, 2022	888,693		1	96,838	_		(88,006)	8,833
Stock–based compensation			_	218	_			218
Net loss			_	_	_		(3,113)	(3,113)
Balance at September 30, 2022	888,693	\$	1	\$ 97,056 \$		\$	(91,119)	\$ 5,938

See accompanying notes to condensed consolidated financial statements.

#### NeuroBo Pharmaceuticals, Inc. Condensed Consolidated Statements of Cash Flows (in thousands) (unaudited)

	For the Nine Months E September 30,						
	2022			2021			
Operating activities							
Net loss	\$	(9,291)	\$	(10,706)			
Adjustments to reconcile net loss to net cash used in operating activities:							
Stock-based compensation		636		474			
Non-cash lease expense		8		18			
Depreciation		19		36			
Loss on sale of property and equipment		75					
Change in assets and liabilities:							
Prepaid expenses and other assets		(627)		(219)			
Accounts payable		114		(1,646)			
Accrued and other liabilities		(839)		(192)			
Net cash used in operating activities		(9,905)		(12,235)			
Investing activities							
Purchases of property and equipment				(3)			
Sale of property and equipment		8					
Net cash provided by (used in) investing activities		8		(3)			
Financing activities							
Proceeds from equity offering		_		10,000			
Payment of issuance costs		(134)		(932)			
Exercise of stock options				72			
Net cash (used in) provided by financing activities		(134)		9,140			
Net decrease in cash		(10,031)		(3,098)			
Net foreign exchange difference		_		(7)			
Cash at beginning of period		16,387		10,089			
Cash at end of period	\$	6,356	\$	6,984			
Supplemental non-cash investing and financing transactions:							
Modification of right-of-use asset and associated lease liability	\$	62	\$				
Unpaid deferred issuance costs	\$	205	\$	25			

See accompanying notes to condensed consolidated financial statements.

#### 1. The Company and Basis of Presentation

NeuroBo Pharmaceuticals, Inc. (together with its subsidiaries, the "Company" or "NeuroBo"), is a clinical-stage biotechnology company with two primary programs focused on treatment of nonalcoholic steatohepatitis ("NASH") obesity, and type 2 diabetes ("T2D"):

- *DA-1241* is a novel G-Protein-Coupled Receptor 119 (GPR119) agonist with development optionality as a standalone and/or combination therapy for both NASH and T2D. We intend to initiate a Phase 2a study with the goal of establishing efficacy of DA-1241 in NASH and T2D.
- *DA-1726* is a novel oxyntomodulin ("OXM") analogue functioning as a GLP1R/GCGR dual agonist for the treatment of NASH and obesity, that is to be administered once weekly subcutaneously. DA-1726 as a dual agonist of GLP-1 receptors ("GLP1R") and glucagon receptors ("GCGR"), leading to weight loss through reduced appetite and increased energy expenditure. We intend to advance DA-1726 through Investigational New Drug application and initiation of human clinical trials.

The Company also has four therapeutics programs designed to impact a range of indications in viral, neurodegenerative and cardiometabolic disease:

- *ANA001*, which is a proprietary oral niclosamide formulation that is being developed as a treatment for patients with moderate coronavirus disease (COVID-19). Enrollment in the Phase 2 clinical trial of ANA001 for treatment of moderate COVID-19 in hospitalized patients was closed in July 2022 and the clinical trial moved to the data analysis phase. Following an analysis of the clinical trial data, which is expected in the fourth quarter of 2022, the Company will be able to begin discussions with the Food and Drug Administration regarding the next steps in the clinical development of ANA001 for treatment of COVID-19;
- *NB-01*, which was primarily focused on the development of a treatment for painful diabetic neuropathy (PDN). The Company is currently exploring alternatives with respect to the future of NB-01, including bringing the NB-01 asset to the market through a different regulatory pathway, such as with an orphan drug indication or as a nutraceutical;
- *NB-02*, which has the potential to treat the symptoms of cognitive impairment and modify the progression of neurodegenerative diseases associated with the malfunction of a protein called tau, and with amyloid beta plaque deposition. The Company has postponed continued work on the Investigation New Drug application to the FDA for NB-02 and the first human clinical trials for NB-02 until global health and macroeconomic conditions improve. The Company is also considering engaging with a strategic partner with respect to further development of NB-02; and
- *Gemcabene*, which is currently being assessed as an acute indication for COVID-19 in combination with ANA001. Gemcabene was previously focused on developing and commercializing therapies for the treatment of dyslipidemia, a serious medical condition that increases the risk of life-threatening cardiovascular disease, focused on orphan indications such as homozygous familial hypercholesterolemia, as well as NAFLD/NASH.

The Company's operations have consisted principally of performing research and development activities, clinical development and raising capital. The Company's activities are subject to significant risks and uncertainties, including failing to secure additional funding before sustainable revenues and profit from operations are achieved.

#### COVID-19

The global COVID-19 pandemic continues to present uncertainty and unforeseeable new risks to the Company's operations and business plan. The Company has closely monitored recent COVID-19 developments, including the lifting of COVID-19 safety measures, the drop in vaccination rates, the implementation of, and reaction to, vaccine mandates, the spread of new strains or variants of coronavirus (such as the Delta and Omicron variants), and supply chain and labor shortages. The Company is subject to risks and uncertainties as a result of the COVID-19 pandemic. The extent of the impact of the COVID-19 pandemic on the Company's business continues to be highly uncertain and difficult to predict, as the responses that the Company and other businesses and governments are taking continue to evolve. The Company continues to actively monitor the evolving effects of COVID-19 and the effects on the Company's business and operations.

To date, with the exception of the postponement of first human clinical trials for NB-02, the Company has not experienced any significant external changes in its business that would have a significant negative impact on its consolidated statements of operations or cash flows.

Exclusive of the development of certain of the Company's proposed therapies, the severity of the impact of the COVID-19 pandemic on the Company's business is dependent on a number of factors, including, but not limited to, the duration and severity of the pandemic and the extent and severity of the impact on the Company's service providers, suppliers, contract research organizations and the Company's clinical trials, all of which are uncertain and cannot be predicted. The economic effect of the COVID-19 pandemic combined with increased geopolitical uncertainty and rising inflation could result in a negative impact on the Company. As of the date of issuance of Company's financial statements, the extent to which the COVID-19 pandemic may in the future materially impact the Company's financial condition, liquidity or results of operations is uncertain.

#### War in Ukraine

The Company is subject to risks and uncertainties as a result of the war in Ukraine that commenced in February 2022. As the Company closed enrollment in its Phase 2 clinical trial for ANA001, it did not ultimately conduct a portion of the clinical trial in Poland and Ukraine.

#### Basis of presentation and consolidation principles

The accompanying condensed consolidated financial statements have been prepared by the Company pursuant to the rules and regulations of the Securities and Exchange Commission ("SEC"). Certain information and footnote disclosures normally included in annual financial statements prepared in accordance with U.S. generally accepted accounting principles ("GAAP") have been condensed or omitted pursuant to such rules and regulations. The condensed consolidated financial statements may not include all disclosures required by GAAP; however, the Company believes that the disclosures are adequate to make the information presented not misleading. These unaudited condensed consolidated financial statements should be read in conjunction with the audited financial statements and the notes thereto for the fiscal year ended December 31, 2021 included in the Company's Annual Report on Form 10-K filed with the SEC on March 31, 2022. The condensed consolidated balance sheet as of December 31, 2021 was derived from the audited financial statements.

In the opinion of management, all adjustments, consisting of only normal recurring adjustments that are necessary to present fairly the financial position, results of operations, and cash flows for the interim periods, have been made. The results of operations for the interim periods are not necessarily indicative of the operating results for the full fiscal year or any future periods.

The condensed consolidated financial statements of the Company include a South Korean subsidiary, NeuroBo



Co., LTD., which is fully owned by the Company. All significant intercompany accounts and transactions have been eliminated in the preparation of the financial statements.

#### **Reverse Stock Split**

The Company's Board of Directors approved a one-for-thirty reverse stock split of the Company's issued and outstanding shares of common stock (the "Reverse Stock Split"). The Reverse Stock Split become effective as of 5:00 p.m. Eastern Time on September 12, 2022.

All issued and outstanding common stock and per share amounts contained in the condensed consolidated financial statements have been retroactively adjusted to reflect this Reverse Stock Split for all periods presented. In addition, a proportionate adjustment was made to the per share exercise price and the number of shares issuable upon the exercise of all outstanding stock options and warrants to purchase shares of common stock. A proportionate adjustment was also made to the number of shares reserved for issuance pursuant to the Company's equity incentive compensation plans to reflect the Reverse Stock Split. Any fraction of a share of common stock that was created as a result of the Reverse Stock Split was rounded down to the next whole share and the stockholder received cash equal to the market value of the fractional share, determined by multiplying such fraction by the closing sales price of the Company's common stock as reported on Nasdaq on the last trading day before the Reverse Stock Split becomes effective (on a split-adjusted basis). The authorized shares and par value of the common stock and preferred stock were not adjusted as a result of the Reverse Stock Split.

#### Liquidity

The accompanying condensed consolidated financial statements have been prepared on the basis that the Company will continue as a going concern. From its inception, the Company has devoted substantially all of its efforts to drug discovery and development and conducting clinical trials. As of September 30, 2022, the Company had \$6.4 million in cash. The Company has experienced net losses and negative cash flows from operating activities since its inception and had an accumulated deficit of \$91.1 million as of September 30, 2022. The Company's net losses were \$3.1 million and \$3.5 million for the three months ended September 30, 2022 and 2021, respectively, and \$9.3 million and \$10.7 million for the nine months ended September 30, 2022 and 2021, respectively. These conditions previously raised substantial doubt about the Company's ability to continue as a going concern.

Subsequent to September 30, 2022, the Company raised aggregate gross proceeds of approximately \$32.3 million from the sale of common stock, preferred stock and warrants in a public offering and a private placement. Net proceeds from these sales are intended to be used for the development of DA-1241 and DA-1726 and for other general corporate purposes. Management believes that the Company, as a result of these cash flows received, has adequate liquidity to fund its operations without raising additional funds for at least twelve months from the date of issuance of these financial statements. The Company will need to continue to raise additional funds until it is able to generate sufficient revenues to fund its development activities. The Company's future operating activities, coupled with its plans to raise capital or issue debt financing, may provide additional liquidity in the future, however these actions are not solely within the control of the Company and the Company is unable to predict the ultimate outcome of these actions to generate the liquidity ultimately required.

#### 2. Summary of Significant Accounting Policies

#### 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, liabilities, expenses, and related disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements and the reported amounts of expenses during

the reporting period. The most significant estimates in the Company's condensed consolidated financial statements relate to accrued expenses and the fair value of stock-based compensation and warrant issuances. The Company bases its estimates on historical experience and on various other assumptions that are believed to be reasonable, the results of which form the basis for making judgements about the carrying values of assets and liabilities. Actual results could differ from those estimates. Changes in estimates are reflected in reported results in the period in which they become known.

#### General and Administrative Expenses

General and administrative expenses consist primarily of personnel-related costs, including salaries and stock-based compensation costs, for personnel in functions not directly associated with research and development activities. Other significant costs include legal fees related to intellectual property and corporate matters and professional fees for accounting and other services.

#### **Research and Development Costs**

Research and development costs are charged to expense as incurred. Research and development expenses are comprised of costs incurred in performing research and development activities, including clinical trial costs, manufacturing costs for both clinical and pre-clinical materials as well as other contracted services, license fees, and other external costs. Nonrefundable advance payments for goods and services that will be used in future research and development activities are expensed when the activity is performed or when the goods have been received, rather than when payment is made, in accordance with Accounting Standards Codification ("ASC") 730, *Research and Development*.

#### Stock-Based Compensation

The Company accounts for stock-based compensation in accordance with the provisions of ASC 718, *Compensation* — *Stock Compensation* ("ASC 718"). Accordingly, compensation costs related to equity instruments granted are recognized at the grant-date fair value. The Company records forfeitures when they occur. Stock-based compensation arrangements to non-employees are accounted for in accordance with the applicable provisions of ASC 718 using a fair value approach.

#### **Other Expense**

Other expense represents non-operating costs, including losses on the sale of property and equipment, and on translations of foreign currency, when incurred.

#### **Recent Accounting Pronouncements Not Yet Adopted**

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board ("FASB") or other standard setting bodies that are adopted by the Company as of the specified effective date. Unless otherwise discussed, the Company believes that the impact of recently issued standards that are not yet effective will not have a material impact on its consolidated financial position or results of operations upon adoption.

In June 2016, the FASB issued ASU 2016-13, "*Financial Instruments – Credit Losses*". The ASU sets forth a "current expected credit loss" (CECL) model which requires the Company to measure all expected credit losses for financial instruments held at the reporting date based on historical experience, current conditions, and reasonable supportable forecasts. This replaces the existing incurred loss model and is applicable to the measurement of credit losses on financial assets measured at amortized cost and applies to some off-balance sheet credit exposures. This ASU is effective for fiscal years beginning after December 15, 2022 for smaller reporting companies, including interim periods within those fiscal years, with early adoption permitted. The Company is currently assessing the impact of the adoption of this ASU on its condensed consolidated financial statements.

#### 3. Balance Sheet Detail

#### **Property and Equipment**

Property and equipment consist of the following as of:

	Septe	mber 30,	Dec	ember 31,
		2022		2021
Research and development equipment	\$	-	\$	158
Office equipment		30		63
Total property and equipment		30		221
Less accumulated depreciation		(27)		(111)
Property and equipment, net	\$	3	\$	110

During the nine months ended September 30, 2022, the Company sold its property and equipment in relation to its termination of its lease in Korea, as further described in Note 4, "*Commitments and Contingencies*" and recognized a loss on sale of \$75 included in other expense in the Company's condensed, consolidated statement of operations and comprehensive loss.

#### Accrued liabilities

Accrued liabilities consist of the following as of:

	September 30,	De	cember 31,		
	2022		2021		
External research and development expenses	\$ 356	\$	854		
Payroll related	—		376		
Professional services	94		59		
Other	94		12		
Total	\$ 544	\$	1,301		

#### 4. Commitments and Contingencies

#### **Operating Leases**

#### **Boston Lease**

On May 14, 2021, the Company entered into a non-cancelable operating lease for its corporate headquarters located in Boston Massachusetts. The agreement, effective August 1, 2021, had a six month term, and rental costs of approximately \$3 per month prior to the application of certain rent concessions granted by the landlord in the amount of approximately \$2 over the term of the lease. In December 2021, the Company signed an amendment to its corporate headquarters lease to extend the term until March 31, 2022 for rental costs of approximately \$1 per month. In February 2022, April 2022, and August, 2022. the Company signed amendments to extend the lease term until June 30, 2022, September 30, 2022, and December 31, 2022, respectively.

Prior to August 2021, the Company entered a non-cancelable operating lease for its corporate headquarters effective

February 1, 2021. The lease had a six-month term, and rental costs of approximately \$3 per month prior to the application of certain rent concessions granted by the landlord in the amount of approximately \$1 over the term of the lease. Prior to February 1, 2021, a non-cancelable operating lease was in effect as of February 1, 2020 which had a one-year term and rental costs of \$21 per month prior to the application of certain rent concessions granted by the landlord in the amount of \$32.

No assets and liabilities were recognized for the corporate headquarters leases at September 30, 2022 and December 31, 2021. Due to the short-term nature of the leases, the Company recognized lease payments as an expense on a straight-line basis over the remaining lease term. For the three months ended September 30, 2022 and 2021, expense under the corporate headquarters leases was in the aggregate \$3 and \$7, respectively. For the nine months ended September 30, 2022 and 2021, expense under the corporate headquarters leases was in the aggregate \$11 and \$41, respectively.

#### Lease in Korea

In May 2019, the Company entered an operating lease for its new facility in Korea (the "Korea Lease"). The initial lease term was five years with an option to renew for an additional five-year term. The lease commenced on July 2, 2019 and was to expire on July 1, 2024. On April 19, 2022, the Company terminated its Korea Lease effective April 30, 2022, at which time, the Company's unamortized right-of-use asset and lease liabilities were fully amortized and extinguished with no gain or loss.

The operating lease was subject to a deposit, base rent payments and additional charges for utilities and other common costs. The Company recorded non-cash expense related to the Korea Lease of \$8 and \$18 for the nine months ended September 30, 2022 and 2021, respectively. During the nine months ended September 30, 2022 and 2021, the Company made cash payments of \$11 and \$24 for amounts included in the measurement of lease liabilities.

#### ANA Merger Milestone Payments

On December 31, 2020, the Company acquired 100% of ANA Therapeutics, Inc., a Delaware corporation ("ANA"), pursuant to an Agreement and Plan of Merger, dated December 31, 2020 (the "2020 Merger Agreement" or "2020 Merger"). Pursuant to the 2020 Merger Agreement, following the closing of the 2020 Merger, the Company is obligated to pay milestone payments (each, a "Milestone Payment") to certain persons identified in the 2020 Merger Agreement (each a "Stakeholder" and collectively, the "Stakeholders") in the form, time and manner as set forth in the 2020 Merger Agreement, upon the achievement of the following milestone events set forth below by the Company or any of its affiliates (each, a "Milestone Event"):

Milestone Event	Milestone Payment
First receipt of Marketing Approval (as defined in the 2020 Merger Agreement) from	
the FDA for any Niclosamide Product (as defined in the 2020 Merger Agreement)	\$ 45.0 million

Sales Milestones:

#### Milestone Event - Worldwide Cumulative Net Sales of a Niclosamide Product

equal to or greater than:	Milestone Payment
\$500 million	\$ \$9.0 million
\$1 billion	\$ 13.5 million
\$3 billion	\$ 36.0 million
\$5 billion	\$ 72.0 million

Additionally, pursuant to the 2020 Merger Agreement, the Company is obligated to pay a royalty of two and a half percent (2.5%) of annual worldwide net sales of each Niclosamide Product (as defined in the 2020 Merger Agreement) (each such payment, a "Royalty Payment") to the Stakeholders in the form, time and manner as set forth in the 2020 Merger Agreement, following the first commercial sale of each Niclosamide Product (as defined in the 2020 Merger Agreement) on a country by-country and Niclosamide Product-by-Niclosamide Product basis.

As of September 30, 2022, no Royalty Payments had been accrued as there were no potential milestones yet considered probable.

#### YourChoice License Agreement

In connection with the 2020 Merger, the Company assumed the license agreement between ANA and Your Choice Therapeutics, Inc. (the "YourChoice Agreement"). Prior to the 2020 Merger, YourChoice Therapeutics, Inc. granted to ANA, during the term of the YourChoice Agreement, an exclusive, worldwide, fee-bearing license derived from the licensed intellectual property throughout the world. The fees due under the YourChoice Agreement include royalty payments of 0.5% of annual worldwide net sales of each Niclosamide Product (as defined in the 2020 Merger Agreement) and milestone payments in the aggregate of \$19.5 million. The first milestone payment due is \$5 million upon first receipt of Marketing Approval (as defined in the 2020 Merger Agreement) from the U.S. Food and Drug Administration ("FDA") for any Niclosamide Product (as defined by the 2020 Merger Agreement), followed by sales milestones of \$1 million, \$1.5 million, \$4 million, and \$8 million if worldwide cumulative net sales of a Niclosamide Product are equal to or greater than \$500 million, \$1, billion, \$3, billion, and \$5 billion, respectively. The term of the YourChoice Agreement will expire on the expiration or invalidation of the last of the licensed patents under the YourChoice Agreement. As of September 30, 2022, there was sufficient uncertainty with regard to both the outcome of the clinical trials and the ability to obtain sufficient funding to support any of the cash milestone payments under the YourChoice Agreement, and as such, no liabilities were recorded.

#### Gemphire Contingent Value Rights Agreement.

On December 30, 2019, the Company was party to a definitive merger agreement (the "2019 Merger") with Gemphire Therapeutics, Inc. ("Gemphire"). In connection with the 2019 Merger, Gemphire entered into the Contingent Value Rights Agreement (the "CVR Agreement") with Grand Rapids Holders' Representative, LLC, as representative of Gemphire's stockholders prior to the 2019 Merger (the "Holders' Representative"), and Computershare Inc. and Computershare Trust Company, N.A. as the rights agents (collectively, the "Rights Agent"). Under the CVR Agreement, which NeuroBo assumed in connection with the 2019 Merger, the holders of Gemphire shares at the time of the 2019 Merger (collectively, the "CVR Holders") were entitled to receive 80% of the proceeds from the grant, sale, or transfer of rights to Gemcabene.

On March 23, 2021, NeuroBo, the Holders' Representative, and the Rights Agent entered into the First Amendment to Contingent Value Rights Agreement (the "CVR Amendment") to amend the CVR Agreement. Pursuant to the CVR Amendment, (i) the CVR Holders will continue to have the right to receive 80% of the proceeds from the grant, sale, or transfer of rights to Gemcabene as a treatment for cardiovascular conditions and (ii) the CVR Holders will now also receive 10% of the proceeds from the grant, sale, or transfer of rights to Gemcabene as a treatment for any indication outside of treating cardiometabolic diseases, including COVID-19.

As of September 30, 2022, no obligations had been accrued as there were no potential payments under the CVR Agreement or the CVR Amendment that were yet considered probable.

#### **Pfizer License Agreement**

Upon the close of the 2019 Merger, an exclusive license agreement with Pfizer, Inc. ("Pfizer") for the clinical product candidate Gemcabene (the "Pfizer Agreement") was assumed by the Company. Under the Pfizer Agreement, in exchange for this worldwide exclusive right and license to certain patent rights to make, use, sell, offer for sale and import the clinical product Gemcabene, the Company has agreed to certain milestone and royalty payments on future sales.

The Company agreed to make milestone payments totaling up to \$37 million upon the achievement of certain milestones, including the first new drug application (or its foreign equivalent) in any country, regulatory approval in each of the United States, Europe and Japan, the first anniversary of the first regulatory approval in any country, and upon achieving

certain aggregate sales levels of Gemcabene. Future milestone payments under the Pfizer Agreement, if any, are not expected to begin for at least several years and extend over a number of subsequent years.

The Company also agreed to pay Pfizer tiered royalties on a country-by-country basis based upon the annual amount of net sales, as specified in the Pfizer Agreement, until the later of: (a) five (5) years after the first commercial sale in such country; (b) the expiration of all regulatory or data exclusivity for Gemcabene in such country; and (c) the expiration or abandonment of the last valid claim of the licensed patents, including any patent term extensions or supplemental protection certificates in such country (collectively, the "Royalty Term"). Under the Pfizer Agreement, the Company is obligated to use commercially reasonable efforts to develop and commercialize Gemcabene.

As of September 30, 2022, there was sufficient uncertainty with regard to both the outcome of the clinical trials and the ability to obtain sufficient funding to support any of the cash milestone payments, and as such, no liabilities were recorded related to the Pfizer Agreement.

#### Contingencies

From time to time, the Company may be subject to various claims and suits arising in the ordinary course of business. The Company does not expect that the resolution of these matters will have a material adverse effect on its financial position or results of operations.

#### 5. License and Collaboration Agreement

#### Beijing SL License and Collaboration Agreement

Upon the close of the 2019 Merger, the License and Collaboration Agreement (the "Beijing SL Agreement") with Beijing SL Pharmaceutical Co., Ltd. ("Beijing SL") was assumed by the Company, pursuant to which the Company granted Beijing SL an exclusive royalty-bearing license to research, develop, manufacture and commercialize pharmaceutical products comprising, as an active ingredient, Gemcabene in mainland China, Hong Kong, Macau and Taiwan. The terms of the Beijing SL Agreement include payments based upon achievement of milestones and royalties on net product sales. Under the Beijing SL Agreement, the Company has variable consideration in the form of milestone payments. As of September 30, 2022, no revenue under the Beijing SL Agreement has been recognized.

#### 6. Stockholders' Equity

#### Warrants

The following warrants were outstanding as of September 30, 2022 and December 31, 2021:

	Number o	f Warrants:			
Warrant Issuance	September 30, 2022	December 31, 2021	Exe	ercise Price	Expiration Date
March 2017	-	1,315	\$	7,800.00	March 2022
July 2018	48	48	\$	5,602.50	July 2028
April 2020	1,252	1,252	\$	375.00	April 2025
January 2021	83,338	83,338	\$	180.90	July 2026
October 2021	143,597	143,597	\$	112.50	April 2025
Total	228,235	229,550			

#### 7. Stock-based Compensation

Stock-based compensation expense was included in general and administrative costs as follows in the accompanying statements of comprehensive loss:

		Three Months Ended September 30,				Nine Mor	Ionths Ended		
						September 30,			
		2022	2021		2022			2021	
General and administrative	\$	218	\$	107	\$	636	\$	474	

#### Stock Options

In December 2019, in connection with the 2019 Merger, the Company assumed a previously adopted stock option plan (the "2018 Plan") and adopted the 2019 Equity Incentive Plan (the "2019 Plan"), and in November 2021, the Company adopted the 2021 Inducement Plan. The 2018 Plan, the 2019 Plan and the 2021 Inducement Plan provide for the grant of stock options, restricted stock and other equity awards of the Company's common stock to employees, officers, consultants, and directors. Options expire within a period of not more than ten years from the date of grant.

On May 11, 2022, the Company terminated the 2018 Plan. As of the date of termination, there were no outstanding awards under the 2018 Plan.

The following table summarizes the Company's activity related to its stock options for the nine months ended September 30, 2022:

	Number of Options	Weighted Average Exercise Price	Weighted- Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2021	32,498	\$ 119.72	9.3	\$ 
Granted	5,995	\$ 17.83	—	—
Exercised	-	\$ 	—	\$ 
Forfeited/Cancelled	(2,000)	\$ 181.20	—	_
Outstanding at September 30, 2022	36,493	\$ 99.62	8.8	\$ -
Vested and expected to vest at September				 
30, 2022	36,493	\$ 99.62	8.8	\$ -
Options exercisable at September 30, 2022	8,236	\$ 234.37	7.5	\$ -

During the nine months ended September 30, 2022, 5,995 stock options were granted to non-employee directors that vest over a period of one to three years. There were no stock options granted during the three months ended September 30, 2022. During the three and nine months ended September 30, 2021, there were 2,000 stock options granted to a non-employee director that vest over a three year period. The weighted average fair value per share of options granted during the nine months ended September 30, 2022 and during the three and nine months ended September 30, 2021 was \$12.43 and \$90.35, respectively.

The Company measures the fair value of stock options on the date of grant using the Black-Scholes option pricing model. The Company does not have history to support a calculation of volatility and expected term. As such, the Company has used a weighted-average volatility considering the volatilities of several guideline companies.

For purposes of identifying similar entities, the Company considered characteristics such as industry, length of trading history, and stage of life cycle. The assumed dividend yield was based on the Company's expectation of not paying dividends in the foreseeable future. The average expected life of the options was determined based on the mid-point between the vesting date and the end of the contractual term according to the "simplified method" as described in Staff Accounting Bulletin 110. The risk-free interest rate is determined by reference to implied yields available from U.S. Treasury securities with a remaining term equal to the expected life assumed at the date of grant. The Company records forfeitures when they occur.

The assumptions used in the Black-Scholes option-pricing model are as follows:

		Nine Months Ended September 30,		
	2022 2021			
Expected stock price volatility	80.7-85.2 %	79 %		
Expected life of options (years)	5.5-5.8	5.8		
Expected dividend yield	<u> </u>	%		
Risk free interest rate	1.72-3.08 %	0.9 %		

#### Evergreen provision

Under the 2019 Plan, the shares reserved automatically increase on January 1st of each year, for a period of not more than ten years commencing on January 1, 2020 and ending on (and including) January 1, 2029, to an amount equal to the lesser of (i) 4% of the common shares outstanding as of January 1<sup>st</sup>, or (ii) an amount as determined by the board of directors. The aggregate maximum number of shares of common stock that may be issued pursuant to the 2019 Plan under the evergreen provision is 222,666 shares of common stock. On January 1, 2022, 35,549 shares were added to the 2019 Plan as a result of the evergreen provision.

During the three months ended September 30, 2022 and 2021, 775 and 830 stock options vested, respectively. During the nine months ended September 30, 2022 and 2021, 2,351 and 2,500 stock options vested, respectively. During the three months ended September 30, 2022 and 2021, zero and 1,056 stock options were forfeited, respectively. During the nine months ended September 30, 2022 and 2021, 2,000 and 9,798 stock options were forfeited, respectively.

As of September 30, 2022, 180,527 shares in the aggregate were available for future issuance under the 2021 Inducement Plan, and the 2019 Plan. Unrecognized stock-based compensation cost for the stock options issued under all stock options plans was \$0.7 million as of September 30, 2022. The unrecognized stock-based expense is expected to be recognized over a weighted average period of 1.1 years.

#### 8. Net Loss Per Common Share

Basic net loss per share is computed by dividing the net loss by the weighted-average number of common shares outstanding for the period, without consideration for potentially dilutive securities if their effect is antidilutive. Diluted net loss per share is computed by dividing the net loss by the weighted average number of shares of common stock and dilutive common stock equivalents outstanding for the period determined using the treasury stock method. Dilutive common stock equivalents are comprised of options outstanding under the Company's stock option plans and warrants. For all periods presented, there is no difference in the number of shares used to calculate basic and diluted shares outstanding as inclusion of the potentially dilutive securities would be antidilutive.

The following potential common shares were not considered in the computation of diluted net loss per share as their effect would have been anti-dilutive:

	Three Mon	ths Ended	Nine Months Ended		
	Septem	oer 30,	September 30,		
	2022	2021	2022	2021	
Stock options	36,493	18,801	36,493	18,801	
Warrants	228,235	85,953	228,235	85,953	

#### 9. Income Taxes

The effective tax rate for the three and nine months ended September 30, 2022 and 2021 was zero percent. As a result of the analysis of all available evidence as of September 30, 2022 and December 31, 2021, the Company recorded a full valuation allowance on its net deferred tax assets. Consequently, the Company reported no income tax benefit for the three and nine months ended September 30, 2022 and 2021. If the Company's assumptions change and the Company believes that it will be able to realize these deferred tax assets, the tax benefits relating to any reversal of the valuation allowance on deferred tax assets will be recognized as a reduction of future income tax expense. If the assumptions do not change, each period the Company could record an additional valuation allowance on any increases in the deferred tax assets.

On December 27, 2020, the President of the United States signed the Consolidated Appropriations Act, 2021 ("Consolidated Appropriations Act") into law. The Consolidated Appropriations Act is intended to enhance and expand certain provisions of the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act"), allows for the deductions of expenses related to the Paycheck Protection Program funds received by companies, and provides an update to meals and entertainment expensing for 2021. The Consolidated Appropriations Act did not have a material impact to the Company's income tax provision.

#### **10. Related Party Transactions**

#### Manufacturing Agreement with Dong-A ST

On September 28, 2018, the Company entered into a five year manufacturing and supply agreement with Dong-A ST Co., Ltd. ("Dong-A") for manufacturing and supply of NB-01 drug substance and placebos for the purpose of research and development to be used in Phase 3 clinical trials (the "Manufacturing Agreement"). There were no manufacturing related costs under the Manufacturing Agreement for the three and nine months ended September 30, 2022 and 2021. The product manufacturing related costs, when incurred, are reflected as research and development expenses.

On June 7, 2020, the Company entered into a manufacturing and supply agreement (the "Manufacturing and Supply Agreement") with Dong-A ST for the manufacturing and supply of NB-02 drug product and placebo for the purpose of research and development of NB-02, including but not limited to, the use in the first NB-02 human clinical trial to be conducted by the Company. Under the terms of the Manufacturing and Supply Agreement, upon receipt of a purchase order from the Company no later than 270 days prior to the requested delivery date, Dong-A ST has agreed to produce for the Company tablets of the NB-02 drug substance and placebos at a specified supply price. The Company is obligated to manufacture, or have manufactured, and supply to Dong-A ST the active pharmaceutical ingredients which are necessary to manufacture the NB-02 drug product. The Manufacturing and Supply Agreement has a five year term, subject to earlier termination under certain circumstances. The Company recognized no product manufacturing related costs under the Manufacturing and Supply Agreement for during the three and nine months ended September 30, 2022 and 2021. None of the costs incurred under the Manufacturing Agreement remained unpaid as of September 30, 2022 or December 31, 2021.

#### License Agreement and Securities Purchase Agreement with Dong-A ST

On September 14, 2022, the Company and Dong-A entered an exclusive license agreement (the "License Agreement") pursuant to which, subject to the conditions set forth therein, the Company would receive an exclusive global license (other than in the Republic of Korea) to two proprietary compounds for specified indications. The License Agreement covers the rights to DA-1241 for treatment of NASH and DA-1726 for treatment of obesity and NASH. We may also develop DA-1241 for the treatment of T2D. The License Agreement became effective on November 8, 2022.

Under the terms of the License Agreement, (i), the Company agreed to pay Dong-A an upfront payment to be settled with 2,200 shares of a new series of preferred stock designated as "Series A Convertible Preferred Stock", par value \$0.001 per share (the "Series A Preferred Stock"), of the Company ,with a stated value of \$22,000,000, under the terms of a Securities Purchase Agreement) (as defined below) (the "Upfront License Payment"), which will be convertible into common stock upon the Company obtaining the Stockholder Approval (as defined below), which Upfront License Payment was issued in November 2022; (ii) Dong-A be eligible to receive single digit royalties on net sales received by the Company from the commercial sale of products covering DA-1241 or DA-1726; (iii) Dong-A is eligible to receive commercial-based milestone payments, dependent upon the achievement of specific commercial developments; and (iv) Dong-A is eligible to receive regulatory milestone payments of up to \$178 million for DA-1726 and \$138 million for DA-1241, dependent upon the achievement of specific regulatory developments.

The term of the License Agreement continues on a product-by-product and country-by country basis until the latest of (i) the fifth anniversary of the first commercial sale of such product in such country, (ii) the expiration or termination of the last valid patent claim that covers a product in such country and (iii) the loss of regulatory exclusivity for such product in such jurisdiction. Either Dong-A or the Company may terminate the License Agreement (a) if the other party is in material breach of the agreement and has not cured or started to cure the breach within 60 days of notice of such breach; provided that if the breach cannot be cured within the 60-day period and the breaching party started to remedy the breach, if such breach is not cured within 90 days of receipt of written notice or (b) if the other party is subject to a bankruptcy or insolvency event (subject to a 30-day cure period in the case of a petition for bankruptcy).

On September 14, 2022, in connection with the License Agreement, the Company entered into a Securities Purchase Agreement with Dong-A (the "Securities Purchase Agreement"). Pursuant to the Securities Purchase Agreement, upon the consummation of the License Agreement and a Qualified Financing (as defined below) the Company agreed to sell to Dong-A 1,500 shares of Series A Preferred Stock with a stated value of \$15 million, and a number of warrants to purchase shares of our common stock (the "Warrants") substantially equivalent to those issued to investors in respect of the Qualified Financing (the "Dong-A Financing"). The closing of the Dong-A Financing was contingent upon (i) our issuance and sale of common stock or other shares and instruments convertible into or exercisable for shares of our common stock to investors other than Dong-A resulting in gross proceeds of at least \$15 million (a "Qualified Financing"), (ii) delivery of lock-up agreements by all of our directors and officers and their affiliates and support agreements from certain stockholders agreeing to vote their shares of common stock in favor of the proposals to obtain the Stockholder Approval, and (iii) satisfaction or waiver of the other conditions described in the Securities Purchase Agreement. The stockholders party to the support agreements hold, in the aggregate, approximately 38% of the voting power of our common stock outstanding. In November 2022, the Company completed a Qualified Financing, which triggered Dong-A's obligation to purchase the shares under the Securities Purchase Agreement as further described in Note 11 below.

#### **11. Subsequent Events**

On November 8, 2022, the Company closed on an underwritten public offering (the "Public Offering") of units with gross proceeds of approximately \$17.3 million. The underwritten public offering was comprised of (1) 3,147,003 Class A Units, priced at a public offering price of \$3.00 per Class A Unit, with each Class A Unit consisting of one share of common stock, a Series A Warrant (the "Series A Warrants") to purchase one share of common stock at an exercise price of \$3.00 per share that expires on the one year anniversary following the initial exercise date and a Series B Warrant (the "Series B Warrants") to purchase one share of s3.00 per share that expires on the five year anniversary following the initial exercise date, and (2) 2,602,997 Class B Units, priced at a public offering price of \$3.00 per Class B Unit, with each Class B Unit consisting of one share of Series B Convertible Preferred Stock, convertible into one share of common stock, and one Series B Warrants. The Series A Warrants and the Series B Warrants will only be exercisable upon stockholder approval, and each will be exercisable on a cashless basis for one share of common stock. Subsequent to November 8, 2022, 2,467,832 shares of the Series B Convertible Preferred Stock were converted into 2,467,832 shares of common stock.

Pursuant to the Securities Purchase Agreement, the Company, in a concurrent private placement, sold \$15 million of its Series A Convertible Preferred Stock and warrants to purchase shares of common stock to Dong-A. The private placement is comprised of Series A Convertible Preferred Stock, which is convertible into shares of common stock at a price of \$3.00 per share, 5,000,000 Series A Warrants and 5,000,000 Series B Warrants.

The Public Offering is considered a Qualified Financing pursuant to the License Agreement discussed in Note 10. The License Agreement became effective on November 8, 2022, and the Company issued 2,200 shares of its Series A Convertible Preferred Stock to Dong-A as satisfaction of the Upfront License Payment.

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

The following discussion of our financial condition and results of operations should be read in conjunction with the condensed consolidated financial statements and related notes included elsewhere in this report and the audited financial statements and related notes for the fiscal year ended December 31, 2021 included in our Annual Report on Form 10-K ("2021 Form 10-K") filed by the Company with the SEC on March 31, 2022.

#### **Forward-Looking Statements**

Certain statements in this Quarterly Report on Form 10-Q are forward-looking statements within the meaning of the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended ("Exchange Act"), that are based on management's beliefs, assumptions and expectations and information currently available to management. All statements that address future operating performance, events or developments that we expect or anticipate will occur in the future are forward-looking statements, including without limitation, our expectations regarding the potential impacts of the COVID-19 pandemic on our business operations, cash flow, business development, and employees, our ability to execute on our strategic realignments, our clinical activities, benefits of our proposed products to patients, our expectations with respect to product development and commercialization efforts, potentially competitive product offerings, the possibility that we may be unable to raise sufficient funds necessary for our anticipated operations, intellectual property protection, our ability to integrate acquired assets, our expectations regarding anticipated synergies with and benefits from acquired assets and other risks and uncertainties described in our filings with the SEC.

In some cases, you can identify forward-looking statements by the following words: "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "ongoing," "plan," "potential," "predict," "project," "should," "will," "would" or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. Management believes that these forward-looking statements are reasonable as and when made. However, you should not place undue reliance on forward-looking statements because they speak only as of the date when made. We undertake no obligation to revise any forward-looking statements in order to reflect events or circumstances that might subsequently arise.

Forward-looking statements are subject to a number of risks and uncertainties that could cause actual events to adversely differ from the expectations indicated in these forward-looking statements, including without limitation, the risks and uncertainties described in our 2021 Form 10-K and in this Quarterly Report on Form 10-Q for the quarter ended September 30, 2022. We operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for us to predict all risk factors and uncertainties. We may not actually achieve the plans, projections or expectations disclosed in forward-looking statements, and actual results, developments or events could differ materially from those disclosed in the forward-looking statements. Forward-looking statements are subject to a number of risks and uncertainties, including without limitation, the possibility that regulatory authorities do not accept our application or approve the marketing of our products, the possibility we may be unable to raise the funds necessary for the development and commercialization of our products, and those described in our filings with the SEC.

#### Overview

NeuroBo Pharmaceuticals, Inc. (the "Company," "we," "us" or "our") is a clinical-stage biotechnology company with two primary programs focused on treatment of nonalcoholic steatohepatitis ("NASH"), obesity and type 2 diabetes ("T2D"):

• DA-1241 is a novel G-Protein-Coupled Receptor 119 (GPR119) agonist with development optionality as a standalone and/or combination therapy for both NASH and T2D. We intend to initiate a Phase 2a study with the goal of establishing efficacy of DA-1241 in NASH and T2D.

• DA-1726 is a novel oxyntomodulin ("OXM") analogue functioning as a GLP1R/GCGR dual agonist for the treatment of NASH and obesity, that is to be administered once weekly subcutaneously. DA-1726 as a dual agonist of GLP-1 receptors ("GLP1R") and glucagon receptors ("GCGR"), leading to weight loss through reduced appetite and increased energy expenditure. We intend to advance DA-1726 through Investigational New Drug application and initiation of human clinical trials.

We also have four therapeutics programs designed to impact a range of indications in viral, neurodegenerative and cardiometabolic disease:

- *ANA001*, which is a proprietary oral niclosamide formulation is being developed as a treatment for patients with moderate coronavirus disease (COVID-19). Enrollment in the Phase 2 clinical trial of ANA001 for treatment of moderate COVID-19 in hospitalized patients was closed in July 2022 and the clinical trial moved to the data analysis phase. Following an analysis of the clinical trial data, which is expected in the fourth quarter of 2022, we will be able to begin discussions with the Food and Drug Administration regarding the next steps in the clinical development of ANA001 for treatment of COVID-19;
- *NB-01*, which was primarily focused on the development of a treatment for painful diabetic neuropathy (PDN). We are currently exploring alternatives with respect to the future of NB-01, including bringing the NB-01 asset to the market through a different regulatory pathway, such as with an orphan drug indication or as a nutraceutical;
- *NB-02*, which has the potential to treat the symptoms of cognitive impairment and modify the progression of neurodegenerative diseases associated with the malfunction of a protein called tau, and with amyloid beta plaque deposition. We have postponed continued work on the Investigation New Drug application to the FDA for NB-02 and the first human clinical trials for NB-02 until global health and macroeconomic conditions improve. We are also considering engaging with a strategic partner with respect to further development of NB-02; and
- *Gemcabene*, which is currently being assessed as an acute indication for COVID-19 in combination with ANA001. Gemcabene was previously focused on developing and commercializing therapies for the treatment of dyslipidemia, a serious medical condition that increases the risk of life-threatening cardiovascular disease, focused on orphan indications such as homozygous familial hypercholesterolemia, as well as NAFLD/NASH.

For more information on our business and our product candidates, ANA001, NB-01, NB-02 and Gemcabene, see "Business-Overview" in Part I, Item 1 of our Annual Report on Form 10-K filed on March 31, 2022.

#### **Recent Developments**

#### License Agreement with Dong-A ST

On September 14, 2022, we entered an exclusive license agreement (the Dong-A License Agreement" with Dong-A ST Co., Ltd. ("Dong-A") pursuant to which, subject to the conditions set forth therein, we would receive an exclusive global license (other than in the Republic of Korea) to two proprietary compounds for specified indications. The License Agreement covers the rights to a compound referred to as DA-1241 for treatment of nonalcoholic steatohepatitis ("NASH") and a compound referred to as DA-1726 for treatment of obesity and NASH. We may also develop DA-1241 for the treatment of T2D. The License Agreement became effective on November 8, 2022.

Under the terms of the License Agreement, Dong-A (i) received an upfront payment with a stated value of \$22,000,000, which was settled in shares of a new series of preferred stock designated as "Series A Convertible Preferred Stock", par value \$0.001 per share (the "Series A Preferred Stock"), of the Company under the terms of the Securities

Purchase Agreement (as defined below) (the "Upfront *License Payment*"), which is convertible into common stock upon our obtaining the Stockholder Approval (as defined below); (ii) is eligible to receive single digit royalties on net sales received by us from the commercial sale of products covering DA-1241 or DA-1726; (iii) is eligible to receive commercial-based milestone payments, dependent upon the achievement of specific commercial developments; and (iv) is eligible to receive regulatory milestone payments of up to \$178 million for DA-1726 and \$138 million for DA-1241, dependent upon the achievement of specific regulatory developments.

The term of the License Agreement continues on a product-by-product and country-by-country basis until the latest of (i) the fifth anniversary of the first commercial sale of such product in such country, (ii) the expiration or termination of the last valid patent claim that covers a product in such country and (iii) the loss of regulatory exclusivity for such product in such jurisdiction. Either Dong-A or we may terminate the License Agreement (a) if the other party is in material breach of the agreement and has not cured or started to cure the breach within 60 days of notice of such breach; provided that if the breach cannot be cured within the 60-day period and the breaching party started to remedy the breach, if such breach is not cured within 90 days of receipt of written notice or (b) if the other party is subject to a bankruptcy or insolvency event (subject to a 30-day cure period in the case of a petition for bankruptcy).

On September 14, 2022, in connection with the License Agreement, we entered into a Securities Purchase Agreement with Dong-A (the "Securities Purchase Agreement"). Pursuant to the Securities Purchase Agreement, upon the consummation of the License Agreement and the Qualified Financing (as defined below), which occurred on November 8, 2022, (i) Dong-A received the Upfront License Payment and (ii) Dong-A purchased 5,000,000 shares of Series A Preferred Stock and warrants to purchase 10,000,000 shares of our common stock substantially equivalent to those issued to investors in respect of the Qualified Financing (the "Warrants") for a purchase price of \$15 million. (the "Dong-A Financing"). We are obligated to seek stockholder approval for the issuance of common stock underlying the Series A Preferred Stock.

#### **Public Offering**

On November 4, 2022, we entered into an Underwriting Agreement (the "Underwriting Agreement") with Ladenburg Thalmann & Co. Inc., as underwriter (the "Underwriter"), pursuant to which we agreed to issue and sell, in a firm commitment underwritten public offering by us (the "Public Offering"), (i) 2,397,003 Class A Units, consisting of (A) one share of common stock (the "Common Shares"), (B) one Series A Warrants ("Series A Warrants") to purchase one share of common stock, and (B) one Series B Warrant to purchase one shares of common stock ("Series B Warrants") and (ii) Class B Units, consisting of one share of Series B Convertible Preferred Stock (the "Preferred Shares") each convertible into one share of common stock, (B) one Series A Warrant and (c) one Series A Warrant (the Series A Warrants and Series B Warrants included in the Class A Units and the Series A Warrants and the Series B Warrants included in the Class B Units, collectively, the "Warrants"), priced at a public offering price of \$3.00 per Class A Unit or Class B Unit. In addition, pursuant to the Underwriting Agreement, we granted the Underwriter a 45-day option (the "Overallotment Option") to purchase up to (i) 750,000 additional Common Shares, (ii) 750,000 additional Series A Warrants and (iii) 750,000 additional Class B Warrants, solely to cover over-allotments. The Underwriter fully exercised the Overallotment Option on November 7, 2022. The securities we offered were pursuant to the Registration Statement on Form S-1 (File No. 333-267482), which was initially filed with the Securities and Exchange Commission (the "Commission") on September 16, 2022, amended on October 24, 2022, and November 3, 2022 and declared effective by the Commission on November 4, 2022.

On November 8, 2022, the Public Offering closed, and we issued and sold (i) 3,147,003 Class A Units which include 3,147,003 Common Shares, 3,147,003 Series A Warrants and 3,147,003 Series B Warrants and (ii) 2,692,997 Class B Units which include 2,692,007 share of Series B Convertible Preferred Stock, 2,692,997 Class A Warrants and 2,692,997 Class B Warrants. We received gross proceeds of approximately \$17.3 million. The exercise price for Series A Warrants and Series B Warrants was \$3.00 per share.

#### COVID-19

The global COVID-19 pandemic continues to present uncertainty and unforeseeable new risks to our operations and business plan. We have closely monitored recent COVID-19 developments, including the lifting of COVID-19 safety measures, the drop in vaccination rates, the implementation of, and reaction to, vaccine mandates, the spread of new strains or variants of coronavirus (such as the Delta and Omicron variants), and supply chain and labor shortages. We are subject to risks and uncertainties as a result of the COVID-19 pandemic. The extent of the impact of the COVID-19 pandemic on our business is highly uncertain and difficult to predict, as the responses that we, other businesses and governments are taking continue to evolve. We continue to actively monitor the evolving effects of COVID-19 and the effects on our business and operations.

To date, except for the adjustments to scientific activity described under "Current Scientific Activity" below, we have not experienced any external changes in our business that would have a significant negative impact on our condensed consolidated statements of operations and comprehensive loss or cash flows.

Exclusive of the development of certain of our proposed therapies, the severity of the impact of the COVID-19 pandemic on our business will depend on a number of factors, including, but not limited to, the duration and severity of the pandemic and the extent and severity of the impact on our service providers, suppliers, contract research organizations and our clinical trials, all of which are uncertain and cannot be predicted. The economic effect of the COVID-19 pandemic combined with increased geopolitical uncertainty and rising inflation could result in a negative impact on us. As of the date of issuance of our financial statements, the extent to which the COVID-19 pandemic may in the future materially impact our financial condition, liquidity or results of operations is uncertain.

#### **Current Scientific Activity**

Following consummation of the Dong-A License Agreement, we have two primary programs focused on treatment of NASH, obesity and T2D:

DA-1241 is a novel chemical drug candidate selectively activating G protein-coupled receptor 119 (GPR119) which has shown consistent target-related mechanisms and glucose-lowering effects from nonclinical studies to a Phase 1b exploratory clinical trials in patients with T2D in the US. GPR119 is known to be a regulator of both blood glucose and lipid levels. Non-clinical studies suggest DA-1241 selectively activates GPR119, thus stimulating the secretion of insulin and incretin hormones such as GLP-1, GIP, and PYY. Extensive non-clinical studies have shown DA-1241 has therapeutic potential for the reduction in hepatic steatosis, inflammation, fibrosis, improved lipid metabolism, and glucose control regardless of body weight reduction. Other preclinical tests have suggested these therapeutic effects are augmented when co-treated with other oral anti-diabetic agents such as metformin, SGLT2 inhibitors, and DPP4 inhibitors which are widely used for treating patients with T2D in the clinic. Moreover, impaired insulin action and lipid metabolism which are frequently observed in T2D patients are highly associated with the pathogenesis of steatosis and inflammation in NASH. In Phase 1a and 1b human trials DA-1241 was well tolerated in both healthy volunteers and those with T2D. We intend to initiate a Phase 2a study with the goal of establishing efficacy of DA-1241 in NASH and T2D.

**DA-1726** is a novel OXM analogue functioning as a GLP1R/GCGR dual agonist for the treatment of NASH and obesity. Activation of GLP-1R contributes to central anorexic effect (appetite suppression) and activation of GCGR peripherally enhances basal metabolic rate. Accordingly, non-clinical studies have shown DA-1726 not only reduces food intake but also increases energy expenditure even at the basal resting state, leading to persistent weight loss in diet-induced obese animals. In preclinical mice models administration of DA-1726 resulted in improved weight loss, as well as reduced hepatic steatosis, inflammation, and fibrosis compared to semaglutide as well as another OXM analogue in development. Having stabilized the fragile peptide through several unique modifications, DA-1726 is predicted to be available as a onceweekly regimen to humans. We intend to advance DA-1726 through Investigational New Drug application and initiation of human clinical trials.

Prior to consummation of the Dong-A License Agreement, we had four therapeutics programs designed to impact a range of indications in viral, neurodegenerative and cardiometabolic diseases. We are currently considering strategic alternatives for each of these programs.

**ANA001**, which was our lead drug candidate prior to the consummation of the License Agreement, is a proprietary oral niclosamide formulation and is being developed as a treatment for patients with moderate COVID-19. Niclosamide is a potential oral antiviral and anti-inflammatory agent with a long history of use and well-understood safety in humans. Enrollment in the Phase 2 clinical trial of ANA001 for treatment of moderate COVID-19 in hospitalized patients was closed in July 2022 and the clinical trial moved to the data analysis phase. Our determination to close enrollment related in part to the challenges and delays caused by a decreased number of eligible subjects and a changing COVID-19 environment, which was due to a number of factors including, the high prevalence of COVID-19 immunity (through vaccination or previous infection), availability of alternate treatments, and decreased COVID-19 hospitalizations which in turn greatly limits the number of eligible subjects needed for the clinical trial data and achieve the objective of the study, which was determining the safety and tolerability of ANA001 for treatment of COVID-19. Following an analysis of the clinical trial data, which is expected in the fourth quarter of 2022, we will be able to begin discussions with the Food and Drug Administration regarding the next steps in the clinical development of ANA001 for treatment of COVID-19.

*NB-01*. We have determined to cease development of NB-01 on the prior regulatory pathway and not to advance to Phase 3 clinical trials.

We are currently evaluating various alternatives regarding the NB-01 asset. These alternatives include two potential development pathways.

- Orphan drug. Development of NB-01 as an orphan drug is among the alternatives we are considering.
- Nutraceutical. We have considered marketing NB-01 as a nutraceutical (non-pharmaceutical) product, and we may re-explore this pathway if the identified rare disease indication for NB-01 does not proceed.

*NB-02.* In order to preserve operating capital, we have postponed continued work on the Investigation New Drug application to the FDA for NB-02 and the first human clinical trials for NB-02 until global health and macroeconomic conditions improve. We are also considering engaging with a strategic partner with respect to further development of NB-02.

*Gemcabene*. We are currently exploring additional therapeutic indications for Gemcabene that may strengthen our pipeline of assets, this includes COVID-19 in combination with ANA001.

#### **Results of Operations**

The following table summarizes our operating results for the periods indicated:

	For the T	Three Months	Ended	For th	e Nine Months	Ended	
	September 30,			September 30,			
	2022	2021	Change	2022	2021	Change	
			(in t	housands)			
Operating expenses:							
Research and development	\$ 571	\$ 1,394	\$ (823)	\$ 2,473	\$ 4,549	\$ (2,076)	
General and administrative	2,533	2,070	463	6,725	6,171	554	
Total operating expenses	3,104	3,464	(360)	9,198	10,720	(1,522)	
Loss from operations	(3,104)	(3,464)	360	(9,198)	(10,720)	1,522	
Interest income		3	(3)	—	14	(14)	
Other expense, net	(9)		(9)	(93)		(93)	
Loss before income taxes	(3,113)	(3,461)	348	(9,291)	(10,706)	1,415	
Provision for income taxes							
Net loss	\$ (3,113)	\$ (3,461)	\$ 348	\$ (9,291)	\$ (10,706)	\$ 1,415	

#### Comparison of Three Months Ended September 30, 2022 and 2021

#### Research and Development Expenses

Research and development expenses consist primarily of costs incurred in connection with the development of our product candidates. We expense research and development costs to operations as incurred.

Research and development expenses were approximately \$0.6 million for the three months ended September 30, 2022 as compared to approximately \$1.4 million for the three months ended September 30, 2021. The approximate \$0.8 million decrease was primarily related to reduced clinical trial activity and drug manufacturing costs of approximately \$0.5 million as enrollment in our ANA 001 clinical trial slowed, and reduced payroll and consulting costs of approximately \$0.3 million.

#### General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related costs, including stock-based compensation, for personnel in executive, finance and administrative functions. General and administrative expenses also include direct and allocated facility-related costs as well as professional fees for legal, patent, consulting, investor and public relations, accounting, and audit services.

General and administrative expenses were approximately \$2.5 million for the three months ended September 30, 2022, compared to approximately \$2.1 million for the three months ended September 30, 2021. The increase of approximately \$0.5 million in the current period was primarily due to an increase in legal and professional fees of approximately \$0.6 million, partly related to exploration of business opportunities, an increase in stock-based compensation of \$0.1 million, offset by a decrease in insurance costs of approximately \$0.1 million, and decreases in payroll, professional fee and overhead costs in the aggregate of approximately \$0.1 million.

#### Interest Income

Interest income for the three months ended September 30, 2022 was nominal. Interest income for the three months ended September 30, 2021 was approximately \$3,000.

#### Other Expense

Other Expense for the three months ended September 30, 2022 was \$9,000 primarily from a loss on a foreign currency translation. Other Expense for the three months ended September 30, 2021 was nominal.

#### Comparison of Nine Months Ended September 30, 2022 and 2021

#### Research and Development Expenses

Research and development expenses were approximately \$2.4 million for the nine months ended September 30, 2022 as compared to approximately \$4.5 million for the nine months ended September 30, 2021. The approximate \$2.1 million decrease was primarily related to reduced clinical trial activity and drug manufacturing costs of approximately \$1.3 as enrollment for our ANA 001 clinical trial slowed and reduced payroll, consulting and overhead costs of approximately \$0.8 million.

#### General and Administrative Expenses

General and administrative expenses were approximately \$6.7 million for the nine months ended September 30, 2022, compared to approximately \$6.2 million for the nine months ended September 30, 2021. The increase of approximately \$0.5 million in the current period was primarily due to an increase in legal and professional fees of approximately \$1.0 million, partly related to the exploration of business opportunities, offset by a decrease in insurance costs of approximately \$0.3 million, and decreases in payroll, professional fees and overhead costs in the aggregate of approximately \$0.2 million.

#### Interest Income

Interest income for the nine months ended September 30, 2022 was nominal. Interest income for the nine months ended September 30, 2021 was approximately \$14,000.

#### Other Expense

During the nine months ended September 30, 2022, we recorded approximately \$0.1 million of other expense primarily related to the loss on sale of fixed assets and losses on translations of foreign currency. Other Expense for the nine months ended September 30, 2021 was nominal.

#### Liquidity and Capital Resources

#### Cash Flows

The following table summarizes our cash flows for the periods indicated:

		For the Nine Months Ended September 30,		
		2022 2021 (in thousands)		2021
				inds)
Net cash used in operating activities	\$	(9,905)	\$	(12,235)
Net cash provided by (used in) investing activities		8		(3)
Net cash (used in) provided by financing activities		(134)		9,140
Net decrease in cash	\$	(10,031)	\$	(3,098)

#### **Operating Activities**

During the nine months ended September 30, 2022, cash used from operating activities was approximately \$9.9 million, consisting of our net loss of approximately \$9.3 million, changes in working capital cash usage in the amount of approximately \$1.3 million, offset by non-cash expenses related primarily to stock-based compensation of approximately \$0.7 million. The change in working capital consisted primarily of increases in our prepaid expenses due to the annual renewal of our insurance policies in January 2022 as well as due to decreases in our accrued liabilities associated with fluctuations of our operating expenses under the normal course of business.

During the nine months ended September 30, 2021, cash used in operating activities was approximately \$12.2 million which consisted of our net loss of approximately \$10.7 million, changes in working capital cash usage in the amount of approximately \$2.0 million, offset by non-cash expenses related primarily to stock-based compensation of approximately \$0.5 million.

#### **Investing Activities**

Cash provided by investing activities was approximately \$8,000 during the nine months ended September 30, 2022 related to the sale of equipment. Cash used in investing activities during the nine months ended September 30, 2021 was approximately \$3,000 related to the purchase of equipment.

#### Financing Activities

Cash used in financing activities was \$0.1 million related to costs associated with obtaining a Qualified Financing. During the nine months ended September 30, 2021, net cash provided by financing activities was approximately \$9.1 million, consisting primarily of net proceeds from a private placement financing of approximately \$9.1 million, and approximately \$72,000 in proceeds received from the exercise of stock options.

#### **Funding Requirements**

We have incurred significant operating losses since inception. Our ability to generate product revenue sufficient to achieve profitability will depend on the successful development and eventual commercialization of one or more of our current or future product candidates. To date, we have not generated any revenue from product sales, collaborations with other companies, government grants or any other source, and do not expect to generate any revenue in the foreseeable future, and have been dependent on funding operations through the sale of equity securities.

As of September 30, 2022, we had an accumulated deficit of \$91.1 million. Our net losses were \$3.1 million and \$3.5 million for the three months ended September 30, 2022 and 2021, respectively, and \$9.3 million and \$10.7 million for the nine months ended September 30, 2022 and 2021, respectively. We expect to continue to incur significant expenses and increasing operating losses for at least the next several years. We expect that our expenses and capital requirements will increase substantially in connection with our ongoing activities, particularly if and as we:

- pursue clinical development for any of our current product candidates;
- initiate preclinical studies and clinical trials with respect to any additional indications for our current product candidates and any future product candidates that we may pursue;
- acquire or in-license other product candidates and/or technologies;
- develop, maintain, expand and protect our intellectual property portfolio;
- hire additional clinical, scientific and commercial personnel;
- establish a commercial manufacturing source and secure supply chain capacity sufficient to provide commercial quantities of any product candidates for which we may obtain regulatory approval;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;

- establish a sales, marketing and distribution infrastructure and/or enter into partnership arrangements to commercialize any products for which we may obtain regulatory approval; or
- add administrative, operational, financial and management information systems and personnel, including
  personnel to support our product development and planned future commercialization efforts, and to support
  our being a public reporting company

As of September 30, 2022, we had cash of \$6.4 million. Subsequent to September 30, 2022, we have raised aggregate gross proceeds of approximately \$32.3 million from the sale of our common stock, preferred stock and warrants in a public offering and a private placement transaction. Net proceeds from these sales are intended to be used for the development of DA-1241 and DA-1726 and for other general corporate purposes. We expect that our cash will be adequate to fund operations for at least 12 months following the issuance of the financial statements contained in this Quarterly Report. We will need to continue to raise additional funds until it is able to generate sufficient revenues to fund its development activities. Our future operating activities, coupled with its plans to raise capital or issue debt financing, may provide additional liquidity in the future, however these actions are not solely within our control and we are unable to predict the ultimate outcome of these actions to generate the liquidity ultimately required

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

Our financial statements are prepared in accordance with GAAP. These accounting principles require us to make estimates and judgments that can affect the reported amounts of assets and liabilities as of the date of the financial statements as well as the reported amounts of revenue and expense during the periods presented. We believe that the estimates and judgments upon which we rely are reasonably based upon information available to us at the time that we make these estimates and judgments. To the extent that there are material differences between these estimates and actual results, our financial results will be affected. The accounting policies that reflect our more significant estimates and judgments are described in "Management's Discussion and Analysis of Financial Condition and Results of Operations", included in our 2021 Form 10-K filed on March 31, 2022.

During the three and nine months ended September 30, 2022, there were no material changes to our critical accounting policies or estimates disclosed in "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in our 2021 Form 10-K filed on March 31, 2022.

#### **Recent Accounting Pronouncements**

Refer to Note 2— *Summary of Significant Accounting Policies* to our condensed consolidated financial statements included elsewhere in this report for a discussion of recently issued accounting pronouncements.

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

Not applicable.

#### ITEM 4. CONTROLS AND PROCEDURES

#### **Evaluation of Disclosure Controls and Procedures**

We maintain disclosure controls and procedures that are designed to ensure that information we are required to disclose in our Exchange Act reports 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 our management, including our principal executive and financial officer, as appropriate to allow timely decisions regarding required disclosure.

We designed and evaluate our disclosure controls and procedures recognizing that any controls and procedures,



no matter how well designed and operated, can provide only reasonable assurance and not absolute assurance of achieving the desired control objectives. Also, the design of a control system must reflect the fact that there are resource constraints and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. The design of any system of controls is based, in part, upon certain assumptions about the likelihood of future events and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.

Under the supervision of and with the participation of our management, including our principal executive and financial officer, we evaluated the effectiveness of our disclosure controls and procedures, as such term is defined in Rules 13a-15(e) and 15(d)- 15(e) promulgated under the Exchange Act as of September 30, 2022. Based on this evaluation, our principal executive and financial officer concluded that our disclosure controls and procedures were not effective as of September 30, 2022 as a result of the material weaknesses described below and previously reported in our 2021 Form 10-K.

In connection with the preparation of the financial statements included in our 2021 Form 10-K, management identified material weaknesses resulting from a lack of segregation of duties over financial reporting, and logical access over computer applications. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. Specifically, there was a lack of segregation of duties involved in the execution of wire transfers, preparing journal entries, and review over clinical trial accruals, and certain individuals in the accounting department have administrative access to the financial reporting systems. See "Remediation Efforts to Address the Material Weaknesses" below for steps we are taking to correct these material weaknesses.

#### **Changes in Internal Control Over Financial Reporting**

Except as provided below under "Remediation Efforts to Address Material Weaknesses," there were no changes in our internal control over financial reporting (as defined in Rule 13a-15(f) or 15d-15(f) under the Exchange Act) during the quarter ended September 30, 2022, that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

#### **Remediation Efforts to Address Material Weaknesses**

We are in the process of remediating, but have not yet remediated, the material weaknesses described above. Under the oversight of the audit committee, management is developing a detailed plan and timetable for the implementation of appropriate remedial measures to address the material weaknesses. As of the date of this quarterly report, we have taken the following actions and are in the process of making the following changes in our internal control environment to help remediate the material weaknesses:

- we will enhance the controls over wire disbursements, separating the functions of initiating and wiring to two separate individuals;
- we have improved processes in the area of clinical site expense monitoring, including increasing communication between our accounting and clinical personnel, as well as with our clinical vendors;
- we will implement enhanced controls relative to the review and oversight of the accounting for clinical trial expenses and the review of journal entries.
- we will restrict administrator rights to only those individuals who require access.

Management may decide to take additional measures to remediate the material weaknesses as necessary.

#### PART II — OTHER INFORMATION

#### ITEM 1. LEGAL PROCEEDINGS

From time to time, we may be involved in various claims and legal proceedings relating to claims arising out of our operations. We are not currently a party to any legal proceedings that, in the opinion of our management, are likely to have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

#### ITEM 1A. RISK FACTORS

Our business, results of operations, and financial condition are subject to various risks and uncertainties, including those described in Part I, Item 1A: Risk Factors in our 2021 Form 10-K. The following risk factors are being provided to supplement and update the risk factors set forth in our 2021 Form 10-K.

#### **Risks Related to the Business**

# We are initially developing DA-1241 for the treatment of NASH, an indication for which there are no approved products. This makes it difficult to predict the timing and costs of the clinical development of DA-1241 and, if applicable, DA-1726, for the treatment of NASH.

Our research and development efforts are focused in part on developing DA-1241 for the treatment of NASH, an indication for which there are no approved products. The regulatory approval process for novel product candidates such as DA-1241 for NASH can be more expensive and take longer than for other, better known or extensively studied product candidates. As other companies are in later stages of clinical trials for their potential NASH therapies, we expect that the path for regulatory approval for NASH therapies may continue to evolve in the near term as these other companies refine their regulatory approval strategies and interact with regulatory authorities. Such evolution may impact our future clinical trial designs, including trial size and endpoints, in ways that we cannot predict today. Our anticipated development costs would likely increase if development of DA-1241 or any future product candidate is delayed because we are required by the FDA to perform studies or trials in addition to, or different from, those that we currently anticipate. Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to predict the timing or amount of any increase in our anticipated development costs.

#### We may be required to make significant payments under the 2022 License Agreement.

We have acquired exclusive global rights (other than in the Republic of Korea) to DA-1241 and DA-1726 for the specific indications provided in the 2022 License Agreement. Under the 2022 License Agreement, in consideration for the license, we made an upfront payment of \$22.0 million in Series A Convertible Preferred Stock. As additional consideration for the license, we are required to pay Dong-A milestone payments upon the achievement of specified regulatory milestones and milestone payments upon the achievement of specified commercial milestones. Commencing on the first commercial sale of licensed products, we are obligated to pay royalties of single-digit percentages on annual net sales of the products covered by the license. If milestone or other non-royalty obligations become due, we may not have sufficient funds available to meet our obligations, which will materially adversely affect our business operations and financial condition.

## We may not be able to successfully obtain regulatory or marketing approval for, or successfully commercialize, any of our product candidates.

Although we currently have no drug product for sale and may never be able to develop marketable drug products, our business depends heavily on the successful clinical development (for our pharmaceutical drug products), regulatory approval and commercialization of our drug candidates.



The clinical trials of our product candidates are, and the manufacturing and marketing of our product candidates will be, subject to extensive and rigorous review and regulation by government authorities in the United States and in other countries where we intend to test and, if approved, market any product candidate. Before obtaining regulatory approvals for the commercial sale of any product candidate as a pharmaceutical product, we must successfully meet a number of critical developmental milestones, including:

- developing dosages that will be well-tolerated, safe and effective;
- completing the development and scale-up to permit manufacture of our product candidates in commercial quantities and at acceptable costs;
- demonstrating through pivotal clinical trials that the product candidate is safe and effective in patients for the intended indication;
- establishing commercial manufacturing capabilities or making arrangements with third-party manufacturers; and
- obtaining and maintaining exclusive rights, including patent and trade secret protection and non- patent exclusivity for our product candidates.

The time necessary to achieve these developmental milestones for any individual product candidate is long and uncertain, and we may not successfully complete these milestones for any product candidates that we may develop.

We are continuing to test and develop our product candidates and may explore possible design or formulation changes to address safety, efficacy, manufacturing efficiency and performance issues to the extent any arise. The design of a clinical trial may be able to determine whether its results will support approval of a product, and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced or completed. There is no assurance that we will be able to design and complete a clinical trial to support marketing approval. Moreover, nonclinical and clinical data are often susceptible to multiple interpretations and analyses. A number of companies in the pharmaceutical and biotechnology industries have experienced significant setbacks in advanced clinical trials, even after promising results in earlier trials.

We may not be able to complete development of any product candidates that demonstrate safety and efficacy and that will have a commercially reasonable treatment and storage period. If the 2022 License Agreement is consummated and we are unable to complete development of DA-1241 and DA-1726 or any other product candidates that we may develop, we will not be able to commercialize and earn revenue from them.

# The regulatory review and approval processes of the FDA and comparable foreign regulatory authorities are lengthy, time-consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.

Of the large number of drugs in development in the United States, only a small percentage receive FDA regulatory approval and are commercialized in the United States. We would not be permitted to market DA-1241, DA-1726, or any other product candidate as a pharmaceutical drug in the United States until we receive approval of an NDA from the FDA, or in any foreign countries until we receive the requisite approval from such countries or jurisdictions, such as the marketing authorization application, or MAA, in the European Union from the European Medicines Agency, or EMA.

Successfully completing clinical trials and obtaining approval of an NDA is a complex, lengthy, expensive and uncertain process, and the FDA, or a comparable foreign regulatory authority, may delay, limit or deny approval of an NDA for many reasons, including, among others:

• disagreement with the design or implementation of our clinical trials;



- disagreement with the sufficiency of our clinical trials;
- failure to demonstrate the safety and efficacy of the product candidate for the proposed indications;
- failure to demonstrate that any clinical and other benefits of the product candidate outweigh their safety risks;
- a negative interpretation of the data from our nonclinical studies or clinical trials;
- deficiencies in the manufacturing or control processes or failure of third-party manufacturing facilities with which our contracts for clinical and commercial supplies to comply with current Good Manufacturing Practice requirements, or cGMPs;
- deficiencies in the harvesting and processing of botanical raw materials under Good Agricultural and Collection Processes, or GACPs, or the inability to demonstrate that the final product is capable of being therapeutically consistent, as applicable to botanical drug products, as applicable;
- insufficient data collected from clinical trials or changes in the approval requirements that render our nonclinical and clinical data insufficient to support the filing of an NDA or to obtain regulatory approval; or
- changes in clinical practice in or approved products available for the treatment of the target patient population that could have an impact on the indications that we are pursuing for our product candidates.

The FDA or a comparable foreign regulatory authority may also require more information, including additional nonclinical or clinical data, to support approval, which may delay or prevent approval and our commercialization plans, or cause us to abandon the development program. Even if we obtain regulatory approval, our product candidates may be approved for fewer or more limited indications than we request, such approval may be contingent on the performance of costly post-marketing clinical trials, or we may not be allowed to include the labeling claims necessary or desirable for the successful commercialization of such product candidate.

## We may develop DA-1241 and DA-1726, and potentially future product candidates, in combination with other therapies, which exposes us to additional risks.

We may develop DA-1241 and DA-1726 and future product candidates in combination with one or more currently approved therapies. Even if any product candidate we develop were to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA or similar regulatory authorities outside of the United States could revoke approval of the therapy used in combination with our product candidate or that safety, efficacy, manufacturing or supply issues could arise with these existing therapies. This could result in our own products being removed from the market or being less successful commercially.

We may also evaluate DA-1241 and DA-1726 or any other future product candidates in combination with one or more other therapies that have not yet been approved for marketing by the FDA or similar regulatory authorities outside of the United States. We will not be able to market and sell DA-1241 and DA-1726 or any product candidate we develop in combination with any such unapproved therapies that do not ultimately obtain marketing approval. If the FDA or similar regulatory authorities outside of the United States do not approve these other drugs or revoke their approval of, or if safety, efficacy, manufacturing, or supply issues arise with, the drugs we choose to evaluate in combination with DA-1241 and DA-1726 or any other product candidate we develop, we may be unable to obtain approval of or market DA-1241 and DA-1726 or any other product candidate we develop.



#### Enrollment and retention of patients in clinical trials is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside our control, including difficulties in identifying patients with NASH and significant competition for recruiting such patients in clinical trials.

Identifying and qualifying patients to participate in our clinical trials is critical to our success. We may encounter delays in enrolling, or be unable to enroll, a sufficient number of patients to complete any of our clinical trials, and even once enrolled we may be unable to retain a sufficient number of patients to complete any of our trials. In particular, as a result of the inherent difficulties in diagnosing NASH and the significant competition for recruiting patients with NASH in clinical trials, there may be delays in enrolling the patients we need to complete clinical trials on a timely basis, or at all. This risk may be more significant for us than other companies conducting clinical trials for the treatment of patients with NASH because we plan to enroll only patients with a biopsy-confirmed diagnosis of NASH in our planned clinical trials.

Factors that may generally affect patient enrollment include:

- the size and nature of the patient population;
- the number and location of clinical sites we enroll;
- competition with other companies for clinical sites or patients;
- the eligibility and exclusion criteria for the trial;
- the design of the clinical trial;
- inability to obtain and maintain patient consents;
- risk that enrolled participants will drop out before completion; and
- competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating.

In addition, if any significant adverse events or other side effects are observed in any of our future clinical trials, it may make it more difficult for us to recruit patients to our clinical trials and patients may drop out of our trials, or we may be required to abandon the trials or our development efforts of one or more product candidates altogether. Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays, which would increase our costs and have an adverse effect on our company.

## We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.

The development and commercialization of new products is highly competitive. Our future success depends on our ability to demonstrate and maintain a competitive advantage with respect to the development and commercialization of our product candidates. Our objective is to develop and commercialize new products with superior efficacy, convenience, tolerability and safety. In many cases, the products that we commercialize will compete with existing, market-leading products.

Many of our potential competitors have significantly greater financial, manufacturing, marketing, drug development, technical and human resources than we do. Large pharmaceutical companies, in particular, have extensive experience in clinical testing, obtaining regulatory approvals, recruiting patients and in manufacturing pharmaceutical products. In particular, these companies have greater experience and expertise in securing government contracts and grants to support their research and development efforts, conducting testing and clinical trials, obtaining regulatory

approvals to market products, manufacturing such products on a broad scale and marketing approved products. These companies also have significantly greater research and marketing capabilities than we do and may also have products that have been approved or are in late stages of development, and have collaborative arrangements in our target markets with leading companies and research institutions. Established pharmaceutical companies may also invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make the product that we develop obsolete. As a result of all of these factors, our competitors may succeed in obtaining patent protection and/or FDA approval or discovering, developing and commercializing products before, or more effectively than, we do. In addition, any new product that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to overcome price competition and to be commercially successful. If we are not able to compete effectively against potential competitors, our business will not grow and our financial condition and operations will suffer.

To the extent any of our product candidates are approved for cardio-metabolic indications, particularly obesity, the commercial success of our products will also depend on our ability to demonstrate benefits over the then-prevailing standard of care, including diet and exercise. Finally, morbidly obese patients sometimes undergo the gastric bypass procedure, with salutary effects on the many co-morbid conditions of obesity. Some of these programs have been advanced further in clinical development then our clinical programs or have already received regulatory approval.

#### T2D

There are a number of large pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of products for T2D. Some of these competitive products and therapies are based on scientific approaches that are the same as or similar to our approach and others are based on entirely different approaches. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

#### NASH

There are currently no medications approved for the treatment of NASH. However, various therapeutics are used off-label for the treatment of NASH, including vitamin E (an antioxidant), insulin sensitizers (e.g., metformin, pioglitazone), antihyperlipidemic agents (e.g., gemfibrozil), pentoxifylline and ursodeoxycholic acid (UDCA). There are several product candidates in Phase 3 or earlier clinical or preclinical development for the treatment of NASH, including Madrigal Pharmaceuticals, Inc.'s THR beta agonist (resmetirom),

Novo Nordisk's GLP1 agonist (semaglutide), and Inventiva's pan-PPAR agonist (lanifibranor), as well as FXR agonists from Intercept Pharmaceuticals Inc. (obeticholic acid), Novartis AG (tropifexor, nidufexor), Metacrine (MET409, MET642), Terns Pharmaceuticals (TERN-101), Gilead Sciences, Inc. (cilofexor) and Enanta Pharmaceuticals, Inc. (EDP-305).

#### Obesity

Due to the growing overweight and obesity epidemic and consumer demand, there are many competitors in the field of obesity treatment. Obesity treatments range from behavioral modification, to drugs and medical devices, and surgery, generally as a last resort. If DA-1726 were approved for obesity, our primary competition in the obesity treatment market would currently be from approved and marketed products, including, liragluitde (SAXENDA<sup>®</sup>), semaglutide (WEGOVY<sup>®</sup>), phentermine/topiramate (QSYMIA<sup>®</sup>), naltrexone/bupropion (CONTRAVE<sup>®</sup>) and orlistat (XENICAL<sup>®</sup>/ ALLI<sup>®</sup>). Further competition could arise from products currently in development, including Lilly's GLP-1/GIP receptor dual agonist (tierzepatide), Novo Nordisk's CagriSema (a combination drug of semaglutide and a novel amylin analogue), Zafgen's ZGN- 1061 or ZGN-1258 (MetAP2) product candidates and various FGF21 ligands in development.

#### ANA001

We expect that, if approved, ANA001 will compete with a number of drugs that are being studied for the treatment of symptoms of COVID-19. In addition to widely distributed vaccines designed to stop the spread of COVID-19, which could adversely affect the addressable population for ANA001, several antiviral therapies are currently approved by the FDA for the treatment of COVID-19 (remdesivir [VEKLURY<sup>®</sup>], nirmatrelvir/ritonavir [PAXLOVID<sup>™</sup>] and molnupiravir), and several antibody treatments have received emergency use authorization from the FDA (sotrovimab, bebtelovimab, casirivimab/imdevimab [REGEN-COV<sup>®</sup>], tixagevimab/cilgavimab [EVUSHELD<sup>™</sup>] and bamlanivimab/etesevimab). We are aware due to the rapidly changing mutations that some of the EUA approved therapies have been restricted in many states according to the drug's susceptibility to the local variant outbreak. Additional therapies continue to be studied in clinical trials for the treatment of COVID-19.

In addition to the marketed therapies, we are aware of several companies currently developing and commercializing niclosamide for the treatment of COVID-19 symptoms, including Daewoong, Union Therapeutics, TFF and FirstWave. Approved therapies and additional therapies that may be approved in the near term could significantly and adversely affect the market opportunity for ANA001.

#### NB-01 and NB-02

There are a number of large pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of products for the treatment of painful diabetic neuropathy and for the symptomatic and disease modifying treatment of neurodegenerative diseases, including Alzheimer's disease and tauopathies. Some of these competitive products and therapies are based on scientific approaches that are the same as or similar to our approach and others are based on entirely different approaches. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

NB-01 has been in clinical development for the treatment of painful diabetic neuropathy. We are also developing NB-02 for the symptomatic and disease modifying treatment of neurodegenerative diseases, including Alzheimer's disease and tauopathies. For painful diabetic neuropathy, there are no products currently marketed for disease modification, although there are products available to treat painful diabetic neuropathy. For Alzheimer's disease, current symptomatic treatments have limited effectiveness and no disease- modifying therapy is currently available. Some of the currently approved drug therapies are branded and subject to patent protection, and others are available on a generic basis. Many of these approved drugs are well- established therapies and are widely accepted by physicians, patients and third-party payors. Insurers and other third-party payors may also encourage the use of generic products.

#### **Risks Relating to Our Common Stock and Ownership**

## If we receive stockholder approval for the conversion of the Series A Preferred Stock to common stock, Dong-A will have a significant interest in and may control us, and its interests may conflict with ours or yours in the future.

If we receive stockholder approval for conversion of the Series A Convertible Preferred Stock to common stock, Dong-A will have a significant interest in and may own more than 50% of our outstanding common stock. In addition, pursuant to the Investor Rights Agreement between us and Dong-A, if this offering is consummated and we receive stockholder approval, Dong-A will have the right to appoint a number of our directors commensurate with its percentage holding of our common stock, which may result in Dong-A controlling both the determinations of the Board of Directors and the vote of all matters submitted to a vote of our shareholders, which enables them to control all corporate decisions. This concentration of ownership may delay, deter or prevent acts that would be favored by our other shareholders. The interests of Dong-A may not always coincide with our interests or the interests of our other shareholders. For as long as Dong-A owns shares of our common stock and the Investor Rights Agreement is effective,

Dong-A will have significant influence with respect to our management, business plans and policies, including the appointment and removal of our officers, decisions on whether to raise future capital and amending our charter and bylaws, which govern the rights attached to our common stock. In particular, if Dong-A owns a significant percentage of our stock, the Principal Shareholders will be able to cause or prevent a change of control of us or a change in the composition of our Board and could preclude any unsolicited acquisition of us. The concentration of ownership could deprive you of an opportunity to receive a premium for your shares of common stock as part of a sale of us and ultimately might affect the market price of our common stock. In addition, this concentration of ownership may adversely affect the trading price of our common stock because investors may perceive disadvantages in owning shares in a company with significant stockholders.

Dong-A and its affiliates engage in a broad spectrum of activities, including investments in the healthcare industry generally. In the ordinary course of its business activities, Dong-A and its affiliates may engage in activities where their interests conflict with our interests or those of our other shareholders, such as investing in or advising businesses that directly or indirectly compete with certain portions of our business or are suppliers or customers of ours. Our certificate of incorporation provides that neither Dong-A or any of their affiliates or any director who is not employed by us (including any non-employee director who serves as one of our officers in both her or his director and officer capacities) or its affiliates have any duty to refrain from engaging, directly or indirectly, in the same business activities or similar business activities or lines of business in which we operate. Dong-A also may pursue acquisition opportunities that may be complementary to our business, and, as a result, those acquisition opportunities may not be available to us. In addition, Dong-A may have an interest in pursuing acquisitions, divestitures and other transactions that, in their judgment, could enhance its investment, even though such transactions might involve risks to you.

# If we receive stockholder approval for conversion of the Series A Convertible Preferred Stock to common stock, we may be a "controlled company" within the meaning of the Nasdaq listing rules and may follow certain exemptions from certain corporate governance requirements that could adversely affect our public shareholders.

If we receive stockholder approval for conversion of the Series A Convertible Preferred Stock to common stock, Dong-A may own more than 50% of our outstanding common stock. In that case, we would meet the definition of a "controlled company" under the corporate governance standards for Nasdaq listed companies and for so long as we remain a "controlled company" under this definition, we would be eligible to utilize certain exemptions from the corporate governance requirements of Nasdaq, including the requirements (i) that a majority of the Board consist of independent directors, (ii) to have a governance committee that is composed entirely of independent directors with a written charter addressing the committee's purpose and responsibilities, (iii) to have a compensation committee that is composed entirely of independent directors with a written charter addressing the committee's purpose and responsibilities, (iv) that the compensation committee consider certain independence factors when engaging legal counsel and other committee advisors and (v) for an annual performance evaluation of the governance and compensation committees. Although we do not intend to rely on the "controlled company" exemptions under the Nasdaq listing rules even if we are deemed a "controlled company," we could elect to rely on these exemptions in the future. If we were to elect to rely on the "controlled company" exemptions, a majority of the members of the Board might not be independent directors and our nominating and corporate governance and compensation committees might not consist entirely of independent directors. Accordingly, if we rely on the exemptions, during the period we remain a *controlled company* and during any transition period following a time when we are no longer a controlled company, you would not have the same protections afforded to shareholders of companies that are subject to all of the corporate governance requirements of Nasdaq.

## The terms of the Series B Convertible Preferred Stock and the warrants could impede our ability to enter into certain transactions or obtain additional financing.

The terms of the Series B Convertible Preferred Stock issued in the Public Offering and the Series A Warrants and Series B Warrants require us, upon the consummation of any "fundamental transaction" (as defined in the

securities), to, among other obligations, cause any successor entity resulting from the fundamental transaction to assume all of our obligations under the Series B Convertible Preferred Stock and the Series A Warrants and Series B Warrants and the associated transaction documents. In addition, holders of Series B Convertible Preferred Stock and the Series A Warrants and Series B Warrants are entitled to participate in any fundamental transaction on an as-converted or as-exercised basis, which could result in the holders of our common stock receiving a lesser portion of the consideration from a fundamental transaction. The terms of the Series B Convertible Preferred Stock and the Series B Warrants could also impede our ability to enter into certain transactions or obtain additional financing in the future.

#### We may be required to repurchase certain of our warrants.

Under the terms of Series A Warrants and Series B Warrants, in the event of certain "Fundamental Transactions" (as defined in the related warrant agreement, which generally includes any merger with another entity, the sale, transfer or other disposition of all or substantially all of our assets to another entity, or the acquisition by a person of more than 50% of our common stock), each warrant holder will have the right at any time prior to the consummation of the Fundamental Transaction to require us to repurchase the warrant for a purchase price in cash equal to the Black Scholes value (as calculated under the warrant agreement) of the then remaining unexercised portion of such warrant on the date of such Fundamental Transaction, which may materially adversely affect our financial condition and/or results of operations and may prevent or deter a third party from acquiring us.

## The Series A Warrants and Series B Warrants may be exercised on a "cashless" basis for shares of common stock on a one-for-one basis.

If any outstanding warrants to purchase shares of our common stock are exercised, there would be further dilution. In addition, following the receipt of the Warrant Stockholder Approval, the Series A Warrants and Series B Warrants can be exercised on a "cashless" basis for shares of common stock on a one-for-one basis, regardless of whether the market price of our common stock is above the exercise price, which may result in additional dilution and no additional proceeds to us in connection with such exercises.

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

None.

#### ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

#### ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

#### ITEM 5. OTHER INFORMATION

Not applicable

#### ITEM 6. EXHIBITS

EXHIBIT NUMBER	DESCRIPTION OF DOCUMENT
3.1	Third Amended and Restated Certificate of Incorporation of Registrant (incorporated by reference to
5.1	Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed on August 10, 2016).
3.2	<u>Certificate of Amendment (Reverse Stock Split) to the Third Amended and Restated Certificate of</u>
5.2	Incorporation of the Company (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on
	Form 8-K, filed on December 31, 2019).
3.3	Certificate of Amendment (Name Change) to the Third Amended and Restated Certificate of Incorporation
	of the Company (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K, filed on December 31, 2019).
3.4	Second Amended and Restated Bylaws of Registrant (incorporated by reference to Exhibit 3.4 to the
	Registrant's Annual Report on Form 10-K, filed on March 30, 2020).
3.5	<u>Certificate of Amendment to Certificate of Incorporation of NeuroBo Pharmaceuticals, Inc. (incorporated by</u>
	reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed on September 12, 2022).
3.6	Amendment to Second Amended and Restated Bylaws of NeuroBo Pharmaceuticals, Inc. (incorporated by
	reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed on November 4, 2022).
3.7	<u>Certificate of Designation of Preferences, Rights and Limitations, filed with the Delaware Secretary of State</u>
5.7	on November 4, 2022, with respect to the Series A Convertible Preferred Stock (incorporated by reference to
	Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed on November 8, 2022).
3.8	<u>Certificate of Designation of Preferences, Rights and Limitations, filed with the Delaware Secretary of State</u>
5.0	on November 4, 2022, with respect to the Series B Convertible Preferred Stock (incorporated by reference to
	Exhibit 3.2 to the Registrant's Current Report on Form 8-K, filed on November 8, 2022).
4.1	Form of Series A Warrant to purchase shares of common stock (incorporated by reference to Exhibit 4.1 to
4.1	the Registrant's Current Report on Form 8-K, filed on November 8, 2022).
4.2	Form of Series B Warrant to purchase shares of common stock (incorporated by reference to Exhibit 4.2 to
4.2	the Registrant's Current Report on Form 8-K, filed on November 8, 2022).
4.3	Warrant Agency Agreement (incorporated by reference to Exhibit 4.3 to the Registrant's Current Report on
4.5	Form 8-K, filed on November 8, 2022).
4.4	Form of Dong-A Series A Warrant to purchase shares of common stock (incorporated by reference to Exhibit
4.4	4.4 to the Registrant's Current Report on Form 8-K, filed on November 8, 2022),
4.5	Form of Dong-A Series B Warrant to purchase shares of common stock (incorporated by reference to Exhibit
4.5	4.5 to the Registrant's Current Report on Form 8-K, filed on November 8, 2022).
10.1*	
10.1*	Amendment to Membership Agreement, dated August 30, 2022, by and between WeWork and the
10.2+	Registrant.
10.2†	License Agreement, between by and between Dong-A ST Co., Ltd. and the Company, dated September 14,
	2022 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on
10.0	September 14, 2022).
10.3	Shared Services Agreement, between by and between Dong-A ST Co., Ltd. and the Company, dated
	September 14, 2022 (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-
	K, filed on September 14, 2022).
10.4††	Securities Purchase Agreement, by and between Dong-A ST Co., Ltd. and the Company, dated
	September 14, 2022 (incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-
	<u>K, filed on September 14, 2022).</u>

- 10.5 Registration Rights Agreement, by and among Dong-A ST Co., Ltd., The E&Healthcare Investment Fund II, The E&Healthcare Investment Fund No. 6, The E&Healthcare Investment Fund No. 7 and the Company, dated September 14, 2022 (incorporated by reference to Exhibit 10.4 to the Registrant's Current Report on Form 8-K, filed on September 14, 2022).
- 10.6
   Investor Rights Agreement, by and between Dong-A ST Co. Ltd. and the Company, dated September 14, 2022 (incorporated by reference to Exhibit 10.5 to the Registrant's Current Report on Form 8-K, filed on September 14, 2022).
- 10.7 <u>Underwriting Agreement dated as of November 4, 2022, by and between NeuroBo Pharmaceuticals, Inc. and Ladenburg Thalmann & Co. Inc. (incorporated by reference to Exhibit 1.1 to the Registrant's Current Report on Form 8-K, filed on November 8, 2022)</u>
- 10.8 Form of Leak-Out Agreement (incorporated by reference to Exhibit 10.42 to the Registrant's Registration Statement on Form S-1/A, filed on November 3, 2022).
- 10.9 Form of Voting Agreement to be executed by Dong-A ST Co. Ltd and Roy Lester Freeman (incorporated by reference to Exhibit 10.43 to the Registrant's Registration Statement on Form S-1/A, filed on November 3, 2022).
- 10.10 Form of Lock-Up Agreement to be executed by Dong-A ST Co. Ltd and Roy Lester Freeman (incorporated by reference to Exhibit 10.44 to the Registrant's Registration Statement on Form S-1/A, filed on November 3, 2022).
- 10.11 Form of Voting Agreement to be executed by entities affiliated with E&Investment, Inc. (incorporated by reference to Exhibit 10.45 to the Registrant's Registration Statement on Form S-1/A, filed on November 3, 2022).
- 10.12 Form of Lock-Up Agreement to be executed by entities affiliated with E&Investment, Inc. (incorporated by reference to Exhibit 10.46 to the Registrant's Registration Statement on Form S-1/A, filed on November 3, 2022).
- 31.1\* Certification of Principal Executive Officer and Principal Financial Officer Pursuant to Exchange Act Rule 13a-14(a) or 15d-14(a), as Adopted Pursuant to Section 302 of The Sarbanes Oxley Act of 2002.
- 32.1\*\* Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- 101.INS\* Inline XBRL Instance Document
- 101.SCH\* Inline XBRL Taxonomy Extension Schema Document
- 101.CAL\* Inline XBRL Taxonomy Extension Calculation Linkbase Document
- 101.DEF\* Inline XBRL Taxonomy Extension Definition Linkbase Document
- 101.LAB\* Inline XBRL Taxonomy Extension Label Linkbase Document
- 101.PRE\* Inline XBRL Taxonomy Extension Presentation Linkbase Document
  - 104 Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)
    - \* Filed herewith
    - \*\* Furnished herewith. The certification attached as Exhibit 32.1 that accompanies this Quarterly Report on Form 10-Q is deemed furnished and not filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of NeuroBo Pharmaceuticals, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Quarterly Report on Form 10-Q, irrespective of any general incorporation language contained in such filing.
    - Certain portions of the License Agreement that are not material and is of the type that the registrant treats as private or confidential have been redacted pursuant to Item 601(b)(10)(iv) of Regulation S-K. A copy of the unredacted License Agreement will be furnished to the SEC upon request
  - ++ Certain schedules and exhibits have been omitted pursuant to Item 601(a)(5) 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.

Registrant: NeuroBo Pharmaceuticals, Inc.

#### SIGNATURE

/s/ GIL PRICE, M.D.

Gil Price President and Chief Executive Officer (Principal Financial Officer and duly authorized to sign on behalf of the registrant) November 14, 2022

DATE

### wework

## AMENDMENT TO MEMBERSHIP AGREEMENT

#### HI ADAM PERLISH

#### Please review the Amendment to your Membership Agreement below.

If you have any questions or concerns, please don't hesitate to reach out to us at we-us-39470@wework.com

Reference is hereby made to the Membership Agreement between 200 Berkeley Street Tenant LLC ("WeWork") and NeuroBo Pharmaceuticals, Inc. dated January 29, 2020, including the accompanying Membership Details Form and any other amendments thereto (the "Agreement"). The parties agree that the following terms shall be considered binding amendments to the Agreement (the "Amendment"). Capitalized terms not defined herein shall have the meaning ascribed to them in the Agreement.

#### MEMBER INFORMATION

#### NeuroBo Pharmaceuticals, Inc.

Primary member: Adam Perlish

#### AMENDED MEMBERSHIP DETAILS

#### WeWork 200 Berkeley

#### **Current Office(s)**

19-120 • 2 person office

#### Membership Fee:

\$1,750.00/mo from October 1, 2022

#### Commitment term

Start date: October 1, 2022 End date: December 31, 2022

Amendment to Membership Agreement

#### MEMBERSHIP FEE SUMMARY

OFFICE	DATES	MEMBERSHIP FEE	DISCOUNT	NET DISCOUNTED FEE
19-120	10/01/2022 12/31/2022	\$1,750.00	\$262.50	\$1,487.50

#### ANNUAL ESCALATION

On each anniversary of the start date for the office, the Membership Fee will be subject to an automatic three and a half percent (3.5%) increase over the then current Membership Fee.

This amendment may alter the date upon which Member Company's annual increase of the Membership Fee occurs, but in no event shall it occur on a date earlier than the next anniversary of the Start Date of the Agreement.

In the event of any inconsistency between the Agreement and this Amendment, the terms of this Amendment shall prevail. The parties further agree that other than the terms modified by this Amendment, the Agreement remains otherwise unchanged, including the annual Membership Fee increases set forth in the Agreement.

By electronically signing this Amendment you represent that you have the proper authority to execute this Amendment on behalf of NeuroBo Pharmaceuticals, Inc. and incur the obligations described in this Amendment on behalf of NeuroBo Pharmaceuticals, Inc.

#### Community Manager's signature

Electronic Signature Gil Price

Erika Nedwell 200 Berkeley Street Tenant LLC

NeuroBo Pharmaceuticals, Inc. Signed on August 30, 2022

Wework 200 Berkeley Street Boston, MA, 02116, USA VAT: 834152702

(646) 491-9060 we-us-39470@wework.com

Amendment to Membership Agreement

#### CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER PURSUANT TO EXCHANGE ACT RULE 13a-14(a) OR 15d-14(a), AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES OXLEY ACT OF 2002

I, Gil Price, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of NeuroBo Pharmaceuticals, Inc. for the quarterly period ended September 30, 2022;

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. I am 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 my supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to me 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 my 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 my 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. I have disclosed, based on my 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: November 14, 2022

/s/ GIL PRICE

Name:Gil Price Title: President and Chief Executive Officer (Principal Executive Officer and Principal Financial Officer)

#### CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER, PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002\*

Pursuant to the requirement set forth in Rule 13a-14(b) or Rule 15d-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code, Gil Price, President and Chief Executive Officer of NeuroBo Pharmaceuticals, Inc. (the "Company") hereby certifies that, to the best of his knowledge:

1. The Company's Quarterly Report on Form 10-Q for the period ended September 30 2022, to which this certification is attached as Exhibit 32.1 (the "Quarterly Report") fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act, and

2. The information contained in the Quarterly Report fairly presents, in all material respects, the financial condition of the Company at the end of the period covered by the Quarterly Report and results of operations of the Company for the period covered by the Quarterly Report.

/s/ GIL PRICE President and Chief Executive Officer (Principal Executive Officer and Principal Financial Officer)

Dated: November 14, 2022

<sup>\*</sup> This certification accompanies the report to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of NeuroBo Pharmaceuticals, Inc. under the Securities Act of 1933, as amended, or the Exchange Act made before or after the date of the report, irrespective of any general incorporation language contained in such filing.