

As filed with the Securities and Exchange Commission on September 16, 2022

Registration No. 333-

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

**FORM S-1**  
REGISTRATION STATEMENT  
*UNDER*  
**THE SECURITIES ACT OF 1933**

**NEUROBO PHARMACEUTICALS, INC.**  
(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**2834**  
(Primary Standard Industrial  
Classification Code Number)

**47-2389984**  
(I.R.S. Employer  
Identification Number)

**200 Berkeley Street, Office 19th Floor  
Boston, Massachusetts, 02116  
(857) 702-9600**

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

**Gil Price, M.D.**  
**President and Chief Executive Officer**  
**200 Berkeley Street, Office 19th Floor**  
**Boston, Massachusetts, 02116**  
**(857) 702-9600**

(Name, address, including zip code, and telephone number, including area code, of agent for service)

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**Approximate date of commencement of proposed sale to the public:** As soon as practicable after this registration statement becomes effective.

If any of the securities being registered on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box.

If this form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

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

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities Act.

**The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, or until the registration statement shall become effective on such date as the Commission acting pursuant to said Section 8(a) may determine.**

Subject to completion, dated September 16, 2022

## PRELIMINARY PROSPECTUS



## NEUROBO PHARMACEUTICALS, INC.

**Class A Units consisting of shares of common stock and warrants and  
Class B Units consisting of shares of Series B Convertible Preferred Stock and warrants  
(and shares of common stock underlying shares of Series B Convertible Preferred Stock and warrants)**

This preliminary prospectus (“prospectus”) relates to the offering of Class A Units of NeuroBo Pharmaceuticals, Inc., a Delaware corporation (the “Class A Units”) at an assumed public offering price of \$29.90 per Class A Unit, the last reported sales price of our common stock on the Nasdaq Capital Market on September 13, 2022. Each Class A Unit consists of one share of our common stock and one warrant to purchase shares of our common stock at an exercise price of \$ per share (or % of the price of each Class A Unit sold in the offering) which will be immediately exercisable upon issuance and will expire on the five-year anniversary of the original issuance date.

We are also offering to those purchasers, if any, whose purchase of Class A Units in this offering would otherwise result in such purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding shares of common stock immediately following the consummation of this offering, the opportunity to purchase, if any such purchaser so chooses, Class B Units, in lieu of Class A Units that would otherwise result in such purchaser’s beneficial ownership exceeding 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding shares of common stock. Each Class B Unit consists of one share of our Series B Convertible Preferred Stock (the “Series B Convertible Preferred Stock”), convertible into shares of common stock and a warrant to purchase shares of common stock (together with the shares of common stock underlying such shares of Series B Convertible Preferred Stock and such warrants, the “Class B Units” and, together with the Class A Units, the “units”) at a public offering price of \$ per Class B Unit.

The Class A Units and the Class B Units have no stand-alone rights and will not be issued or certificated as stand-alone securities. The shares of common stock, Series B Convertible Preferred Stock and warrants comprising such units are immediately separable and will be issued separately in this offering. The shares of common stock or Series B Convertible Preferred Stock, as the case may be, and the warrants included in the Class A Units and the Class B Units can only be purchased together in this offering, but the securities contained in the Class A Units or Class B Units will be immediately separable upon issuance and will be issued separately. The shares of common stock issuable from time to time upon exercise of the warrants are also being offered by this prospectus.

Our common stock is listed on the Nasdaq Capital Market (“Nasdaq”) under the symbol “NRBO”. We have assumed a public offering price of per Class A Unit, which represents the last reported sale price of our common stock as reported on Nasdaq on , 2022. The final public offering price will be determined through negotiation between us and the underwriters in the offering and may be at a discount to the current market price. Therefore, the assumed public offering price used throughout this prospectus may not be indicative of the final public offering price.

There is no established trading market for the Series B Convertible Preferred Stock or warrants being offered, and we do not expect a market to develop. In addition, we do not intend to apply for the listing of the Series B Convertible Preferred Stock or the warrants on any national securities exchange or other trading market. Without an active trading market, the liquidity of the warrants will be limited. Except as otherwise indicated, all share and per share information in this prospectus gives effect to the reverse stock split of our outstanding common stock, which was effected at a ratio of one-for-thirty as of 5:00 p.m. Eastern Time on September 12, 2022.

We have entered into a securities purchase agreement with Dong-A ST Co. Ltd., (“Dong-A”) which currently holds 10.8% of our outstanding common stock, pursuant to which, concurrently with and as a

The information in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities, and we are not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

condition to the closing of the offering of units, (i) Dong-A will receive \$22 million of our Series A Convertible Preferred Stock as an upfront payment in respect of the license agreement between us and Dong-A, dated as of September 14, 2022, and (ii) Dong-A will purchase, in a private offering, \$15 million of our Series A Convertible Preferred Stock together with warrants substantially equivalent to the warrants. At such time as we obtain stockholder approval for the issuance of the common stock underlying the Series A Convertible Preferred Stock issued for the upfront payment and the Series A Convertible Preferred Stock issued in the private offering and the exercise of the warrants issued in the private offering, such shares of Series A Convertible Preferred Stock will be convertible into shares of common stock at a conversion price equal to the public offering price of the units being sold pursuant to this prospectus, subject to customary adjustments for forward and reverse stock splits, stock dividends and the like.

**An investment in our securities involves a high degree of risk. Before making any investment decision, you should carefully read the discussion of the material risks of investing in securities in “Risk Factors” beginning on page 8 of this prospectus.**

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.**

	Per Class A Unit <sup>(1)</sup>	Per Class B Unit <sup>(2)</sup>	Total
Public offering price	\$	\$	\$
Underwriter discounts and commissions <sup>(3)</sup>	\$	\$	\$
Proceeds, before expenses, to us	\$	\$	\$

- (1) The public offering price and underwriting discount corresponds, in respect of the Class A Units, to (i) a public offering price per share of common stock of \$ ( net of the underwriting discount) and (ii) a public offering price per warrant of \$ ( net of the underwriting discount).
- (2) The public offering price and underwriting discount in respect of the Class B Units corresponds to (i) a public offering price per share of Series B Convertible Preferred Stock of \$ ( net of the underwriting discount) and (ii) a public offering price per warrant of \$ ( net of the underwriting discount).
- (3) Does not include the fee paid to the underwriters with respect to the private offering described in this prospectus. We have agreed to pay certain expenses of the underwriters in this offering. We refer you to “Underwriting” on page for additional information regarding underwriting compensation.

The offering is being underwritten on a firm commitment basis. We have granted a 45-day option to the underwriters to purchase up to an additional shares of common stock and warrants to purchase an additional shares of common stock from us at the public offering price, less the underwriting discounts payable by us, to cover over-allotments, if any. The option may be used to purchase shares of common stock and/or warrants, or any combination thereof, as determined by the underwriters.

The underwriters expect to deliver the securities to investors on or about , 2022.

*Sole Book-Running Manager*

## **Ladenburg Thalmann**

The date of this prospectus is , 2022

## TABLE OF CONTENTS

	<u>Page</u>
<u>SUMMARY</u>	<u>1</u>
<u>SELECTED FINANCIAL DATA</u>	<u>7</u>
<u>RISK FACTORS</u>	<u>8</u>
<u>SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS</u>	<u>48</u>
<u>USE OF PROCEEDS</u>	<u>49</u>
<u>CAPITALIZATION</u>	<u>50</u>
<u>DILUTION</u>	<u>52</u>
<u>UPFRONT LICENSE PAYMENT AND PRIVATE OFFERING</u>	<u>54</u>
<u>DIVIDEND POLICY</u>	<u>55</u>
<u>BUSINESS</u>	<u>56</u>
<u>BENEFICIAL OWNERSHIP</u>	<u>73</u>
<u>CERTAIN RELATIONSHIPS AND RELATED PERSON TRANSACTIONS</u>	<u>75</u>
<u>DESCRIPTION OF SECURITIES WE ARE OFFERING</u>	<u>76</u>
<u>UNDERWRITING</u>	<u>78</u>
<u>DESCRIPTION OF CAPITAL STOCK</u>	<u>82</u>
<u>LEGAL MATTERS</u>	<u>88</u>
<u>EXPERTS</u>	<u>88</u>
<u>WHERE YOU CAN FIND MORE INFORMATION</u>	<u>88</u>
<u>INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE</u>	<u>88</u>

## ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement that we filed with the Securities and Exchange Commission, or the SEC. Before making your investment decision, we urge you to carefully read this prospectus and all of the information contained in the documents incorporated by reference in this prospectus, as well as the additional information described under the headings “Where You Can Find More Information” and “Incorporation of Certain Documents by Reference.”

This prospectus does not constitute an offer to sell or the solicitation of an offer to buy any securities other than the securities described in this prospectus or an offer to sell or the solicitation of an offer to buy such securities in any circumstances in which such offer or solicitation is unlawful. You should assume that the information appearing in this prospectus, the documents incorporated by reference and any related free writing prospectus is accurate only as of their respective dates. Our business, financial condition, results of operations and prospects may have changed materially since those dates.

Neither we nor the underwriters have authorized anyone to provide you with any information or to make any representations other than that contained in this prospectus or in any free writing prospectus we may authorize to be delivered or made available to you. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. Neither we nor the underwriters are making an offer to sell securities in any jurisdiction in which the offer or sale is not permitted. The information in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or of any sale of our securities and the information in any free writing prospectus that we may provide to you in connection with this offering is accurate only as of the date of that free writing prospectus. Our business, financial condition, results of operations and prospects may have changed since those dates.

To the extent there is a conflict between the information contained in this prospectus, on the one hand, and the information contained in any document incorporated by reference in this prospectus, on the other hand, you should rely on the information in this prospectus, provided that if any statement in one of these documents is inconsistent with a statement in another document having a later date — for example, a document incorporated by reference in this prospectus — the statement in the document having the later date modifies or supersedes the earlier statement.

We further note that the representations, warranties and covenants made by us in any agreement that is filed as an exhibit to any document that is incorporated by reference herein were made solely for the benefit of the parties to such agreement, including, in some cases, for the purpose of allocating risk among the parties to such agreement, and should not be deemed to be a representation, warranty or covenant to you. Moreover, such representations, warranties or covenants were accurate only as of the date when made. Accordingly, such representations, warranties and covenants should not be relied on as accurately representing the current state of our affairs.

For investors outside the United States: We have not, and the underwriters have not, done anything that would permit this offering, or possession or distribution of this prospectus, in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the shares of common stock and the distribution of this prospectus outside of the United States.

## SUMMARY

*This summary highlights information contained elsewhere in this prospectus and does not contain all of the information that you should consider in making your investment decision. Before deciding to invest in our securities, you should read this entire prospectus and the documents incorporated by reference herein and therein carefully, including our financial statements and related notes, the information in the section “Risk Factors,” “Where You Can Find More Information” and “Incorporation of Certain Documents by Reference.” Unless otherwise specified or the context otherwise requires, references in this prospectus to the “Company,” “NeuroBo,” “Registrant,” “we,” “us,” and “our” refer to NeuroBo Pharmaceuticals, Inc. and its wholly owned subsidiaries.*

*All trademarks or trade names referred to in this prospectus are the property of their respective owners. Solely for convenience, the trademarks and trade names in this prospectus are referred to without the ® and ™ symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto. We do not intend the use or display of other companies’ trademarks and trade names to imply a relationship with, or endorsement or sponsorship of us by, any other companies.*

### Company Overview

NeuroBo Pharmaceuticals, Inc. (the “Company,” “NeuroBo,” “we,” “us” or “our”) is a clinical-stage biotechnology company which has entered into a license agreement (the “2022 License Agreement”) with Dong-A ST Co. Ltd. (“Dong-A”) to inlicense the rights to two assets, focused on treatment of nonalcoholic steatohepatitis (“NASH”) and obesity. The effectiveness of the 2022 License Agreement is subject to consummation of a Qualified Financing (as described below). Concurrently with the 2022 License Agreement, we entered into a securities purchase agreement with Dong-A (the “Securities Purchase Agreement”) pursuant to which Dong-A agreed to purchase \$15 million in Series A Convertible Preferred Stock and warrants on substantially the same terms as this offering subject to consummation of a Qualified Financing. It is intended that this offering will be a Qualified Financing and, if this offering is consummated, the 2022 License Agreement will be effective and Dong-A will consummate the purchase under the Securities Purchase Agreement. Prior to this offering, we have been focused on four therapeutic programs designed to impact a range of indications in coronavirus, neurodegenerative and cardiometabolic disease, which we have currently suspended. Additional information regarding the general development of our business is set forth in our [Annual Report on Form 10-K for the year ended December 31, 2021](#).

On September 14, 2022, we entered into an exclusive license agreement with Dong-A (the “2022 License Agreement”) pursuant to which, subject to the conditions set forth therein, we would hold an exclusive license (other than in the Republic of Korea) to two proprietary compounds for specified indications. The 2022 License Agreement covers the rights to a compound referred to as DA-1241 for treatment of 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 type 2 diabetes mellitus (“T2D”). The 2022 License Agreement calls for an upfront payment of \$22,000,000, which will be paid in Series A Convertible Preferred Stock of NeuroBo at the public offering price, milestone payments and royalties. The effectiveness of the 2022 License Agreement is contingent upon our raising a total of at least \$15 million in a Qualified Financing upon which Dong-A will fund an additional \$15 million, which is being sold in the private offering.

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. Agonism of GPR119 in the gut promotes the release of key gut peptides GLP-1, GIP, and PYY. These peptides play a further role in glucose metabolism, lipid metabolism and weight loss. DA-1241 has beneficial effects on glucose, lipid profile and liver inflammation, supported by potential efficacy demonstrated during in vivo preclinical studies. The therapeutic potential of DA-1241 has been demonstrated in multiple pre-clinical animal models of NASH where DA-1241 reduced hepatic steatosis, inflammation, and fibrosis. Furthermore, in Phase 1a and 1b human trials DA-1241 was well tolerated in both healthy volunteers and those with T2D. If this offering is consummated and the 2022 License Agreement is effective, then we intend to initiate a Phase 2a study with the goal of establishing efficacy of DA-1241 in the treatment of NASH.

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. DA-1726 has a well understood mechanism and, in preclinical mice models, resulted in improved weight loss, as well as reduced hepatic steatosis, inflammation, and fibrosis compared to semaglutide and cotadutide (another OXM analogue).

Each of DA-1241 and DA-1726 is currently being developed for the treatment of NASH. NASH is a severe form of nonalcoholic fatty liver disease (“NAFLD”), characterized by inflammation and fibrosis in the liver that can progress to cirrhosis, liver failure, hepatocellular carcinoma (“HCC”) and death. There are currently no approved products for the treatment of NASH.

The prevalence of NAFLD, which affects approximately 25% of the global population, and NASH, which develops in approximately 12% to 14% of NAFLD patients, is growing and is driven primarily by the worldwide obesity epidemic. The critical pathophysiologic mechanisms underlying the development and progression of NASH include reduced ability to handle lipids, increased insulin resistance, injury to hepatocytes and liver fibrosis in response to hepatocyte injury. Patients with NASH frequently have other significant metabolic co-morbidities such as obesity, hyperglycemia, dyslipidemia and systemic hypertension (a constellation of which is commonly referred to as metabolic syndrome) and these further contribute to the risk of cardiovascular disease. The number of NASH cases in the United States is projected to expand from 16.5 million in 2015 to 27 million in 2030, with similar prevalence growth expected in Europe. Diet and exercise are currently the standard of care for NAFLD and NASH, but adherence to this treatment regimen is poor and there remains a high unmet need in the treatment of NASH.

We have other product candidates focused on the developing novel pharmaceuticals to treat COVID-19 and neurodegenerative disorders. We do not intend to use the proceeds of this offering or the private offering for further development of these product candidates.

- *ANA001* 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. 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* has the potential to treat painful diabetic neuropathy (PDN) as a first-line pain management therapy for PDN.
- *NB-02* 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.
- *Gemcabene* is currently being assessed for various indications including COVID-19 in combination with ANA001.

### Strategy

NeuroBo’s goal is to discover, develop and commercialize novel therapeutics for the treatment of cardiovascular and metabolic diseases. The key elements of NeuroBo’s business strategy to achieve this goal include:

- Advance DA-1241 through the FDA regulatory process to obtain approval for the treatment of NASH and T2D initially by starting a Phase 2a combination trial in NASH before progressing to T2D.
- Explore various avenues to advance DA-1241 to FDA approval, including, if the Phase 2 clinical trials are successful, securing a pharmaceutical partner to advance work on a global Phase 3 program.
- Advance DA-1726 through IND and initiation of human clinical trials with the initial goal of have DA-1726 be IND-ready by the first quarter of 2023.



- Pursue ANA001 as a treatment and/or prophylaxis for COVID-19.
- Explore alternatives for the future of NB-01, including assessing whether to pursue NB-01 as an orphan drug and/or as a nutraceutical product.
- Explore out licensing opportunities for NB-02.
- Explore additional acute therapeutic indications for gemcabene that may strengthen our pipeline of assets.
- Extend the pipeline of drugs as NeuroBo continues to build and develop its product portfolio by opportunistically pursue strategic partnerships.
- Continue to hire highly qualified management and personnel in advancing drug development, achieving marketing approval, and implementing its corporate growth strategy.

**Other Recent Developments**

On September 12, 2022, we effected a reverse stock split of our outstanding shares of our common stock at a ratio of one-for-thirty. The ratio was approved by our Board on September 9, 2022 and the reverse stock split was approved by our stockholders on June 9, 2022. Our common stock began trading on a split-adjusted basis on Nasdaq on September 13, 2022.

**Corporate Information**

Our principal executive offices are located at 200 Berkeley Street, 19th Floor, Boston, Massachusetts, 02116 and our telephone number is 857-702-9600. We maintain a corporate website at [www.neurobopharma.com](http://www.neurobopharma.com). We make available free of charge through our Internet website our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K, and any amendments to these reports, as soon as it is reasonably practicable after we electronically file such material with, or furnish such material to, the SEC. We are not including the information on our website as a part of, nor incorporating it by reference into, this prospectus or the registration statement of which it forms a part. Additionally, the SEC maintains a website that contains annual, quarterly, and current reports, proxy statements, and other information that issuers (including us) file electronically with the SEC. The SEC's website address is <http://www.sec.gov>.



<b>The Offering</b>	
Class A Units offered by us	We are offering        Class A units, each Class A unit consisting of one share of common stock and one warrant to purchase share of common stock.
Public Offering Price Per Class A Unit	\$        per Class A Unit
Class B Units offered by us	We are also offering to those purchasers, if any, whose purchase of Class A Units in this offering would otherwise result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding shares of common stock immediately following the consummation of this offering, the opportunity to purchase, if such purchasers so choose, Class B Units, in lieu of Class A Units that would otherwise result in any such purchaser's beneficial ownership exceeding 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding shares of common stock. Each Class B Unit consists of        shares of Series B Convertible Preferred Stock convertible into        shares of common stock and one warrant to purchase        share of common stock (together with the shares of our common stock underlying such shares of Series B Convertible Preferred Stock and warrants).
Public Offering Price Per Class B Unit	\$        per Class B Unit
Warrants offered by us	Each unit includes one warrant. will have an exercise price of \$        per share, will be immediately exercisable upon issuance and will expire on the fifth anniversary of the original issuance date. This prospectus also relates to the offering of the shares of common stock issuable upon exercise of the warrants.
Issuance of Series A Convertible Preferred Stock for Upfront License Payment and Private Offering	<p>We have entered into the Securities Purchase Agreement with Dong-A pursuant to which, concurrently with and as a condition to the closing of the offering of units, Dong-A will receive \$22 million of our Series A Convertible Preferred Stock for the Upfront License Payment and Dong-A will purchase, in a private offering, \$15 million of our Series A Convertible Preferred Stock and warrants with substantially the same terms as the warrants sold in this offering. At such time as we obtain stockholder approval for the issuance of the common stock underlying the Series A Convertible Preferred Stock issued for the upfront payment and the Series A Convertible Preferred Stock issued in the private offering and the exercise of the warrants issued in the private offering, such shares of Series A Convertible Preferred Stock will be convertible into shares of common stock at a conversion price equal to the public offering price of the Class A Units being sold pursuant to this prospectus, subject to customary adjustments for forward and reverse stock splits, stock dividends and the like.</p> <p>The closing of the offering of units being made pursuant to this prospectus is contingent upon the completion of the private offering and the closing of the private offering is contingent upon the completion of the offering of units being made pursuant to this</p>

Shares of common stock to be outstanding after this offering <sup>(1)</sup>	<p>prospectus. The underwriters shall receive compensation for the purchase or sale of the shares of the Series A Convertible Preferred Stock in the private offering. See “Upfront License Payment and Private Offering,” “Business — 2022 License Agreement,” “Description of Capital Stock — Preferred Stock — Series A Convertible Preferred Stock” and “Securities Being Sold in this Offering — Series B Convertible Preferred Stock”.</p> <p>shares of common stock (or shares of common stock if the underwriters exercise their option in full) (assuming the sale of all units covered by this prospectus, no sale of Class B Units, no exercise of any warrants issued in this offering and no exercise of outstanding options issued under our equity incentive plans and based on 888,693 shares outstanding as of September 14, 2022).</p>
Underwriters’ option to purchase additional shares and/or warrants	<p>We have granted the underwriters an option, exercisable for forty-five (45) days after the date of this prospectus, to purchase up to an additional shares of common stock and warrants at the public offering price less the underwriting discounts payable by us, which may be purchased in any combination of common stock and warrants.</p>
Use of proceeds	<p>We estimate that we will receive net proceeds from this offering of approximately \$ , or \$ if the underwriters exercise their over-allotment option in full, based upon an assumed public offering price of \$ per Class A Unit. We intend to use the net proceeds from this offering for funding development of our licensed product candidates, general corporate purposes and working capital.</p>
Risk factors	<p>You should carefully consider the risk factors described in the section of this prospectus titled “<u>Risk Factors</u>,” together with all of the other information included and incorporated by reference in this prospectus, before deciding to invest in our securities.</p>
Market and trading symbol	<p>Our common stock is listed on the Nasdaq Capital Market under the symbol “NRBO”. We do not intend to list the shares of Series B Convertible Preferred Stock or the warrants on any securities exchange or nationally recognized trading system. Without a trading market, the liquidity of the Series B Convertible Preferred Stock or the warrants will be extremely limited.</p>
<p>(1) Does not give effect to any conversion of the Series A Convertible Preferred Stock being issued as part of the Upfront License Payment or the private offering or the exercise of the warrants being offered pursuant to the private offering.</p>	
<p><b>Assumptions Used Throughout This Prospectus</b></p>	
<p>Unless otherwise stated in this prospectus, the total number of shares of common stock outstanding as of the date of this prospectus and after this offering is based on 888,693 shares outstanding as of June 30, 2022 after giving effect to the 2022 Reverse Stock Split, assumes the sale of units based on an assumed public offering price of \$ , the last reported sales price of our shares of common stock on the Nasdaq Capital Market on , 2022, and excludes the following other securities as of June 30, 2022:</p>	

- 36,493 shares of common stock issuable upon the exercise of stock options outstanding as of June 30, 2022, at a weighted-average exercise price of \$99.62 per share;
- 228,235 shares of common stock issuable upon the exercise of warrants outstanding as of June 30, 2022, at a weighted-average exercise price of \$140.07;
- 167,748 shares of common stock reserved for future issuance under our 2019 Equity Incentive Plan as of June 30, 2022;
- 12,778 shares of common stock reserved for future issuance under our 2021 Inducement Plan as of June 30, 2022;
- shares of common stock issuable upon exercise of the warrants included in this offering at an exercise price of \$         per share;
- shares of common stock issuable upon conversion of the Series A Convertible Preferred Stock issued as part of the Upfront License Payment; and
- shares of common stock issuable upon conversion of the Series A Convertible Preferred Stock issued in the private offering and         shares of common stock issuable upon exercise of the warrants included in the private offering.

On September 12, 2022, we effected a reverse stock split of our outstanding shares of our common stock at a ratio of one-for-thirty, or the 2022 Reverse Stock Split. The ratio was approved by our Board on September 9, 2022 and the 2022 Reverse Stock Split was approved by our stockholders on June 9, 2022. As a result of the 2022 Reverse Stock Split, every thirty (30) shares of our common stock outstanding was automatically changed and reclassified into one (1) new share of common stock. Holders of common stock that would have otherwise received a fractional share of common stock pursuant to the 2022 Reverse Stock Split received cash in lieu of the fractional share. Unless indicated otherwise, the numbers set forth in this prospectus have been adjusted to reflect the 2022 Reverse Stock Split.

Except as otherwise noted, all information in this prospectus reflects and assumes (i) no sale of Series B Convertible Preferred Stock, which, if sold, for each share of common stock underlying a share of Series B Convertible Preferred Stock, the number of shares of common stock that we are offering will be decreased on a one-for-one basis, (ii) no exercise of outstanding options issued under our equity incentive plans, (iii) no exercise of any warrants issued in this offering and (iv) no exercise of the underwriters' option to purchase additional shares of common stock and/or warrants to purchase additional shares of common stock.

### SELECTED FINANCIAL DATA

On September 12, 2022, we effected the 2022 Reverse Stock Split. The following selected financial data presents the Statement of Operations data reflecting the effect of the 2022 Reverse Stock Split on the years ended December 31, 2021 and 2020 and the six-month periods ended June 30, 2022 and 2021. We derived the selected financial data from our consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2021 and our condensed consolidated financial statements included in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2022, as adjusted to reflect the 2022 Reverse Stock Split for all periods presented. Our results for interim periods are not necessarily indicative of the results that may be expected for the full year or any other future period.

Statement of Operations data: (in thousands, except share and per share amounts)	As Reported		As Adjusted	
	For the Year Ended December 31,		For the Year Ended December 31,	
	2021	2020	2021	2020
<b>Operating expenses:</b>				
Research and development	\$ 6,546	\$ 4,531	\$ 6,546	\$ 4,531
Acquired in-process research and development	—	17,339	—	17,339
General and administrative	8,752	7,846	8,752	7,846
<b>Total operating expenses</b>	<b>15,298</b>	<b>29,716</b>	<b>15,298</b>	<b>29,716</b>
Loss from operations	(15,298)	(29,716)	(15,298)	(29,716)
Other income, net	14	38	14	38
Net loss	\$ (15,284)	\$ (29,678)	\$ (15,284)	\$ (29,678)
Net loss per share, basic and diluted	\$ (0.66)	\$ (1.83)	\$ (19.81)	\$ (54.90)
Weighted average shares of common stock outstanding, basic and diluted	23,143,792	16,217,339	771,422	540,534
Statement of Operations data: (in thousands, except share and per share amounts)	As Reported		As Adjusted	
	For the Six Months Ended June 30,		For the Six Months Ended June 30,	
	2022	2021	2022	2021
<b>Operating expenses:</b>				
Research and development	\$ 1,902	\$ 3,155	\$ 1,902	\$ 3,155
General and administrative	4,192	4,101	4,192	4,101
<b>Total operating expenses</b>	<b>6,094</b>	<b>7,256</b>	<b>6,094</b>	<b>7,256</b>
Loss from operations	(6,094)	(7,256)	(6,094)	(7,256)
Other (expense) Income, net	(84)	11	(84)	11
Net loss	\$ (6,178)	\$ (7,245)	\$ (6,178)	\$ (7,245)
Net loss per share, basic and diluted	\$ (0.23)	\$ (0.33)	\$ (6.95)	\$ (9.92)
Weighted average shares of common stock outstanding, basic and diluted	26,661,771	21,909,464	888,693	730,276

## RISK FACTORS

*An investment in our securities has a high degree of risk. Before you invest you should carefully consider the risks and uncertainties described below and the other information in this prospectus. Any of the risks and uncertainties set forth herein and therein could materially and adversely affect our business, results of operations and financial condition, which in turn could materially and adversely affect the trading price or value of our securities. Additional risks not currently known to us or which we consider immaterial based on information currently available to us may also materially adversely affect us. As a result, you could lose all or part of your investment.*

### **Risk Factor Summary**

- NeuroBo expects to incur losses for the foreseeable future and may never achieve or maintain profitability, and there is substantial doubt about NeuroBo's ability to continue as a going concern;
- NeuroBo will need additional financings to fund operations and such additional financings may cause dilution to existing stockholders, restrict NeuroBo's operations or require NeuroBo to relinquish its technologies;
- The timing and costs related to the clinical development of NeuroBo's products are difficult to predict, and any delays in NeuroBo's clinical trials may lead to a delay in the submission of marketing approval applications;
- NeuroBo may be required to make significant payments under the 2022 License Agreement;
- The regulatory review and approval processes of the FDA and comparable foreign regulatory authorities are lengthy, time-consuming and inherently unpredictable;
- NeuroBo's pursuit of potential therapeutic and prophylactic treatments for COVID-19 is in an early stage and subject to many risks, and its COVID-19 product candidates may not be approved in a timely manner, if at all;
- In light of the COVID-19 pandemic, it is possible that one or more government entities may take actions that directly or indirectly have the effect of abrogating some of NeuroBo's rights or opportunities;
- We are currently evaluating alternatives with respect to NB-01 and may not be able to develop NB-01 pursuant to other pathways, including as an orphan drug or as a nutraceutical candidate;
- Undesirable side effects from future product candidates could delay or prevent their marketing approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, and the development of such product candidates exposes NeuroBo to additional risks;
- NeuroBo may engage in future acquisitions, in-licenses of technology, strategic alliances or enter into additional licensing arrangements that could disrupt its business, cause dilution to the organization's stockholders, harm its financial condition and operating results or result in no benefits being realized from such engagement;
- 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 of NeuroBo's control;
- NeuroBo faces substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than it does;
- NeuroBo's commercial success depends upon attaining significant market acceptance of its product candidates, if approved, among hospitals, physicians, patients and healthcare payors;
- Product liability lawsuits against NeuroBo could cause it to incur substantial liabilities and could limit commercialization of any product candidate that it may develop;
- NeuroBo relies on third parties to develop NeuroBo's preclinical studies, clinical trials, research programs and product candidates and to manufacture its product candidates and preclinical and

clinical drug supplies. If these third parties do not successfully carry out their contractual duties or meet expected deadlines or if they engage in misconduct or other improper activities or if NeuroBo is unable to engage with these third parties, it could have a material adverse effect on NeuroBo's business and NeuroBo's obtaining of regulatory approval and commercialization of its product candidates;

- Any product candidate for which NeuroBo obtains marketing approval could be subject to marketing restrictions or withdrawal from the market, and NeuroBo may be subject to penalties if it fails to comply with regulatory requirements or if it experiences unanticipated problems with our products;
- NeuroBo or any of its potential collaborators may never receive regulatory approval to market NeuroBo's product candidates outside of the United States;
- Mechanisms that NeuroBo may utilize to expedite and/or reduce the cost for development or approval of its product candidates may not lead to faster or less expensive development, regulatory review or approval process;
- Legislation may increase the difficulty and cost to obtain marketing approval of and commercialize its product candidates, and governments outside the United States tend to impose strict price controls, which also may adversely affect NeuroBo's revenues;
- NeuroBo's relationships with healthcare providers and third-party payors will be subject to applicable healthcare laws and regulations, which could expose NeuroBo to certain penalties and consequences;
- NeuroBo's compliance with legal standards related to foreign trade could impair its ability to compete in domestic and international markets, and NeuroBo could face criminal liability and other serious consequences for violations;
- Certain tax matters, including NeuroBo's ability to use its NOLs to offset future taxable income may be subject to certain limitations, could impact its results of operations and financial conditions;
- Inadequate funding for the FDA and other government agencies could prevent those agencies from performing normal business functions on which the operation of NeuroBo's business may rely, which could negatively impact NeuroBo's business;
- Federal legislation and actions by state and local governments may permit reimportation of drugs from foreign countries into the United States, including foreign countries where the drugs are sold at lower prices than in the United States, which could adversely affect NeuroBo's operating results;
- If NeuroBo is unable to obtain, maintain and protect sufficient intellectual property rights, its competitive position could be harmed;
- NeuroBo may become involved in lawsuits to protect or enforce its intellectual property, which could be expensive, time consuming, unsuccessful and could distract NeuroBo's personnel from their normal responsibilities;
- If NeuroBo receives stockholder approval for the conversion of the Series A Convertible Preferred Stock that will be issued to Dong-A if this offering is completed, Dong-A may have a significant interest in and control NeuroBo, and as a result, Dong-A's interests may conflict with NeuroBo's or yours in the future;
- Provisions in NeuroBo's corporate charter documents and under Delaware law could make an acquisition of NeuroBo more difficult and may prevent attempts by NeuroBo's stockholders to replace or remove NeuroBo's current management;
- NeuroBo is a "smaller reporting company", which could make its common stock less attractive to investors;
- NeuroBo has identified material weaknesses in its internal control over financial reporting that could, if not remediated, result in material misstatements in its financial statements or impair its ability to produce accurate and timely consolidated financial statements;
- NeuroBo's obtaining and maintaining patent protection could be reduced or eliminated for non-compliance with certain requirements imposed by governmental patent agencies;

- NeuroBo’s business and operations would suffer in the event of system failures or unplanned events;
- Any failure, inadequacy, interruption or security lapse of NeuroBo’s information technology could prevent NeuroBo from accessing critical information or expose NeuroBo to liability;
- An active trading market for NeuroBo’s common stock may not be maintained, and there is no public market for the Series B Convertible Preferred Stock or warrants;
- If securities analysts do not publish research or reports about NeuroBo’s business or if they publish negative evaluations of NeuroBo’s stock, the price of NeuroBo’s stock could decline;
- NeuroBo incurs increased costs as a result of operating as a public company and its management is required to devote substantial time to compliance initiatives;
- NeuroBo does not anticipate declaring or paying, in the foreseeable future, any cash dividends on its capital stock and, consequently, the ability of its stockholders to achieve a return on their investment will depend on appreciation in the price of NeuroBo’s common stock;
- NeuroBo’s Bylaws designate the Court of Chancery of the State of Delaware as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by NeuroBo’s stockholders, which could limit the ability of NeuroBo’s stockholders to obtain a favorable judicial forum for disputes with NeuroBo or its directors, officers or employees;
- Unstable market and economic conditions may have serious adverse consequences on NeuroBo’s business, financial condition and stock price;
- NeuroBo’s management will have broad discretion and flexibility in how the net proceeds from this offering are used, and it may use the net proceeds in ways with which you disagree or which may not prove effective;
- The liquidity and trading volume of NeuroBo’s common stock could be low, its ownership will be concentrated and the market price of its common stock may be highly volatile;
- NeuroBo’s common stock may be delisted from the Nasdaq Capital Market if its noncompliance with the continued listing requirements continues;
- You will incur immediate and substantial dilution as a result of this offering; and
- The terms of the Series B Convertible Preferred Stock and the warrants could impede NeuroBo’s ability to enter into certain transactions or obtain additional financing.

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

***We have incurred losses since inception, we anticipate that we will incur continued losses for the foreseeable future and there is substantial doubt about our ability to continue as a going concern for the full one-year period following the date of this prospectus. We require additional financing to accomplish our long-term business plan and failure to obtain necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our operations.***

We have experienced net losses and negative cash flows from operating activities since our inception and have an accumulated deficit of \$88.0 million as of June 30, 2022. It is possible we will never generate revenue or profit.

As of June 30, 2022, we had cash and cash equivalents of \$8.8 million. If we do not raise funds in this offering, we will not be able to consummate the 2022 License Agreement and we expect that our cash and cash equivalents will be adequate to fund operations into the first quarter of 2023.

If we consummate this offering and the consummate the 2022 License Agreement, we expect that our costs will increase significantly as we advance the development of these product candidates through clinical trials and other research. Because of the numerous risks and uncertainties associated with our commercialization efforts and future product development and ongoing government investigation, we are unable to predict when we will become profitable, and we may never become profitable. Even if we do achieve profitability, we may not be able to sustain or increase our profitability.



The amount and timing of any expenditures needed to implement our commercial strategy will depend on numerous factors, including:

- timing of clinical trials, including our ability to recruit clinical sites and enroll patients and timing of receipt of necessary approvals to commence clinical trials;
- timing and cost structure of product manufacturing for our clinical trials;
- our ability to establish and maintain strategic sub-licensing, collaboration, partnering or other arrangements and the financial terms of such agreements;
- the timing, receipt, and amount of license fees and sales of, or royalties on, our future products or future improvements on our existing products, if any;
- the cost to establish, maintain, expand, and defend the scope of our intellectual property portfolio, as well as any other action required in connection with licensing, preparing, filing, prosecuting, defending, and enforcing any patents or other intellectual property rights;
- the emergence of competing technologies and other adverse market developments; and
- our ability to achieve sufficient market acceptance, the ability for our customers to get coverage and adequate reimbursement from third-party payors and our ability to achieve acceptable market share.

If we raise additional capital or develop and/or commercialize our products with third parties through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements, we may have to develop our products on a slower timeline or relinquish certain valuable rights to our products, technologies, future revenue streams or research programs or grant licenses on terms that may not be favorable to us. If we raise additional capital through public or private equity offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt or making capital expenditures. If we are unable to obtain adequate financing on commercially reasonable terms when needed, we may have to delay, reduce the scope of or suspend our sales and marketing efforts, which would have a material adverse effect on our business, financial condition, and results of operations. We also expect the continuing economic uncertainty resulting from the COVID-19 pandemic to have a negative impact on our ability to secure additional financing in a timely manner or on favorable terms, if at all.

***We have determined that there is substantial doubt about our ability to continue as a going concern, and we will need additional financings to execute our business plan and to fund our operations. We will need to raise additional funds to operate our business, but additional funds may not be available on acceptable terms, or at all. Any inability to raise required capital when needed could harm our liquidity, financial condition, business, operating results and prospects.***

We do not yet generate revenues from our operations to fund our activities and are therefore dependent upon external sources for financing our operations. As a result, our financial statements include disclosures expressing substantial doubt about our ability to continue as a going concern. Our financial statements do not include any adjustments that might result from the outcome of the uncertainty regarding our ability to continue as a going concern. This disclosure with respect to our ability to continue as a going concern could materially limit our ability to raise additional funds through the issuance of equity or debt securities or otherwise. Future reports on our financial statements may continue to include such disclosures. If we cannot continue as a going concern, our stockholders may lose their entire investment in our common stock.

Historically, we have financed our operations through private and public placement of equity securities. Our ability to obtain financing is subject to multiple risks, many of which are beyond our control. We intend to raise additional capital in order to fund our operations and grow our business. We expect that we will continue to generate substantial operating losses for the foreseeable future assuming that the 2022 License Agreement is consummated and this offering is consummated until we complete development of DA-1241 or DA-1726 or our other product candidates and seek regulatory approvals to market such product candidates.

We plan to continue to fund our operations primarily through utilization of our current financial resources and additional raises of capital. We may raise funds from our current investors as well as potential outside investors. We expect to finance future cash needs through public or private equity or debt offerings or product collaborations. However, there is no assurance that such funding will be available to us or that it will be obtained on terms favorable to us or will provide us with sufficient funds to meet our objectives. Any failure to raise capital as and when needed could have a negative impact on our financial condition and on our ability to pursue our business plans and strategies.

***Raising additional capital may cause dilution to existing stockholders, restrict our operations or require us to relinquish rights to our technologies.***

Existing stockholders could suffer dilution or be negatively affected by fixed payment obligations we may incur if we raise additional funds through the issuance of additional equity securities or debt. Furthermore, these securities may have rights senior to those of our common stock and could contain covenants or protective rights that would restrict our operations and potentially impair our competitiveness, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. If we need to secure additional financing, such additional fundraising efforts may divert our management and research efforts from our day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates.

To the extent we obtain additional funding through product collaborations, these arrangements would generally require us to relinquish rights to some of our technologies, product candidates or products, and we may not be able to enter into such agreements, on acceptable terms, if at all. If we are unable to obtain additional funding on a timely basis, we may be required to curtail or terminate some or all of our development programs or product candidates.

***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.***

Assuming this offering is consummated and the 2022 License Agreement is consummated, our research and development efforts will be 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.***

Upon the consummation of this offering and the consummation of the 2022 License Agreement, we will have acquired exclusive 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 are making 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.

***Even if we obtain favorable clinical results, we may not be able to obtain regulatory approval for, or successfully commercialize, ANA001 or gemcabene.***

We are not permitted to market ANA001 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. As a condition to submitting an NDA to the FDA for ANA001, we must complete our ongoing Phase 2 clinical trial, conduct and complete further Phase 3 clinical trials, and any additional nonclinical studies or clinical trials required by the FDA. To date, we have completed the Phase 1 Single Ascending Dosing (SAD) study and two Multiple Ascending Dosing (MAD) studies for ANA001. ANA001 may not be successful in clinical trials or receive regulatory approval. Further, ANA001 may not receive regulatory approval even if it is successful in clinical trials. Obtaining approval of an NDA is a complex, lengthy, expensive and uncertain process that typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, the policies or regulations, or the type and amount of clinical data necessary to gain approval, may change during the course of a product candidate's clinical development and may vary among jurisdictions. Our development activities could be harmed or delayed by a partial shutdown of the U.S. government, including the FDA. We have not obtained regulatory approval for any product candidate and it is possible that ANA001 will never obtain regulatory approval. The FDA may delay, limit or deny approval of ANA001 for many reasons, including, among others:

- the results of our clinical trials may not meet the level of statistical or clinical significance required by the FDA for marketing approval;
- the FDA may disagree with the number, design, size, conduct or implementation of our clinical trials;
- the FDA may not approve the formulation, labeling or specifications of ANA001;
- the FDA may require that we conduct additional clinical trials;
- the contract research organizations (“CROs”) or the clinical investigators that we retain to conduct our clinical trials may take actions outside of our control that materially adversely impact our clinical trials;
- we, our CROs or clinical investigators may fail to perform in accordance with the FDA’s good clinical practice (“GCP”) requirements;
- the FDA may disagree with our interpretation of data from our preclinical studies and clinical trials;
- the FDA may find deficiencies with the manufacturing processes or facilities of third-party manufacturers with which we contract; or
- the policies or regulations of the FDA may significantly change in a manner that renders our clinical data insufficient for approval or may require that we amend or submit new clinical protocols.

In addition, similar reasons may cause the EMA or other regulatory authorities to delay, limit or deny approval of ANA001 or gemcabene outside the United States. Any of these factors, many of which are beyond our control, could jeopardize our ability to obtain regulatory approval for and successfully market ANA001 or gemcabene.

Alternatively, even if we obtain regulatory approval, that approval may be for indications or patient populations that are not as broad as we intend or desire or may require labeling that includes significant use or distribution restrictions or safety warnings. We may also be required to perform additional, unanticipated clinical trials to obtain approval or be subject to additional post marketing testing requirements to maintain regulatory approval. In addition, regulatory authorities may withdraw their approval of a product or the FDA may require a risk evaluation and mitigation strategy (“REMS”) for a product, which could impose restrictions on its distribution. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

Gemcabene was being evaluated in a Phase 2 randomized, double-blind, placebo-controlled study to assess its efficacy safety and tolerability in patients with severe hypertriglyceridemia. In January 2016, the gemcabene Phase 2 clinical study was placed on partial clinical hold as the FDA requested 2-year rat and

mouse carcinogenicity studies to be completed and submitted. The study currently remains on partial clinical hold for the treatment of dyslipidemia. NeuroBo is currently assessing the path forward for gemcabene for additional indications including COVID-19. As a result, there is a significant uncertainty around our development of gemcabene.

***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.

***Our pursuit of potential therapeutic and prophylactic treatments for COVID-19 is in an early stage and subject to many risks. We may be unable to receive approval for any of our COVID-19 product candidates a timely manner, if at all, and our COVID-19 product candidates may never be approved.***

We may experience difficulties or delays in enrolling patients in clinical trials due to the impact of the global COVID-19 pandemic or other reasons. Many of the risks related to the development of these product candidates are beyond our control, including risks related to clinical development, the regulatory submission process, potential threats to our intellectual property rights, macro issues such as the ongoing invasion of Ukraine and manufacturing delays or difficulties. We may be unable to produce an efficacious and/or approved product for the treatment of patients with early COVID-19 in a timely manner, if at all.

The results of preclinical studies from our COVID-19 product candidates may not be predictive of the results of clinical trials, and the results of any early-stage clinical trials we commence may not be predictive of the results of the later-stage clinical trials. There can be no assurance that any of our clinical trials for our COVID-19 product candidates, or any other of our product candidates, will ultimately be successful or support further clinical development. In addition, the interpretation of the data from our clinical trials of ANA001 or Gemcabene by the FDA and other regulatory agencies may differ from our interpretation of such data and the FDA or other regulatory agencies may require that we conduct additional studies or analyses. Any of these factors could delay or prevent us from receiving regulatory approval of ANA001 or Gemcabene and there can be no assurance that any such product candidate will be approved in a timely manner, if at all.

If the COVID-19 outbreak is effectively contained or the risk of coronavirus infection is diminished or eliminated before we can successfully develop and manufacture our product candidates, the commercial viability of such product candidate may be diminished or eliminated. We are also committing financial resources and personnel to the development of these product candidates which may cause delays in or otherwise negatively impact our other development programs, despite uncertainties surrounding the longevity and extent of coronavirus as a global health concern. Our business could be negatively impacted by our allocation of significant resources to a global health threat that is unpredictable and could rapidly dissipate or against which our treatment, if successfully developed, may not be effective. In addition, other parties are currently producing therapeutic and vaccine candidates for COVID-19, which may be more efficacious or may be approved prior to our product.

***The regulatory pathway for ANA001 and Gemcabene is continually evolving, and may result in unexpected or unforeseen challenges.***

The speed at which parties are acting to create and test many therapeutics and vaccines for COVID-19 is unusual, and evolving or changing plans or priorities within the FDA, including those based on new knowledge of COVID-19 and how the disease affects the human body, may significantly affect the regulatory timeline for our product candidates. Results from ongoing clinical trials and discussions with regulatory authorities may raise new questions and require us to redesign proposed clinical trials, including revising proposed endpoints or adding new clinical trial sites or cohorts of subjects. Any such developments could delay the development timeline for our product candidates and materially increase the cost of the development for such candidates.

***In light of the COVID-19 pandemic, it is possible that one or more government entities may take actions that directly or indirectly have the effect of abrogating some of our rights or opportunities. If we were to develop a treatment for COVID-19, the economic value of such a therapeutic treatment to us could be limited.***

Various government entities, including the U.S. government, are offering incentives, grants and contracts to encourage additional investment by commercial organizations into preventative and therapeutic agents against coronavirus, which may have the effect of increasing the number of competitors and/or providing advantages to known competitors. Accordingly, there can be no assurance that we will be able to successfully establish a competitive market share for our COVID-19 therapeutic treatments, if any.

***We are currently evaluating alternatives with respect to NB-01 and may not be able to develop NB-01 pursuant to other pathways, including as an orphan drug or as a nutraceutical candidate.***

NB-01 has successfully completed two Phase 2 proof-of-concept clinical trials for PDN. However, in light of the present business environment including the impact of the COVID-19 disease that emerged in December 2019 as a global pandemic, we have determined to cease development of NB-01 on the prior regulatory pathway and not advance to Phase 3 clinical trials. We are currently evaluating alternatives with respect to the NB-01 asset. Among these alternatives, we may bring this asset to the market through a different regulatory pathway. Development of NB-01 as an orphan drug is among the alternatives we are considering, and we may conduct feasibility studies to identify a rare disease relevant to NB-01. Additionally, we are considering marketing the NB-01 product line as nutraceutical (non-pharmaceutical) products. There is no assurance that we will be able to pursue an alternative to take NB-01 to market using one of the alternatives referred to above or otherwise.

Our ability to successfully develop NB-01 as an orphan drug would be subject to the following additional risks, among others:

- the results from different types of animal models could be inconsistent from the previous data we have;
- a limited number of potential participants could make clinical trials for NB-01 difficult;
- disparate locations of a limited number of potential participants could make clinical trials difficult; and
- batch-by-batch consistency is difficult to achieve in clinical trials with small numbers of participants.



Our ability to successfully develop NB-01 as a nutraceutical product would be subject to the following risks, among others:

- the future growth and profitability of NB-01 would depend in large part upon our ability to successfully hire personnel with requisite marketing expertise, the effectiveness and efficiency of our marketing efforts and our ability to select effective markets and media in which to market and advertise;
- our inability to properly manage, motivate and retain third party distributors for NB-01, as applicable, could have a material adverse effect on us;
- the success of NB-01 would likely be linked to the size and growth rate of the vitamin, mineral and dietary supplement market, and an adverse change in the size or growth rate of that market could have a material adverse effect on us; and
- unfavorable publicity or consumer perception of NB-01 and any similar products distributed by other companies could have a material adverse effect on us.

***Product candidates may cause undesirable side effects that could delay or prevent their marketing approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any, including marketing withdrawal.***

Undesirable side effects caused by any of our product candidates that we may develop or acquire could cause us or the FDA or other regulatory authorities to interrupt, delay or halt our clinical trials and could result in more restrictive labels or the delay or denial of marketing approval by the FDA or other regulatory authorities of such product candidates. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of these or other side effects. In such an event, our trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. In addition, any drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

Further, clinical trials by their nature utilize a sample of the potential patient population. With a limited number of patients, rare and severe side effects of our product candidates may only be uncovered with a significantly larger number of patients exposed to the product candidate. If our product candidates receive marketing approval and we or others identify undesirable side effects caused by such product candidates (or any other similar drugs) after such approval, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw or limit their approval of such product candidates;
- regulatory authorities may require the addition of labeling statements, such as a “boxed” warning or a contraindication;
- we may be required to recall the product, change the way such product candidates are distributed or administered, conduct additional clinical trials or change the labeling of the product candidates;
- regulatory authorities may require a Risk Evaluation and Mitigation Strategy (REMS) plan to mitigate risks, which could include medication guides to be distributed to patients, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools;
- we may be subject to regulatory investigations and government enforcement actions;
- we may be subject to fines, injunctions or the imposition of civil or criminal penalties;
- we may decide to remove such product candidates from the marketplace after they are approved;
- the product may be rendered less competitive and sales may decrease;
- we could be sued and held liable for injury caused to individuals exposed to or taking its product candidates; and
- our reputation may suffer.



We believe that any of these events could prevent us from achieving or maintaining market acceptance of the affected product candidates and could substantially increase the costs of commercializing our product candidates, if approved, and significantly impact our ability to successfully commercialize our product candidates and generate revenues.

***Delays in our clinical trials may lead to a delay in the submission of marketing approval applications and jeopardize our ability to potentially receive approvals and generate revenues from the sale of our products.***

We may experience delays in clinical trials. We do not know whether planned clinical trials will begin or enroll subjects on time, need to be redesigned or be completed on schedule, if at all. Clinical trials may be delayed, suspended or terminated for a variety of reasons, such as:

- delay or failure in reaching agreement with the FDA or a comparable foreign regulatory authority on a trial design that we are able to execute;
- delay or failure in obtaining authorization to commence a trial or inability to comply with conditions imposed by a regulatory authority regarding the scope or design of a clinical trial;
- inability, delay or failure in identifying and maintaining a sufficient number of trial sites, many of which may already be engaged in competing clinical trial programs;
- issues with the manufacture of drug substance for use in clinical trials;
- delay or failure in recruiting and enrolling suitable subjects to participate in a trial;
- delay or failure in having subjects complete a trial or return for post-treatment follow-up;
- clinical sites and investigators deviating from trial protocol, failing to conduct the trial in accordance with regulatory requirements, or dropping out of a trial;
- delay or failure in reaching agreement on acceptable terms with prospective clinical research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- delay or failure in obtaining institutional review board, or IRB, approval to conduct a clinical trial at each site;
- delays resulting from negative or equivocal findings of the Data Safety Monitoring Board, or DSMB, if any;
- ambiguous or negative results;
- decision by the FDA, a comparable foreign regulatory authority, or recommendation by a DSMB to suspend or terminate clinical trials at any time for safety issues or for any other reason;
- conflicts affecting clinical trial sites and regions where clinical trials are being completed;
- lack of adequate funding to continue the product development program; or
- changes in governmental regulations or requirements.

Any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may significantly harm our business, financial condition and prospects. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

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

If the 2022 License Agreement is consummated, 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 than 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, liraglutide (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.

#### ***Our commercial success depends upon attaining significant market acceptance of our product candidates, if approved, among hospitals, physicians, patients and healthcare payors.***

Even if we obtain regulatory approval for any of our product candidates that we may develop or acquire in the future, the product may not gain market acceptance among hospitals, physicians, health care payors, patients and the medical community. Market acceptance of any of our product candidates for which we receive regulatory approval depends on a number of factors, including:

- the clinical indications for which the product candidate is approved;
- acceptance by major operators of hospitals, physicians and patients of the product candidate as a safe and effective treatment, particularly the ability of our product candidates to establish themselves as a new standard of care in the treatment paradigm for the indications that we are pursuing;
- the potential and perceived advantages of our product candidates over alternative treatments as compared to the relative costs of the product candidates and alternative treatments;

- the willingness of physicians to prescribe, and patients to take, a product candidate that is based on a botanical source;
- the prevalence and severity of any side effects with respect to our product candidates, and any elements that may be imposed by the FDA under a REMS program that could discourage market uptake of the products;
- the availability of adequate reimbursement and pricing for any approved products by third party payors and government authorities;
- inability of certain types of patients to take our product;
- demonstrated ability to treat patients and, if required by any applicable regulatory authority in connection with the approval for target indications, to provide patients with incremental cardiovascular disease benefits, as compared with other available therapies;
- the relative convenience and ease of administration of our product candidates, including as compared with other treatments available for approved indications;
- limitations or warnings contained in the labeling approved by the FDA;
- availability of alternative treatments already approved or expected to be commercially launched in the near future;
- the effectiveness of our sales and marketing strategies;
- guidelines and recommendations of organizations involved in research, treatment and prevention of various diseases that may advocate for alternative therapies;
- the willingness of patients to pay out-of-pocket in the absence of third-party coverage;
- physicians or patients may be reluctant to switch from existing therapies even if potentially more effective, safe or convenient;
- efficacy, safety, and potential advantages compared to alternative treatments;
- the ability to offer our product for sale at competitive prices;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- any restrictions on the use of our product together with other medications;
- interactions of our product with other medicines patients are taking; and
- the timing of market introduction of our products as well as competitive products.

There may be delays in getting our product candidates, if approved, on hospital or insurance formularies or limitations on coverages that may be available in the early stages of commercialization for newly approved drugs. If any of our product candidates are approved but fail to achieve market acceptance among hospitals, physicians, patients or health care payors, we will not be able to generate significant revenues, which would have a material adverse effect on our business, prospects, financial condition and results of operations.

***Even if we are able to commercialize a future pharmaceutical drug candidate, the profitability of such product candidate will likely depend in significant part on third-party reimbursement practices, which, if unfavorable, would harm our business.***

Our ability to commercialize a drug successfully will depend in part on the extent to which coverage and adequate reimbursement will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that coverage will be available for

any product candidate that we commercialize and, if coverage is available, whether the level of reimbursement will be adequate. Assuming we obtain coverage for our product candidates, if approved, by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. Patients who are prescribed medications for the treatment of their conditions, and their prescribing physicians, generally rely on third-party payors to reimburse all or part of the costs associated with their prescription drugs. Patients are unlikely to use a product candidate, if approved, unless coverage is provided and reimbursement is adequate to cover all or a significant portion of the cost of our products. Therefore, coverage and adequate reimbursement is critical to new product acceptance. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval.

There may be significant delays in obtaining reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which a product candidate is approved by the FDA or similar regulatory authorities outside the United States. Moreover, eligibility for reimbursement does not imply that any product will be paid for in all cases or at a rate that covers its costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for a new product, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the product and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost medicines and may be incorporated into existing payments for other services. Net prices for products may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of medicines from countries where they may be sold at lower prices than in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. However, no uniform policy requirement for coverage and reimbursement for drug products exists among third-party payors in the United States. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payors for any approved products that we develop could have an adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

***Product liability lawsuits against us could cause us to incur substantial liabilities and could limit commercialization of any product candidate that we may develop.***

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk if we commercially sell any product that we may develop. Product liability claims might be brought against us by patients, healthcare providers or others selling or otherwise coming into contact with any of our products or future product candidate during product testing, manufacturing, marketing or sale. For example, we may be sued on allegations that a product candidate caused injury or that the product is otherwise unsuitable. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, including as a result of interactions with alcohol or other drugs, negligence, strict liability, and a breach of warranties. Claims could also be asserted under state consumer protection acts.

If we cannot successfully defend against claims that our product caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidate that we are developing;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- increased FDA warnings on product labels;
- significant costs to defend the related litigation;



- substantial monetary awards to trial participants or patients;
- distraction of management's attention from our primary business;
- loss of revenue;
- the inability to commercialize any product candidate that we may develop;
- the removal of a product from the market; and
- increased insurance costs.

We do not currently maintain clinical trial insurance coverage for clinical trials. Even if we obtain such insurance in the future, it may not be adequate to cover all liabilities that we may incur. Insurance coverage is increasingly expensive. We may not be able to obtain or maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

***If we or our third-party manufacturers fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have an adverse effect on the success of our business.***

Our research and development activities involve the controlled use of potentially hazardous substances, including chemical and biological materials, by us and our third-party manufacturers. Our manufacturers are subject to federal, state and local laws and regulations in the United States and abroad governing laboratory procedures and the use, manufacture, storage, handling and disposal of medical and hazardous materials. Although we believe that our manufacturers' procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards, we cannot completely eliminate the risk of contamination or injury resulting from medical or hazardous materials. As a result of any such contamination or injury, we may incur liability or local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. We do not have any insurance for liabilities arising from medical or hazardous materials. Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. Compliance with applicable environmental, health and safety laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business, prospects, financial condition or results of operations.

***We rely and will continue to rely on collaborative partners regarding the development of our research programs and product candidates.***

We are and expect to continue to be dependent on collaborations with partners relating to the development and commercialization of our existing and future research programs and product candidates. We had, have and will continue to have discussions on potential partnering opportunities with various pharmaceutical and medical device companies. If we fail to enter into or maintain collaborative agreements on reasonable terms or at all, our ability to develop our existing or future research programs and product candidates could be delayed, the commercial potential of our products could change, and our costs of development and commercialization could increase.

Our dependence on collaborative partners subjects it to a number of risks, including, but not limited to, the following:

- We may not be able to control the amount or timing of resources that collaborative partners devote to our research programs and product candidates;
- We may be required to relinquish significant rights, including intellectual property, marketing and distribution rights;
- We rely on the information and data received from third parties regarding our research programs and product candidates and will not have control of the process conducted by the third party in gathering and composing such data and information. We may not have formal or appropriate guarantees from our contract parties with respect to the quality and the completeness of such data;



- A collaborative partner may develop a competing product either by itself or in collaboration with others, including one or more of our competitors;
- Our collaborative partners' willingness or ability to complete their obligations under our collaboration arrangements may be adversely affected by business combinations or significant changes in a collaborative partner's business strategy; and/or
- We may experience delays in, or increases in the costs of, the development of our research programs and product candidates due to the termination or expiration of collaborative research and development arrangements.

***If we are unable to establish sales and marketing capabilities to market and sell our product candidates, if they are approved for such marketing, we may be unable to generate any revenue.***

In order to market and sell our product candidates in development, we currently intend to build and develop our own sales, marketing and distribution operations. Although our management team has previous experience with such efforts for pharmaceutical products, there can be no assurance that we will be successful in building these operations. The establishment and development of our own commercial sales and marketing teams to discuss any products we may develop will be expensive and time-consuming and could delay any product launch.

If we are unable to establish adequate sales, marketing and distribution capabilities, we may not be able to generate product revenue and may not become profitable. We will also be competing with many companies that currently have extensive and well-funded sales and marketing operations. If any of our product candidates are approved, we may be unable to compete successfully against these more established companies.

***If, in the future, we are unable to establish sales and marketing capabilities or to selectively enter into agreements with third parties to sell and market our product candidates, we may not be successful in commercializing our product candidates if and when they are approved.***

We do not have a sales or marketing infrastructure and have no experience in the sale, marketing or distribution of pharmaceutical products. To achieve commercial success for any approved product for which we retain sales and marketing responsibilities, we must either develop a sales and marketing organization or outsource these functions to other third parties. In the future, we may choose to build a focused sales and marketing infrastructure to sell some of our product candidates if and when they are approved.

There are risks involved both with establishing our own sales and marketing capabilities and with entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to commercialize our product candidates on our own include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe any future pharmaceutical products; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we enter into arrangements with third parties to perform sales, marketing and distribution services, our product revenue or the profitability of these product revenue may be lower than if we were to market and sell any products that we develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell and market our product candidates or may be unable to do so on terms that are favorable to us. We may have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we do not establish

sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

***Any product candidate for which we obtain marketing approval could be subject to marketing restrictions or withdrawal from the market, and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our products.***

Any pharmaceutical product candidate for which we obtain marketing approval will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, cGMP requirements, quality assurance and corresponding maintenance of records and documents and requirements regarding the distribution of samples to physicians and recordkeeping. Even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the medicine. The FDA closely regulates the post-approval marketing and promotion of drugs to ensure that they are marketed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use and if we do not market our products for their approved indications, we may be subject to enforcement action for off-label marketing and/or promotion.

In addition, later discovery of previously unknown problems with our products, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on such products, manufacturers or manufacturing processes;
- restrictions on the labeling, marketing, distribution or use of a product;
- requirements to conduct post-approval clinical trials;
- warning or untitled letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- fines, restitution or disgorgement of profits or revenue;
- suspension or withdrawal of marketing approvals for the drug products;
- refusal to permit the import or export of our products;
- product seizure; and
- injunctions or the imposition of civil or criminal penalties.

Any product marketed as a nutraceutical could also be subject to FDA review or adverse action and we could be forced to remove such product from the market.

***We or any potential collaborator may never receive regulatory approval to market our product candidates outside of the United States.***

The activities associated with the development and commercialization of pharmaceutical drugs are subject to comprehensive regulation by the FDA, other regulatory agencies in the United States and by comparable authorities in other countries. Failure to obtain regulatory approval for our product candidates will prevent us or any potential collaborator from commercializing our product candidates as pharmaceutical drugs. We have not received regulatory approval to market any of our product candidates in any jurisdiction, and we do not expect to obtain FDA or any other regulatory approvals to market any of our product candidates for the foreseeable future, if at all. The process of obtaining regulatory approvals is expensive,

often takes many years, if approval is obtained at all, and can vary substantially based upon the type, complexity and novelty of the product candidates involved.

***We may seek to avail ourselves of mechanisms to expedite and/or reduce the cost for development or approval of any of our product candidates or product candidates we may pursue in the future, such as fast track designation or orphan drug designation, but such mechanisms may not actually lead to a faster or less expensive development or regulatory review or approval process.***

We may seek fast track designation, priority review, orphan drug designation, or accelerated approval for any product candidate we may pursue in the future. For example, if a drug is intended for the treatment of a serious or life-threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the drug sponsor may apply for FDA fast track designation. However, the FDA has broad discretion with regard to these mechanisms, and even if we believe a particular product candidate is eligible for any such mechanism, it cannot assure you that the FDA would decide to grant it. Even if we obtain fast track or priority review designation or pursue an accelerated approval pathway, we may not experience a faster and/or less costly development process, review or approval compared to conventional FDA procedures. The FDA may withdraw a particular designation if it believes that the designation is no longer supported by data from our clinical development program.

***Current and future legislation may increase the difficulty and cost to obtain marketing approval of and commercialize our product candidates and affect the prices we may obtain.***

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict post-approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval. See the section titled “Item 1-Business-Government Regulation” above.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. New legislation or regulations may adversely affect the potential for our products as nutraceuticals. We cannot be sure whether additional legislative changes will be enacted, or whether FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals, if any, of our product candidates may be. In addition, increased scrutiny by the U.S. Congress of the FDA’s approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing conditions and other requirements.

***Governments outside the United States tend to impose strict price controls, which may adversely affect our revenues, if any.***

In some countries, particularly the countries of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of its product candidate to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed, possibly materially.

***Our relationships with healthcare providers and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings, among other penalties and consequences.***

Healthcare providers and third-party payors will play a primary role in the recommendation and prescription of any product candidate for which we obtain marketing approval. Our arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute any product candidate for which we obtain marketing approval.

Restrictions and obligations under applicable federal and state healthcare laws and regulations are noted in the section “Business -Government Regulation” below.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to it, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion of products from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

***We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws, and anti-money laundering laws and regulations. Compliance with these legal standards could impair its ability to compete in domestic and international markets. We can face criminal liability and other serious consequences for violations which can harm its business.***

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, various economic and trade sanctions regulations administered by the U.S. Treasury Department’s Office of Foreign Assets Controls, the U.S. Foreign Corrupt Practices Act of 1977, as amended, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors, and other partners from authorizing, promising, offering, or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties for clinical trials outside of the United States to sell our products abroad and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors, and other partners, even if it does not explicitly authorize or have actual knowledge of such activities. Our violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences.

***Our ability to use our NOLs to offset future taxable income may be subject to certain limitations***

In general, under Section 382 of Internal Revenue Code of 1986, as amended (the “Code”), a corporation that undergoes an “ownership change” is subject to limitations on its ability to utilize its carryforwards to offset future taxable income. Our existing NOL carryforwards, or NOLs, may be subject to limitations arising from previous ownership changes, including in connection with the 2019 and 2020 Mergers. Future changes in our stock ownership, some of which are outside of our control, could result in further ownership changes under Section 382 of the Code. There is also a risk that due to regulatory changes, such as suspensions on the use of NOLs, or other unforeseen reasons, our existing and any future NOLs could expire or otherwise be unavailable to offset future income tax liabilities.

We believe that we have undergone an ownership change as a result of our transactions in 2019 and 2020 and may undergo an additional ownership change if the 2022 License Agreement is consummated, however, we have not conducted a study to assess whether there have been multiple ownership changes since inception due to the significant complexity and cost associated with such a study.

***Tax matters, including the changes in corporate tax rates, disagreements with taxing authorities and imposition of new taxes could impact our results of operations and financial condition.***

We are subject to income and other taxes in the United States and our operations, plans and results are affected by tax and other initiatives. On December 22, 2017, comprehensive changes to the Code were signed

into law, informally titled the Tax Cuts and Jobs Act (the “Tax Act”). The Tax Act included significant changes that could materially impact the taxation of corporations, like us, including, among other things, changes to the corporate income tax rate, limitation of the tax deduction for interest expense to business interest income plus 30% of adjusted taxable income (except for certain small businesses), immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits (including changes to the orphan drug tax credit and changes to the deductibility of research and experimental expenditures that will be effective in the future). The Tax Act also included a limitation of the deduction for net operating losses (“NOLs”) generated in tax years beginning after December 31, 2017 to 80% of current year taxable income and the general elimination of carrybacks of NOLs generated in taxable years ending after December 31, 2017. However, the Coronavirus Aid, Relief, and Economic Security Act (“CARES Act”) signed into law on March 27, 2020, provided that NOLs generated in a taxable year beginning in 2018, 2019, or 2020 may now be carried back five years. In addition, the 80% taxable income limitation is temporarily removed, allowing NOLs to fully offset net taxable income. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the Tax Act and any future tax reform is uncertain and our business and financial condition could be adversely affected. The impact of the Tax Act and any future tax reform on holders of our common stock is likewise uncertain and could be adverse.

We are also subject to regular reviews, examinations, and audits by the IRS and other taxing authorities with respect to our taxes. Although we believe our tax estimates are reasonable, if a taxing authority disagrees with the positions we have taken, we could face additional tax liability, including interest and penalties. There can be no assurance that payment of such additional amounts upon final adjudication of any disputes will not have a material impact on our results of operations and financial position.

We also need to comply with new, evolving or revised tax laws and regulations. The enactment of or increases in tariffs, or other changes in the application or interpretation of the Tax Act, or on specific products that we may ultimately sell or with which our products compete, may have an adverse effect on our business or on our results of operations.

***Inadequate funding for the FDA and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.***

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, the ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies on which the combined organization’s operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, in our operations as a public company, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

***Federal legislation and actions by state and local governments may permit reimportation of drugs from foreign countries into the United States, including foreign countries where the drugs are sold at lower prices than in the United States, which could adversely affect our operating results.***

We may face competition for our product candidates, if approved, from cheaper alternatives sourced from foreign countries that have placed price controls on pharmaceutical products. The Medicare Modernization Act contains provisions that may change U.S. importation laws and expand pharmacists’

and wholesalers' ability to import cheaper versions of an approved drug and competing products from Canada, where there are government price controls. These changes to U.S. importation laws will not take effect unless and until the Secretary of Health and Human Services certifies that the changes will pose no additional risk to the public's health and safety and will result in a significant reduction in the cost of products to consumers. In July of 2021 President Biden issued an executive order to bolster health-care industry competition in the interest of lowering drug prices. Among its proposals are a push for the Food and Drug Administration to work with states to import prescription drugs from Canada. It remains to be seen how this action will affect the Company and the pharmaceutical industry as a whole.

#### **Risks Related to Dependence on Third Parties**

***We have relied and will rely on third-party clinical research organizations (CROs) to conduct our preclinical studies and clinical trials. If these CROs do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.***

We have relied upon and plan to continue to rely upon CROs and clinical data management organizations to monitor and manage data for our ongoing preclinical and clinical programs. Although we control only certain aspects of their activities, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities. We also rely on third parties to conduct our preclinical studies in accordance with Good Laboratory Practice, or GLP, requirements and the Laboratory Animal Welfare Act of 1966 requirements. We, our CROs and our clinical trial sites are required to comply with regulations and current Good Clinical Practices, or GCP, and comparable foreign requirements to ensure that the health, safety and rights of patients are protected in clinical trials, and that data integrity is assured. Regulatory authorities ensure compliance with GCP requirements through periodic inspections of trial sponsors and trial sites. If we, any of our CROs or our clinical trial sites fail to comply with applicable GCP requirements, the clinical data generated in our clinical trials or a specific site may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications.

Our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our ongoing clinical and preclinical programs. If CROs do not successfully carry out their contractual obligations or meet expected timelines or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed.

***We rely on third parties to manufacture our product candidates and preclinical and clinical drug supplies.***

We have no experience manufacturing our product candidates on a large clinical or commercial scale and have no manufacturing facility. We are currently dependent on Dong-A ST as our sole third party manufacturer for the manufacture of NB-01. We rely completely on third parties to supply and manufacture our preclinical and clinical drug supplies for Gemcabene and ANA001, and we intend to rely on third parties to produce commercial supplies of these product candidates.

We do not own or operate facilities for the manufacture of Gemcabene. We currently have no plans to build our own clinical or commercial scale manufacturing capabilities. We currently work exclusively with Dong-A ST as the sole manufacturer for the production of NB-01 and rely completely on third parties to supply and manufacture our preclinical and clinical drug supplies for Gemcabene and ANA001. To meet our projected needs for clinical supplies to support our activities through regulatory approval and commercial manufacturing, Dong-A ST or our other third party providers will need to provide sufficient scale of production for these projected needs. If any issues arise in the manufacturing and we are unable to arrange for alternative third-party manufacturing sources, we are unable to find an alternative third party capable of



reproducing the existing manufacturing method or we are unable to do so on commercially reasonable terms or in a timely manner, we may not be able to complete development of our product candidates, or market or distribute them.

In addition, under FDA's guidelines for botanical drug products, the harvesting and processing of the botanical raw materials that are the basis of our product candidates must be done in compliance with Good Agricultural and Collection Processes, or GACPs. We are relying on Dong-A ST and other third parties to ensure that their practices comply with applicable GACPs.

Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured our product candidates and preclinical and clinical drug supplies, including:

- reliance on the third party for regulatory compliance and quality assurance;
- the possibility of breach of the manufacturing agreement by the third party because of factors beyond our control (including a failure to synthesize and manufacture our product candidates or any products that we may eventually commercialize in accordance with our specifications);
- the possibility of termination or nonrenewal of the agreement by the third party, based on our own business priorities, at a time that is costly or damaging to us;
- delay in, or failure to obtain, regulatory approval of any of our product candidates because of the failure by our third-party manufacturer to comply with cGMP or failure to scale up manufacturing processes; and
- current manufacturer and any future manufacturers may not be able to manufacture our product candidates at a cost or in quantities or in a timely manner necessary to make commercially successful products.

If third-party manufacturers do not successfully carry out their contractual obligations or meet expected timelines or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates.

***We may engage in future acquisitions or in-licenses of technology that could disrupt our business, cause dilution to the organization's stockholders and harm our financial condition and operating results.***

While we currently have no specific plans to acquire any other businesses or in-license any additional products or technology, we may, in the future, make acquisitions or licenses of, or investments in, companies, products or technologies that we believe are a strategic or commercial fit with its current product candidates and business or otherwise offer opportunities for us. In connection with these acquisitions or investments, the organization may:

- issue stock that would dilute its stockholders' percentage of ownership;
- expend cash;
- incur debt and assume liabilities; and
- incur amortization expenses related to intangible assets or incur large and immediate write-offs.

We also may be unable to find suitable acquisition or license candidates and we may not be able to complete acquisitions or licenses on favorable terms, if at all. If we do complete an acquisition or license, we cannot assure you that it will ultimately strengthen our competitive position or that it will not be viewed negatively by customers, financial markets or investors. Further, future acquisitions or licenses could also pose numerous additional risks to our operations, including:

- problems integrating the purchased or licensed business, products or technologies;
- increases to our expenses;
- the failure to have discovered undisclosed liabilities of the acquired or licensed asset or company;



- diversion of management’s attention from their day-to-day responsibilities;
- harm to our operating results or financial condition;
- entrance into markets in which we have limited or no prior experience; and
- potential loss of key employees, particularly those of the acquired entity.

We may not be able to complete one or more acquisitions or effectively integrate the operations, products or personnel gained through any such acquisition without a material adverse effect on our business, financial condition and results of operations.

***We may form or seek strategic alliances or enter into additional licensing arrangements in the future, and we may not realize the benefits of such alliances or licensing arrangements.***

We may form or seek strategic alliances, create joint ventures or collaborations or enter into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our products and any future product candidates that we may develop. Any strategic alliance or collaboration may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business. Our likely collaborators include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies. If we enter into any such arrangements with any third parties, we will likely have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our products or any future product candidate. Our ability to generate revenues from these arrangements will depend on our collaborators’ abilities to successfully perform the functions assigned to them in these arrangements. We cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction.

Collaborations involving our product candidates or any future product candidate pose the following risks to us:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;
- collaborators may not pursue development and commercialization or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborator’s strategic focus or available funding or external factors such as an acquisition that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive;
- a collaborator with marketing and distribution rights to one or more product candidates may not commit sufficient resources to the marketing and distribution of any such product candidate;
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information or expose us to potential litigation;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- disputes may arise between the collaborators and us that result in the delay or termination of the research, development or commercialization of our product candidate or that result in costly litigation or arbitration that diverts management’s attention and resources;

- we may lose certain valuable rights under circumstances identified in its collaborations, including if it undergoes a change of control;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates;
- collaborators may learn about our discoveries and use this knowledge to compete with us in the future;
- the results of collaborators' preclinical or clinical studies could harm or impair other development programs;
- there may be conflicts between different collaborators that could negatively affect those collaborations and potentially others;
- the number and type of our collaborations could adversely affect our attractiveness to future collaborators or acquirers;
- collaboration agreements may not lead to development or commercialization of our product candidate in the most efficient manner or at all. If our present or future collaborator were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program under such collaboration could be delayed, diminished or terminated; and
- collaborators may be unable to obtain the necessary marketing approvals.

If future collaboration partners fail to develop or effectively commercialize our product candidates or any future product candidate for any of these reasons, such product candidate may not be approved for sale and our sales of such product candidate, if approved, may be limited, which would have an adverse effect on our operating results and financial condition.

***If we are not able to establish new collaborations on commercially reasonable terms, we may have to alter our development and commercialization plans.***

We may selectively seek additional third-party collaborators for the development and commercialization of our product candidates. Our likely collaborators for any collaboration arrangements include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies. If we enter into any such arrangements with any third parties, we will likely have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidates. Our ability to generate revenue from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements.

We may be restricted under existing collaboration agreements from entering into future agreements on certain terms with potential collaborators. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay our development program or one or more of our other development programs, delay our potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidate or bring it to market and generate product revenue.

***Our employees, principal investigators, CROs and consultants may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have a material adverse effect on our business.***

We are exposed to the risk that our employees, principal investigators, CROs and consultants may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include failures to

comply with FDA regulations or similar regulations of comparable foreign regulatory authorities, to provide accurate information to the FDA or comparable foreign regulatory authorities, to comply with manufacturing standards we have established, to comply with federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable foreign regulatory authorities, to report financial information or data accurately or to disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee or third-party misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity, such as employee training, may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending such action or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant fines or other sanctions.

### **Risks Related to Intellectual Property**

***If we are unable to obtain and maintain sufficient intellectual property rights, our competitive position could be harmed.***

Our commercial success depends in part on our ability to protect our proprietary technology and products. We rely on trade secret, patent, copyright and trademark laws, and confidentiality, licensing and other agreements with employees and third parties, all of which offer only limited protection. We depend in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our proprietary technology and products. Where we are permitted to do so under our license agreements, we seek to protect our proprietary position by filing patent applications in the United States and other countries that are related to our novel technologies and products that are important to our business.

The patent positions of biotechnology and pharmaceutical companies generally are highly uncertain, involve complex legal and factual questions and have in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patents, including those patent rights licensed to us by third parties, are highly uncertain.

The steps we have taken to protect our proprietary rights may not be sufficient to prevent misappropriation of our proprietary information or infringement of our intellectual property rights, both inside and outside the United States. If we are unable to adequately protect our intellectual property and proprietary technology, including through obtaining and maintaining patent protection for our technology and products, or if the scope of the patent protection obtained is not sufficient, our competitors could develop and commercialize technology and products similar or superior to ours, which could erode or negate any competitive advantage we may have and adversely affect our business.

With respect to patent rights, we do not know whether any of our owned or licensed pending patent applications for any of our product candidates will result in the issuance of patents that protect our technology or products, or which will effectively prevent others from commercializing competitive technologies and products. Our owned or licensed pending applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. Further, the examination process may require us or our licensors to narrow the claims, which may limit the scope of patent protection that may be obtained. Although we currently have, and the 2022 License Agreement includes, a number of issued patents that are exclusively licensed to us, the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and so issued patents that we own or have licensed from third parties may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in the loss of patent protection, the narrowing of claims in such patents, or the invalidity or unenforceability of such patents, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent

protection for our technology and products. Protecting against the unauthorized use of our owned and licensed patented technology, trademarks and other intellectual property rights is expensive, difficult and may, in some cases, not be possible. In some cases, it may be difficult or impossible to detect third party infringement or misappropriation of our intellectual property rights, even in relation to issued patent claims, and proving any such infringement may be even more difficult.

***Laws and rulings by U.S. courts make it difficult to predict how patents will be issued or enforced in the biotechnology industry.***

Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may have a significant impact on our ability to protect our technology and enforce our intellectual property rights. There have been numerous changes to the patent laws and to the rules of the United States Patent and Trademark Office, or USPTO, which may have a significant impact on our ability to protect our technology and enforce our intellectual property rights. For example, the Leahy-Smith America Invents Act, which was signed into law in 2011, includes a transition from a “first-to-invent” system to a “first-to-file” system, and changes the way issued patents are challenged. Certain changes, such as the institution of inter partes review proceedings, came into effect on September 16, 2012. Substantive changes to patent law associated with the America Invents Act may affect our ability to obtain patents, and, if obtained, to enforce or defend them in litigation or post-grant proceedings, all of which could harm our business.

Furthermore, the patent positions of companies engaged in the development and commercialization of biologics and pharmaceuticals are particularly uncertain. Two cases involving diagnostic method claims and “gene patents” have been decided by the Supreme Court. On March 20, 2012, the Supreme Court issued a decision in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, or *Prometheus*, a case involving patent claims directed to measuring a metabolic product in a patient to optimize a drug dosage amount for the patient. According to the Supreme Court, the addition of well-understood, routine or conventional activity such as “administering” or “determining” steps was not enough to transform an otherwise patent ineligible natural phenomenon into patent eligible subject matter. On July 3, 2012, the USPTO issued guidance indicating that process claims directed to a law of nature, a natural phenomenon or an abstract idea that do not include additional elements or steps that integrate the natural principle into the claimed invention such that the natural principle is practically applied and the claim amounts to significantly more than the natural principle itself should be rejected as directed to non-statutory subject matter. On June 13, 2013, the Supreme Court issued its decision in *Association for Molecular Pathology v. Myriad Genetics, Inc.*, or *Myriad*, a case involving patent claims held by Myriad Genetics, Inc. relating to the breast cancer susceptibility genes BRCA1 and BRCA2. Myriad held that isolated segments of naturally occurring DNA, such as the DNA constituting the BRCA1 and BRCA2 genes, is not patent eligible subject matter, but that complementary DNA, which is an artificial construct that may be created from RNA transcripts of genes, may be patent eligible. We cannot assure you that our current patent protection and our efforts to seek patent protection for our technology and products will not be negatively impacted by the decisions described above, rulings in other cases or changes in guidance or procedures issued by the USPTO.

Moreover, although the Supreme Court has held in *Myriad* that isolated segments of naturally occurring DNA are not patent-eligible subject matter, certain third parties could allege that activities that we may undertake infringe other gene-related patent claims, and we may deem it necessary to defend against these claims by asserting non-infringement and/or invalidity positions, or pay to obtain a license to these claims. In any of the foregoing or in other situations involving third-party intellectual property rights, if we are unsuccessful in defending against claims of patent infringement, we could be forced to pay damages or be subjected to an injunction that would prevent us from utilizing the patented subject matter. Such outcomes could harm our business.

***We may not be able to protect or practice our intellectual property rights throughout the world.***

In jurisdictions where we or our licensors have not obtained patent protection, competitors may use our owned or licensed intellectual property to develop their own products and, further, may export otherwise infringing products to territories where we or our licensors have patent protection, but where it is more difficult to enforce a patent as compared to the U.S. Such competitor products may compete with our product candidates, including ANA001, NB-01 and NB-02 and, if the 2022 License Agreement is consummated,

DA-1241 and DA-1726, if approved, or any future product candidate in jurisdictions where we or our licensors do not have issued or granted patents or where our owner or licensed issued or granted patent claims or other intellectual property rights are not sufficient to prevent competitor activities in these jurisdictions. The legal systems of certain countries, particularly certain developing countries, make it difficult to enforce patents and such countries may not recognize other types of intellectual property protection, particularly that relate to pharmaceuticals. This could make it difficult for us to prevent the infringement of our owned or licensed patents or marketing of competing products in violation of our proprietary rights generally in certain jurisdictions. Proceedings to enforce our owned or licensed patent rights in foreign jurisdictions could result in substantial cost and divert its efforts and attention from other aspects of our business.

The laws of some jurisdictions do not protect intellectual property rights to the same extent as the laws in the United States, and many companies have encountered significant difficulties in protecting and defending such rights in such jurisdictions. If we, or our licensors, encounter difficulties in protecting, or are otherwise precluded from effectively protecting, the intellectual property rights important for our business in such jurisdictions, the value of these rights may be diminished and we may face additional competition from others in those jurisdictions. Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we, or any of our licensors, are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position in the relevant jurisdiction may be impaired and our business and results of operations may be adversely affected.

***We may become involved in lawsuits to protect or enforce our owned or licensed intellectual property, which could be expensive, time consuming and unsuccessful.***

In addition to the possibility of litigation relating to infringement claims asserted against us, we may become a party to other patent litigation and other proceedings, including inter partes review proceedings, post-grant review proceedings, derivation proceedings declared by the USPTO and similar proceedings in foreign countries, regarding intellectual property rights with respect to our current or future technologies or product candidates or products. The cost to us of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Patent litigation and other proceedings may also absorb significant management time. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could impair our ability to compete in the marketplace.

Competitors may infringe or otherwise violate our intellectual property, including patents that may issue to or be licensed by us. As a result, we may be required to file claims in an effort to stop third-party infringement or unauthorized use. Any such claims could provoke these parties to assert counterclaims against us, including claims alleging that we infringe their patents or other intellectual property rights. This can be prohibitively expensive, particularly for a company of our size, and time-consuming, and even if we are successful, any award of monetary damages or other remedy we may receive may not be commercially valuable. In addition, in an infringement proceeding, a court may decide that our asserted intellectual property is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our owned or licensed intellectual property does not cover its technology. An adverse determination in any litigation or defense proceedings could put our owned or licensed intellectual property at risk of being invalidated or interpreted narrowly and could put our owned or licensed patent applications at risk of not issuing.

If the breadth or strength of our patent or other intellectual property rights, whether owned or licensed, is compromised or threatened, it could allow third parties to commercialize our technology or products or result in our inability to commercialize our technology and products without infringing third-party intellectual property rights. Further, third parties may be dissuaded from collaborating with us.

Interference or derivation proceedings brought by the USPTO or its foreign counterparts may be necessary to determine the priority of inventions with respect to our patent applications, and we or our

licensors may also become involved in other proceedings, such as re-examination proceedings, before the USPTO or its foreign counterparts. Due to the substantial competition in the pharmaceutical space, the number of such proceedings may increase. This could delay the prosecution of our pending patent applications or impact the validity and enforceability of any future patents that we may obtain. In addition, any such litigation, submission or proceeding may be resolved adversely to us and, even if successful, may result in substantial costs and distraction to our management.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. Moreover, intellectual property law relating to the fields in which we operate is still evolving and, consequently, patent and other intellectual property positions in our industry are subject to change and are often uncertain. We may not prevail in any of these suits or other efforts to protect its technology, and the damages or other remedies awarded, if any, may not be commercially valuable. During the course of this type of litigation, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, the market price for our common stock could be significantly harmed.

***Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.***

Our commercial success depends upon our ability to develop, manufacture, market and sell our product candidates, including ANA001, NB-01 and NB-02 and, if the 2022 License Agreement is consummated, DA-1241 and DA-1726, and to use our proprietary technologies without infringing the proprietary rights of third parties. We may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our products and technology, including interference and various post grant proceedings before the USPTO or non-U.S. opposition proceedings. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future.

As a result of any such infringement claims, or to avoid potential claims, we may choose or be compelled to seek intellectual property licenses from third parties. These licenses may not be available on acceptable terms, or at all. Even if we are able to obtain a license, the license would likely obligate us to pay license fees or royalties or both, and the rights granted to us likely would be nonexclusive, which would mean that our competitors also could obtain licenses to the same intellectual property. Ultimately, we could be prevented from commercializing a product candidate or technology or be forced to cease some aspect of our business operations if, as a result of actual or threatened infringement claims, we are unable to enter into licenses of the relevant intellectual property on acceptable terms. Further, if we attempt to modify a product candidate or technology or to develop alternative methods or products in response to infringement claims or to avoid potential claims, we could incur substantial costs, encounter delays in product introductions or interruptions in sales. Ultimately, such efforts could be unsuccessful.

***Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities.***

Litigation or other legal proceedings relating to intellectual property claims, with or without merit, is unpredictable and generally expensive and time consuming and is likely to divert significant resources from our core business, including distracting our technical and management personnel from their normal responsibilities. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock and negatively impact our ability to raise additional funds. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities.

We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings



more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating or from successfully challenging our intellectual property rights. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

***Our trade secrets are difficult to protect and if we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.***

In addition to seeking patents for some of our technologies and product candidates, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality, non-competition, non-solicitation, and invention assignment agreements with our employees and consultants that obligate them to assign to us any inventions developed in the course of their work for us. However, we cannot guarantee that we have executed these agreements with each party that may have or have had access to our trade secrets or that the agreements we have executed will provide adequate protection. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to seek patent protection on technology relating to our product candidates or obtain adequate remedies for such breaches. As a result, we may be forced to bring claims against third parties, or defend claims that they bring against us, to determine ownership of what we regard as our intellectual property. Monitoring unauthorized disclosure is difficult and we do not know whether the procedures that we have followed to prevent such disclosure are or will be adequate. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States may be less willing or unwilling to protect trade secrets.

Furthermore, if any of the technology or information that we protect as trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to, or independently developed by, a competitor, our competitive position would be harmed.

***Obtaining and maintaining our patent protection depends on compliance with various procedural, documentary, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.***

Periodic maintenance fees on any issued patent are due to be paid to the USPTO, and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other requirements during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we or our licensors fail to maintain the patents and patent applications covering our product candidates, our competitors might be able to enter the market, which would have a material adverse effect on our business.

***Intellectual property rights do not necessarily address all potential threats to our competitive advantage.***

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make product candidates that are similar to our candidates but that are not covered by the claims of the patents that we own or have exclusively licensed;



- we or our future licensors or collaborators might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed;
- we or our future licensors or collaborators might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our owned or exclusively licensed pending patent applications will not lead to issued patents;
- issued patents that we own or have exclusively licensed may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

Should any of these events occur, they could significantly harm our business, results of operations and prospects.

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

***If this offering is completed and the Series A Convertible Preferred Stock are issued to Dong-A and we receive stockholder approval for its conversion 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 this offering is completed and the Series A Convertible Preferred Stock are issued to Dong-A and we receive stockholder approval for its conversion 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 this offering is completed and the Series A Convertible Preferred Stock are issued to Dong-A and we receive stockholder approval for its conversion 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.***

Upon the closing of this offering and the Series A Convertible Preferred Stock are issued to Dong-A and we receive stockholder approval for its conversion 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.

***Provisions in our corporate charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.***

Provisions in our certificate of incorporation and the bylaws may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which our stockholders might otherwise receive a premium for their shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by stockholders to replace or remove their current management by making it more difficult for stockholders to replace members of our board. Among other things, these provisions:

- establish a classified board of directors such that not all members of the board are elected at one time;
- allow the authorized number of our directors to be changed only by resolution of our board of directors;
- limit the manner in which our stockholders can remove directors from the board;
- establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our board of directors;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;

- prohibit our stockholders from calling special meetings;
- authorize our board to issue preferred stock without stockholder approval, which preferred stock may include rights superior to the rights of the holders of common stock, and which could be used to institute a shareholder rights plan, or so-called “poison pill,” that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board; and
- require the approval of the holders of at least two-thirds of the votes that all our stockholders would be entitled to cast to amend or repeal certain provisions of our charter or bylaws.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with it for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

***We are a “smaller reporting company” and we cannot be certain if the reduced reporting requirements applicable to such companies could make our common stock less attractive to investors.***

We are a “smaller reporting company”, as defined in the Exchange Act. For as long as we continue to be an smaller reporting company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not “emerging growth companies”, including exemption from compliance with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002 (Sarbanes-Oxley Act), only being required to provide two years of audited financial statements in annual reports and reduced disclosure obligations regarding executive compensation in its periodic reports and proxy statements.

We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

***We have identified material weaknesses in our internal control over financial reporting that could, if not remediated, result in material misstatements in our financial statements or impair our ability to produce accurate and timely consolidated financial statements.***

We concluded that there were material weaknesses relating to our internal control over financial reporting relating to a lack of segregation of duties over certain financial processes, and logical access to financial reporting systems. For more information about these material weaknesses, see Part II, Item 9A (Controls and Procedures) of our Annual Report on Form 10-K for the year ended December 31, 2021, which is incorporated herein by reference. 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 the company’s annual or interim consolidated financial statements will not be prevented or detected on a timely basis.

Although we have begun to take measures to remediate these material weaknesses, the measures we have taken, and expect to take, to improve our internal controls may not be sufficient to address the issues identified, to ensure that our internal controls are effective or to ensure that the identified material weaknesses will not result in a material misstatement of our annual or interim consolidated financial statements. If we are unable to correct material weaknesses or deficiencies in internal controls in a timely manner, our ability to record, process, summarize and report financial information accurately and within the time periods specified in the rules and forms of the SEC will be adversely affected. This failure could negatively affect the market price and trading liquidity of our common stock, cause investors to lose confidence in our reported financial information, subject us to civil and criminal investigations and penalties, and materially and adversely impact our business and financial condition.

## **General Risks**

***Our business and operations would suffer in the event of system failures or unplanned events.***

Despite the implementation of security measures, our internal computer systems and those of our current and future contractors and consultants are vulnerable to damage from computer viruses,

unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we are not aware of any such material system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our product candidates could be delayed.

Furthermore, any unplanned event, such as flood, fire, explosion, tornadoes, earthquake, extreme weather condition, medical epidemics, power shortage, telecommunication failure or other natural or manmade accidents or incidents that result in us being unable to fully utilize the facilities, may have an adverse effect on our ability to operate the business, particularly on a daily basis, and have significant negative consequences on our financial and operating conditions. Loss of access to these facilities may result in increased costs, delays in the development of our product candidates or interruption of our business operations.

***We rely significantly on information technology and any failure, inadequacy, interruption or security lapse of that technology or loss of data, including any cyber security incidents, could compromise sensitive information related to our business, prevent us from accessing critical information or expose us to liability which could harm our ability to operate our business effectively and adversely affect our business and reputation.***

In the ordinary course of our business, our contract research organizations and other third parties on which we rely collect and store sensitive data, including legally protected patient health information, personally identifiable information about our employees, intellectual property, and proprietary business information. We manage and maintain our applications and data utilizing on-site systems. These applications and data encompass a wide variety of business-critical information, including research and development information and business and financial information.

The secure processing, storage, maintenance and transmission of this critical information is vital to our operations and business strategy. Despite the implementation of security measures, our internal computer systems and those of third parties with which we contract are vulnerable to damage from cyber-attacks, computer viruses, breaches, unauthorized access, interruptions due to employee error or malfeasance or other disruptions, or damage from natural disasters, terrorism, war and telecommunication and electrical failures. Any such event could compromise our networks and the information stored there could be accessed by unauthorized parties, publicly disclosed, lost or stolen. We have measures in place that are designed to detect and respond to such security incidents and breaches of privacy and security mandates. Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, government enforcement actions and regulatory penalties. Unauthorized access, loss or dissemination could also disrupt our operations, including our ability to conduct research, development and commercialization activities, process and prepare Company financial information, manage various general and administrative aspects of our business and damage our reputation, in addition to possibly requiring substantial expenditures of resources to remedy, any of which could adversely affect our business. The loss of clinical trial data could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. In addition, there can be no assurance that we will promptly detect any such disruption or security breach, if at all. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and our research, development and commercialization efforts could be delayed.

***An active trading market for our common stock may not be maintained.***

Our common stock is currently traded on the Nasdaq Capital Market, but we can provide no assurance that we will be able to maintain an active trading market for our shares on the Nasdaq Capital Market or any other exchange in the future. If there is no active market for our common stock, it may be difficult for our stockholders to sell shares without depressing the market price for the shares or at all.

***If securities analysts do not publish research or reports about our business or if they publish negative evaluations of our stock, the price of our stock could decline.***

If one or more analysts cover our business and downgrade their evaluations of our stock or publish inaccurate or unfavorable research about our business, the price of our stock could decline. If one or more of these analysts cease to cover our stock, we could lose visibility in the market for our stock, which in turn could cause our stock price and trading volume to decline.

***We incur increased costs as a result of operating as a public company and our management is required to devote substantial time to compliance initiatives.***

The Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the stock exchange upon which our common stock is listed and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations increase our legal and financial compliance costs and make some activities more time-consuming and costly. However, these rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

We are subject to Section 404 of the Sarbanes-Oxley Act and the related rules of the SEC that generally require our management and independent registered public accounting firm to report on the effectiveness of our internal control over financial reporting. However, for so long as we remain an “emerging growth company” as defined in the JOBS Act or a “smaller reporting company”, we intend to take advantage of certain exemptions from various reporting requirements that are applicable to public companies that are not emerging growth companies and/or smaller reporting companies, including, but not limited to, for emerging growth companies, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act. Once we are no longer an “emerging growth company” and if our public float is above \$75 million as of the last business day of our most recently completed second fiscal quarter or, if before such date, we opt to no longer take advantage of the applicable exemption, we will be required to include an opinion from our independent registered public accounting firm on the effectiveness of our internal control over financial reporting.

To achieve compliance with Section 404, we are required to engage in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we must dedicate internal resources, hire additional finance and accounting personnel, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting.

During the course of our review and testing, we may identify deficiencies and be unable to remediate them before we must provide the required reports. We or our independent registered public accounting firm may not be able to conclude on an ongoing basis that we have effective internal control over financial reporting, which could harm our operating results, cause investors to lose confidence in our reported financial information and cause the trading price of our stock to fall.

In addition, as a public company we are required to timely file accurate quarterly and annual reports with the SEC under the Exchange Act. In order to report our results of operations and financial statements on an accurate and timely basis, we will depend on CROs to provide timely and accurate notice of their costs to it. Any failure to report our financial results on an accurate and timely basis could result in sanctions, lawsuits, delisting of our shares from Nasdaq or other adverse consequences that would materially harm our business.

***We do not anticipate declaring or paying, in the foreseeable future, any cash dividends on our capital stock and, consequently, the ability of our stockholders to achieve a return on their investment will depend on appreciation in the price of our common stock.***

We have never declared or paid any cash dividend on our capital stock and do not currently intend to do so in the foreseeable future. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business. Therefore, the success of an investment in shares of our common stock will depend upon any future appreciation in their value. There is no guarantee that shares of our common stock will appreciate in value or even maintain the price at which you purchased them.

***Our Bylaws designate the Court of Chancery of the State of Delaware as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.***

Our Bylaws provide that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will generally be the sole and exclusive forum for any derivative action or proceeding brought on its behalf, any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders, any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, as amended, the certificate of incorporation or the bylaws or any other action asserting a claim governed by the internal affairs doctrine. This provision does not apply to claims arising under the Securities Act and the Exchange Act or any claim for which the federal courts have exclusive jurisdiction. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and to have consented to the provisions of the bylaws described above. This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and employees. Alternatively, if a court were to find this provision inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our business and financial condition.

***Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and stock price.***

The global credit and financial markets have experienced extreme volatility and disruptions in the past several years, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. We cannot assure you that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, or do not improve, it may make any necessary debt or equity financing more difficult, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require it to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive these difficult economic times, which could directly affect our ability to attain our operating goals on schedule and on budget.

#### **Risks Related to This Offering**

***Because our management will have broad discretion and flexibility in how the net proceeds from this offering are used, our management may use the net proceeds in ways with which you disagree or which may not prove effective.***

We currently intend to use the net proceeds from this offering as discussed under "Use of Proceeds" in this prospectus. We have not allocated specific amounts of the net proceeds from this offering for any of the foregoing purposes. Accordingly, our management will have significant discretion and flexibility in applying



the net proceeds of this offering. You will be relying on the judgment of our management with regard to the use of these net proceeds, and you will not have the opportunity, as part of your investment decision, to assess whether the net proceeds are being used appropriately. It is possible that the net proceeds will be invested in a way that does not yield a favorable, or any, return for us. The failure of our management to use such funds effectively could have a material adverse effect on our business, financial condition, operating results and cash flow.

***The liquidity and trading volume of our common stock could be low, and our ownership will be concentrated.***

The liquidity and trading volume of our common stock has at times been low in the past and could again be low in the future. If the liquidity and trading volume of our common stock is low, this could adversely impact the trading price of our shares, our ability to issue stock and our stockholders' ability to obtain liquidity in their shares.

Following this offering, the payment of the Upfront License Payment and the consummation of the private offering, Dong-A will hold approximately % of our outstanding common stock, assuming conversion of all of the Series B Convertible Preferred Stock into common stock and conversion of all of the Series A Convertible Preferred Stock into common stock, following stockholder approval of the issuance of voting shares as part of the Upfront License Payment and in the private offering. As a result, Dong-A will be able to affect the outcome of, or exert significant influence over, all matters requiring stockholder approval, including the election and removal of directors and any change in control. In particular, this concentration of ownership of our common stock could have the effect of delaying or preventing a change in control of us or otherwise discouraging or preventing a potential acquirer from attempting to obtain control of us. This, in turn, could have a negative effect on the market price of our common stock. It could also prevent our stockholders from realizing a premium over the market prices for their shares of common stock. Moreover, the interests of this concentration of ownership may not always coincide with our interests or the interests of other stockholders. The concentration of ownership also contributes to the low trading volume and volatility of our common stock.

***There is no public market for the Series B Convertible Preferred Stock or warrants being offered in this offering.***

The public offering price for the securities will be determined by negotiations between us, the underwriters and prospective investors, and may not be indicative of prices that will prevail in the trading market. We do not intend to apply to list the Series B Convertible Preferred Stock and the warrants on the Nasdaq Capital Market or any nationally recognized trading system, and accordingly, there will be no trading market for such warrants. In the absence of an active public trading market:

- you may not be able to resell your securities at or above the public offering price;
- the market price of our common stock may experience more price volatility; and
- there may be less efficiency in carrying out your purchase and sale orders.

***The market price of our common stock may be highly volatile, and you could lose all or part of your investment.***

The trading price of our common stock has been and is likely to continue to be volatile. This volatility may prevent you from being able to sell your securities at or above the price you paid for your securities.

Our stock price could be subject to wide fluctuations in response to a variety of factors, which include:

- whether we achieve our anticipated corporate objectives;
- termination of the lock-up agreement or other restrictions on the ability of our stockholders and other security holders to sell shares after this offering; and
- general economic or political conditions in the United States or elsewhere.

In addition, the stock market in general, and the stock of biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to



the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance.

***We are not currently in compliance with the continued listing requirements for Nasdaq. If the price of our common stock continues to trade below \$1.00 per share for a sustained period or we do not meet other continued listing requirements, our common stock may be delisted from the Nasdaq Capital Market, which could affect the market price and liquidity for our common stock and reduce our ability to raise additional capital.***

On March 18, 2022, we received written notice (the “Notification Letter”) from The Nasdaq Stock Market LLC (“Nasdaq”) notifying us that the Company was not in compliance with the minimum bid price requirements set forth in Nasdaq Listing Rule 5550(a)(2) for continued listing on the Nasdaq Capital Market. Nasdaq Listing Rule 5550(a)(2) requires listed securities maintain a minimum closing bid price of \$1.00 per share, and Nasdaq Listing Rule 5810(c)(3)(A) provides that a failure to meet the minimum closing bid price requirement exists if the deficiency continues for a period of 30 consecutive business days. Based on the closing bid price of the Company’s common stock for the 30 consecutive business days prior to the date of the Notification Letter, the Company did not meet the minimum closing bid price requirement. To regain compliance, the closing bid price of the Company’s common stock must be at least \$1.00 per share for a minimum of 10 consecutive business days at any time prior to September 14, 2022. On September 12, 2022, we effected a reverse stock split of our outstanding shares of our common stock at a ratio of one-for-thirty. On September 14, 2022, we were granted an extension period by Nasdaq to comply with the minimum closing bid price requirement. We anticipate that as of September 15, 2022, we will regain compliance with the minimum closing bid price requirement.

There can be no assurance that we will be able to regain compliance with the minimum bid price requirement or we will otherwise be in compliance with other Nasdaq listing criteria. If we fail to regain compliance with the minimum bid requirement or to meet the other applicable continued listing requirements for the Nasdaq Capital Market in the future and Nasdaq may delist our common stock.

Delisting from the Nasdaq could adversely affect our ability to raise additional financing through the public or private sale of equity securities, would significantly affect the ability of investors to trade our securities and would negatively affect the value and liquidity of our common stock. Delisting could also have other negative results, including the potential loss of confidence by employees, the loss of institutional investor interest and fewer business development opportunities. If our common stock is delisted by the Nasdaq the price of our common stock may decline and our common stock may be eligible to trade on the OTC Bulletin Board, another over-the-counter quotation system, or on the pink sheets where an investor may find it more difficult to dispose of their common stock or obtain accurate quotations as to the market value of our common stock. Further, if we are delisted, we would incur additional costs under requirements of state “blue sky” laws in connection with any sales of our securities. These requirements could severely limit the market liquidity of our common stock and the ability of our stockholders to sell our common stock in the secondary market.

In addition, if our common stock is delisted from the Nasdaq Capital Market and the trading price remains below \$5.00 per share, trading in our common stock might also become subject to the requirements of certain rules promulgated under the Exchange Act, which require additional disclosure by broker-dealers in connection with any trade involving a stock defined as a “penny stock” (generally, any equity security not listed on a national securities exchange or quoted on Nasdaq that has a market price of less than \$5.00 per share, subject to certain exceptions).

If we seek to implement a reverse stock split to remain listed on the Nasdaq Capital Market, the announcement or implementation of a reverse stock split could significantly negatively affect the price of our common stock. Additionally, in 2020, the SEC approved a previously proposed Nasdaq rule change to expedite delisting of securities with a closing bid price at or below \$0.10 for 10 consecutive trading days during any bid price compliance period and that have had one or more reverse stock splits with a cumulative ratio of one for 250 or more shares over the prior two-year period. In addition, if a company falls out of compliance with the \$1.00 minimum bid price after completing reverse stock splits over the immediately preceding two years that cumulatively result in a ratio one for 250 shares, the company will not be able to avail itself of any bid price compliance periods under Rule 5810(c)(3)(A), and Nasdaq will instead require the issuance of a Staff delisting determination. The company could appeal the determination to a hearings panel, which

could grant the company a 180-day exception to remain listed if it believes the company would be able to achieve and maintain compliance with the bid price requirement. Following the exception, the company would be subject to the procedures applicable to a company with recurring deficiencies (Nasdaq Rule 5815(d)(4)(B)).

***You will incur immediate and substantial dilution as a result of this offering.***

After giving effect to the sale by us of \_\_\_\_\_ shares of common stock (or Series B Convertible Preferred Stock) and accompanying warrants in this offering at an assumed combined public offering price of \$ \_\_\_\_\_ per share of common stock (or \$ \_\_\_\_\_ per share of Series B Convertible Preferred Stock) and accompanying warrants, after deducting underwriter fees and estimated offering expenses payable by us, investors in this offering can expect an immediate dilution of \$ per share. For a further description of the dilution that investors in this offering may experience, see “Dilution.”

In the past, we have issued shares of common stock and warrants in public offerings and private placements of our securities, and we have issued shares of common stock as compensation to our officers and directors. Our issuance of shares of common stock in the future, and the exercise of outstanding warrants or warrants that we may issue in the future, may result in additional dilution to investors in this offering.

***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 and the 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 warrants and the associated transaction documents. In addition, holders of Series B Convertible Preferred Stock and 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 warrants could also impede our ability to enter into certain transactions or obtain additional financing in the future.

***Holders of warrants purchased in this offering will have no rights as stockholders until such holders exercise their warrants and acquire our shares of common stock, except as set forth in the warrants.***

Except as set forth in the warrants, until holders of warrants acquire our shares of common stock upon exercise of the warrants, holders of the warrants have no rights with respect to our shares of common stock underlying such warrants, the holders will be entitled to exercise the rights of a stockholder of shares of common stock only as to matters for which the record date occurs after the exercise date.

***The warrants are speculative in nature.***

The warrants offered hereby do not confer any rights of share of common stock ownership on their holders, such as voting rights or the right to receive dividends, but rather merely represent the right to acquire shares of common stock at a fixed price. Specifically, commencing on the date of issuance, holders of the warrants may acquire the shares of common stock issuable upon exercise of such warrants at an exercise price of \$ \_\_\_\_\_ per share of common stock. Moreover, following this offering, the market value of the warrants is uncertain and there can be no assurance that the market value of the warrants will equal or exceed their respective public offering prices. There can be no assurance that the market price of the shares of common stock will ever equal or exceed the exercise price of the warrants, and consequently, whether it will ever be profitable for holders of warrants to exercise the warrants.

**SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS**

This prospectus contains forward-looking statements that are based on our management's beliefs and assumptions and on information currently available. This section should be read in conjunction with our financial statements and related notes incorporated by reference into this prospectus. The statements contained in this prospectus that are not historical facts are forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act.

Forward-looking statements can be identified by words such as "believe," "anticipate," "may," "might," "can," "could," "continue," "depends," "expect," "expand," "forecast," "intend," "predict," "plan," "rely," "should," "will," "may," "seek," or the negative of these terms and other similar expressions, although not all forward-looking statements contain these words. You should read these statements carefully because they discuss future expectations, contain projections of future results of operations or financial condition, or state other "forward-looking" information. These statements relate to our future plans, objectives, expectations, intentions and financial performance and the assumptions that underlie these statements.

These forward-looking statements are subject to a number of risks, uncertainties, and assumptions, including, but not limited to, those described in "Risk Factors." These forward-looking statements reflect our beliefs and views with respect to future events and are based on estimates and assumptions as of the date of this prospectus and are subject to risks and uncertainties. We discuss many of these risks in greater detail in the section titled "Risk Factors" and elsewhere in this prospectus. Given these uncertainties, you should not place undue reliance on these forward-looking statements. We qualify all of the forward-looking statements in this prospectus by these cautionary statements. Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in any forward-looking statements, whether as a result of new information, future events or otherwise.

In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this prospectus, and although we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted a thorough inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.

This prospectus also contains estimates, projections and other information concerning our industry, our business, and the markets for certain diseases, including data regarding the estimated size of those markets. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information. Unless otherwise expressly stated, we obtained this industry, business, market, and other data from reports, research surveys, studies, and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data, and similar sources.

## USE OF PROCEEDS

Assuming we sell all units offered pursuant to this prospectus, we estimate the net proceeds from this offering will be approximately \$            million (or approximately \$            million if the underwriters exercise their over-allotment option in full), based on an assumed public offering price of \$            per unit (the last reported sale price of our shares of common stock on the Nasdaq Capital Market on           , 2022), after deducting underwriting discounts and commissions and estimated offering expenses payable by us as described in “Underwriting” and excluding the proceeds, if any, from the exercise of the warrants sold in this offering.

We intend to use the net proceeds from this offering and the private offering for funding development of our new inlicensed product candidates, working capital and general corporate purposes.

The allocation of the net proceeds of the offering represents our estimates based upon our current plans and assumptions regarding industry and general economic conditions, our future revenues and expenditures.

The amounts and timing of our actual use of net proceeds will vary depending on numerous factors, including the relative success and cost of our research and development programs and our ability to gain access to additional financing. As a result, our management will have broad discretion in the application of the net proceeds, and investors will be relying on our management’s judgment regarding the application of the net proceeds of this offering. In addition, we might decide to postpone or not pursue certain development activities if the net proceeds from the offering and any other sources of cash are less than expected.

Pending the application of the net proceeds as described above, we will hold the net proceeds from this offering in short-term, interest-bearing, securities.

We believe that the net proceeds of this offering and the private offering, together with cash on hand, will be sufficient to fund our operations throughout           , assuming we sell all of the securities being offered hereby, and we believe that we will need to raise additional capital to fund our operations thereafter. Additional capital may not be available on terms favorable to us, or at all. If we raise additional funds by issuing equity securities, our stockholders may experience dilution. Debt financing, if available, may involve restrictive covenants or additional security interests in our assets. Any additional debt or equity financing that we complete may contain terms that are not favorable to us or our stockholders. If we raise additional funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish some rights to our technologies or products or grant licenses on terms that are not favorable to us. If we are unable to raise adequate funds, we may have to delay, reduce the scope of, or eliminate some or all of, our development programs or liquidate some or all of our assets.

## CAPITALIZATION

The following table summarizes our cash and cash equivalents and capitalization as of June 30, 2022:

- on an actual basis; and
- on an as adjusted basis, giving effect to (i) the sale by us of \_\_\_\_\_ Class A Units (each Class A Unit consisting of one share of common stock and one Warrant to purchase \_\_\_\_\_ shares of common stock) in this offering at an assumed public offering price of \$ \_\_\_\_\_ per Class A Unit, which is the last reported sale price of our shares of common stock on the Nasdaq Capital Market on \_\_\_\_\_, 2022, after deducting the estimated underwriting discounts and commissions and estimated offering expenses, and assuming no sale of Class B Units (each Class B Unit consisting of one share of Series B Convertible Preferred Stock and \_\_\_\_\_ Warrants) in this offering and no exercise of any warrants included in the units, and (ii) the issuance of our Series A Convertible Preferred Stock valued at \$22 million in respect of the Upfront License Payment and the sale of \$15 million of Series A Convertible Preferred Stock to Dong-A in the private offering.

	As of June 30, 2022	
	Actual	As Adjusted <sup>(1)(3)</sup>
	(in thousands, except share data)	
Cash and cash equivalents	\$ 8,849	\$ _____
Stockholders' equity:		
Preferred stock, \$0.001 par value, 10,000,000 shares authorized; none issued, actual and _____ shares of Series A Convertible Preferred Stock, _____ and _____ shares of Series B Convertible Preferred Stock authorized; _____ shares of Series A Convertible Preferred Stock and no shares of Series B Convertible Preferred Stock issued, as adjusted <sup>(2)</sup>	\$ —	\$ _____
Common stock, \$0.001 par value, 100,000,000 shares authorized; 888,693 issued and outstanding, actual; _____ shares issued and outstanding, as adjusted		1
Additional paid-in capital	96,838	
Accumulated deficit	(88,006)	( _____ )
Total stockholders' equity	8,833	_____
Total capitalization	\$ 8,833	\$ _____

- (1) A \$1.00 increase or decrease in the assumed public offering price of \$ \_\_\_\_\_ per Class A Unit, which is the last reported sale price of our shares of common stock on the Nasdaq Capital Market on \_\_\_\_\_, 2022, would increase or decrease, as appropriate, our as adjusted cash and cash equivalents, additional paid-in capital, total assets, total stockholders' equity and total capitalization by approximately \$ \_\_\_\_\_ million, assuming the number of units offered by us as set forth on the cover page of this prospectus remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.
- (2) The shares of our Series A Convertible Preferred Stock being issued as part of the Upfront License Payment and being sold in the private offering are not initially convertible into shares of our common stock. This table does not give effect to such conversion.
- (3) All proceeds from the sale of Class A Units and Series A Convertible Preferred Stock have been reflected within Stockholders' equity for purposes of this table. The Company will be required to complete an assessment of the accounting and valuation for such instruments, which may result in a portion of the proceeds being classified outside of Stockholder's equity and remeasured to fair value each reporting period (if liability-classified instruments). Such assessment will be completed in connection with the preparation of our consolidated financial statements for the period in which the sales occur.

Similarly, an increase or decrease of 10,000 in the number of units offered by us, based on the assumed public offering price of \$ \_\_\_\_\_ per Class A Unit, would increase or decrease our as adjusted cash and cash

equivalents, additional paid-in capital, total assets, total stockholders' equity and total capitalization by approximately \$            million, after deducting underwriting discounts and commissions and estimated offering expenses payable by us. The information discussed above is illustrative only and will adjust based on the actual public offering price, the actual number of units we offer in this offering, and other terms of this offering determined at pricing.

The total number of shares of common stock outstanding as of the date of this prospectus and after this offering is based on 888,693 shares outstanding as of June 30, 2022, assumes the sale of units based on an assumed public offering price of \$            , the last reported sales price of a share of our common stock on the Nasdaq Capital Market on            , 2022, and excludes the following other securities as of June 30, 2022:

- 36,493 shares of common stock issuable upon the exercise of stock options outstanding as of June 30, 2022, at a weighted-average exercise price of \$99.62 per share;
- 228,235 shares of common stock issuable upon the exercise of warrants outstanding as of June 30, 2022, at a weighted-average exercise price of \$140.07;
- 167,748 shares of common stock reserved for future issuance under our 2019 Equity Incentive Plan as of June 30, 2022.
- 12,778 shares of common stock reserved for future issuance under our 2021 Inducement Plan as of June 30, 2022;
- shares of common stock issuable upon exercise of the warrants included in this offering and the substantially similar warrants issued in the private offering, at an exercise price of \$            per share;
- shares of common stock issuable upon conversion of the Series A Convertible Preferred Stock issued as part of the Upfront License Payment; and
- shares of common stock issuable upon conversion of the Series A Convertible Preferred Stock issued in the private offering.

On September 12, 2022, we effected the 2022 Reverse Stock Split. As a result of the foregoing, every thirty (30) shares of our common stock outstanding was automatically changed and reclassified into one (1) new share of common stock. Holders of common stock that would have otherwise received a fractional share of common stock pursuant to the 2022 Reverse Stock Split received cash in lieu of the fractional share. Unless indicated otherwise, the numbers set forth in this prospectus have been adjusted to reflect the 2022 Reverse Stock Split.

Except as otherwise noted, all information in this prospectus reflects and assumes (i) no sale of Class B Units, which, if sold, for each share of common stock underlying a share of Series B Convertible Preferred Stock, the number of shares of common stock that we are offering will be decreased on a one-for-one basis, (ii) no exercise of outstanding options issued under our equity incentive plans, (iii) no exercise of any warrants issued in this offering and (iv) no exercise of the underwriters' option to purchase additional shares of common stock and/or warrants to purchase additional shares of common stock.

## DILUTION

If you invest in our securities, your ownership interest may be diluted to the extent of the difference between the amount per unit paid by purchasers, assuming that only Class A Units are issued and no value is attributed to the warrants, in this public offering and the as adjusted net tangible book value per share of our common stock immediately after the closing of this offering. Such calculation does not reflect any potential dilution associated with the sale and exercise of warrants, which would cause the actual dilution to you to be higher.

Our net tangible book value is the amount of our total tangible assets less our total liabilities. Net tangible book value per share is our net tangible book value divided by the number of shares of common stock outstanding as of June 30, 2022. Our net tangible book value as of June 30, 2022 was \$8.8 million, or \$9.94 per share, based on 888,693 shares of our common stock outstanding as of June 30, 2022.

After giving effect to the sale of Class A Units by us in this offering at an assumed public offering price of \$ per Class A Unit, the issuance by us as part of the Upfront License Payment of an aggregate of \$22 million of our Series A Convertible Preferred Stock and the sale by us in the private offering of an aggregate of \$15 million of our Series A Convertible Preferred Stock, and after deducting estimated underwriting discounts and commissions, placement fees and estimated offering expenses payable by us, our as adjusted net tangible book value as of June 30, 2022, assuming conversion of the all shares of Series A Convertible Preferred Stock would have been approximately \$ million, or \$ per share of common stock. This represents an immediate decrease in net tangible book value of \$ per share to our existing stockholders and an immediate dilution of \$ per share to investors purchasing units in this offering. The final public offering price will be determined through negotiation between us and the underwriters in the offering and may be at a discount to the current market price. Therefore, the assumed public offering price used throughout this prospectus may not be indicative of the final public offering price.

The following table illustrates this dilution on a per share basis:

Assumed public offering price per share	\$
Net tangible book value per share at June 30, 2022	\$9.94
Increase to net tangible book value per share attributable to investors purchasing our common stock in this offering, issuance of Series A Convertible Preferred Stock as part of the Upfront License Payment and in the private offering, and conversion	\$( )
As Adjusted net tangible book value per share as of June 30, 2022, after giving effect to this offering, issuance of Series A Convertible Preferred Stock as part of the Upfront License Payment and in the private offering, and conversion	\$
Dilution per share to investors purchasing our common stock in this offering	\$

If any shares of common stock are issued upon exercise of outstanding options or warrants, you may experience further dilution or accretion.

The total number of shares of common stock outstanding as of the date of this prospectus and after this offering is based on 888,693 shares outstanding as of June 30, 2022, assumes the sale of Class A Units based on an assumed public offering price of \$ , the last reported sales price of our shares of common stock on the Nasdaq Capital Market on , 2022 and shares of common stock upon conversion of the Series A Convertible Preferred Stock, and excludes the following other securities as of June 30, 2022:

- 36,493 shares of common stock issuable upon the exercise of stock options outstanding as of June 30, 2022, at a weighted-average exercise price of \$99.62 per share;
- 228,235 shares of common stock issuable upon the exercise of warrants outstanding as of June 30, 2022, at a weighted-average exercise price of \$140.07;
- 167,748 shares of common stock reserved for future issuance under our 2019 Equity Incentive Plan as of June 30, 2022; and



- 12,778 shares of common stock reserved for future issuance under our 2021 Inducement Plan as of June 30, 2022.

Except as otherwise noted, all information in this prospectus reflects and assumes (i) no sale of Class B Units in this offering, which, if sold, for each share of common stock underlying a share of Series B Convertible Preferred Stock, the number of shares of common stock that we are offering will be decreased on a one-for-one basis, (ii) no exercise of outstanding options issued under our equity incentive plans, (iii) no exercise of any warrants issued in this offering and (iv) no exercise of the underwriters' option to purchase additional shares of common stock and/or warrants to purchase additional shares of common stock.

To the extent that any of these outstanding options or warrants are exercised, or we issue additional shares under our equity incentive plans, there will be further dilution to new investors. In addition, we may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our stockholders.

### UPFRONT LICENSE PAYMENT AND PRIVATE OFFERING

We have entered into the Securities Purchase Agreement with Dong-A pursuant to which, concurrently with and as a condition to the closing of a Qualified Financing, (i) Dong-A will receive \$22 million of our Series A Convertible Preferred Stock for the Upfront License Payment and (ii) Dong-A will purchase, in a private offering, \$15 million of our Series A Convertible Preferred Stock together with warrants substantially equivalent to the warrants, if any, included as part of the Qualified Financing. At such time as we obtain the Stockholder Approval, such shares of Series A Convertible Preferred Stock will automatically convert into shares of our common stock at a conversion price equal to the price at which such shares are sold in the Qualified Financing, subject to customary adjustments for forward and reverse stock splits, stock dividends and the like. It is anticipated that this offering, if consummated, will be a Qualified Offering and upon consummation of this offering, the Series A Convertible Preferred Stock will be issued at a purchase price and with conversion rights (upon stockholder approval) based on the public offering price of the Units being sold pursuant to this prospectus and Dong-A will receive warrants equivalent to those issued in this offering (subject to limitation on exercise prior to Stockholder Approval).

Following the closing of this offering, the issuance of the Upfront License Payment and the closing of the private offering, we will be required to hold a special meeting of the holders of our common stock for the purpose of voting upon the approval and authorization of any and all corporate actions in furtherance of the full conversion of the outstanding shares of Series A Convertible Preferred Stock into shares of common stock, including the approval of the issuance of voting shares in respect of the Upfront License Payment and in the private offering. The closing of the offering of units being made pursuant to this prospectus is contingent upon the completion of the concurrent private offering and the closing of the private offering is contingent upon the completion of the offering of units. As a result, if either of this offering or the private offering does not occur, neither will occur.

We anticipate that the net proceeds from the issuance of the Upfront License Payment and the private offering will equal \$ \_\_\_\_\_, after deducting placement fees and expenses relating to the 2022 License Agreement.

**DIVIDEND POLICY**

We have never declared or paid any dividends on our common stock, and we do not currently intend to pay any dividends on our common stock for the foreseeable future. Any future determination to pay dividends on our common stock will be, subject to applicable law, at the discretion of our Board of Directors and will depend upon, among other factors, our results of operations, financial condition, capital requirements, and contractual restrictions in loan or other agreements.

## BUSINESS

### Overview

We are a clinical-stage biotechnology company which has entered into the 2022 License Agreement with Dong-A to inlicense the rights to two assets, focused on treatment of NASH and obesity. The effectiveness of the 2022 License Agreement is subject to consummation of a Qualified Financing (as described below). Concurrently with the 2022 License Agreement, we entered into the Securities Purchase Agreement with Dong-A pursuant to which Dong-A agreed to purchase \$15 million in Series A Convertible Preferred Stock and warrants on substantially the same terms as this offering subject to consummation of a Qualified Financing. It is intended that this offering will be a Qualified Financing and, if this offering is consummated, the 2022 License Agreement will be effective and Dong-A will consummate the purchase under the Securities Purchase Agreement. Prior to this offering, we have been focused on four therapeutic programs designed to impact a range of indications in coronavirus, neurodegenerative and cardiometabolic disease. Additional information regarding the general development of our business is set forth in our [Annual Report on Form 10-K for the year ended December 31, 2021](#).

On September 14, 2022, we entered into the 2022 License Agreement pursuant to which, subject to the conditions set forth therein, we would have an exclusive license (other than in the Republic of Korea) to two proprietary compounds for specified indications. The 2022 License Agreement covers the rights to a compound referred to as DA-1241 for treatment of NASH and a compound referred to as DA-1741 for treatment of obesity and NASH. We may also develop DA-1241 for the treatment of T2D. The 2022 License Agreement calls for an upfront payment of \$22,000,000, which will be paid in Series A Convertible Preferred Stock of NeuroBo at the public offering price, and milestone payments and royalties. The effectiveness of the 2022 License Agreement is contingent upon our raising a total of at least \$15 million in a Qualified Financing upon which Dong-A will fund an additional \$15 million, which is being sold in the private offering.

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. Agonism of GPR119 in the gut promotes the release of key gut peptides GLP-1, GIP, and PYY. These peptides play a further role in glucose metabolism, lipid metabolism and weight loss. DA-1241 has beneficial effects on glucose, lipid profile and liver inflammation, supported by potential efficacy demonstrated during in vivo preclinical studies. The therapeutic potential of DA-1241 has been demonstrated in multiple pre-clinical animal models of NASH where DA-1241 reduced hepatic steatosis, inflammation, and fibrosis. Furthermore, in Phase 1a and 1b human trials DA-1241 was well tolerated in both healthy volunteers and those with T2D. If this offering is consummated and the 2022 License Agreement is effective, then we intend to initiate a Phase 2a study with the goal of establishing efficacy of DA-1241 in the treatment of NASH.

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. DA-1726 has a well understood mechanism and, in preclinical mice models, resulted in improved weight loss, as well as reduced hepatic steatosis, inflammation, and fibrosis compared to semaglutide and cotadutide (another OXM analogue).

Each of DA-1241 and DA-1726 is currently being developed for the treatment of NASH. NASH is a severe form of nonalcoholic fatty liver disease (“NAFLD”), characterized by inflammation and fibrosis in the liver that can progress to cirrhosis, liver failure, hepatocellular carcinoma (“HCC”) and death. There are currently no approved products for the treatment of NASH.

The prevalence of NAFLD, which affects approximately 25% of the global population, and NASH, which develops in approximately 12% to 14% of NAFLD patients, is growing and is driven primarily by the worldwide obesity epidemic. The critical pathophysiologic mechanisms underlying the development and progression of NASH include reduced ability to handle lipids, increased insulin resistance, injury to hepatocytes and liver fibrosis in response to hepatocyte injury. Patients with NASH frequently have other significant metabolic co-morbidities such as obesity, hyperglycemia, dyslipidemia and systemic hypertension (a constellation of which is commonly referred to as metabolic syndrome) and these further contribute to the risk of cardiovascular disease. The number of NASH cases in the United States is projected to expand

from 16.5 million in 2015 to 27 million in 2030, with similar prevalence growth expected in Europe. Diet and exercise are currently the standard of care for NAFLD and NASH, but adherence to this treatment regimen is poor and there remains a high unmet need in the treatment of NASH.

We have other product candidates focused on the developing novel pharmaceuticals to treat COVID-19 and neurodegenerative disorders.

- *ANA001* 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.
- *NB-01* has the potential to treat painful diabetic neuropathy (PDN) as a first-line pain management therapy for PDN.
- *NB-02* 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.
- *Gemcabene* is currently being assessed for various indications including COVID-19 in combination with ANA001.

Further information regarding these product candidates is set forth in our [Annual Report on Form 10-K for the year ended December 31, 2021, filed on March 31, 2022](#), and our [Quarterly Report on Form 10-Q for the quarter ended June 30, 2022](#), filed on August 12, 2022, which information is incorporated herein by reference.

### Strategy

NeuroBo's goal is to discover, develop and commercialize novel therapeutics for the treatment of cardiovascular and metabolic diseases. The key elements of NeuroBo's business strategy to achieve this goal include:

- Advance DA-1241 through the FDA regulatory process to obtain approval for the treatment of NASH and T2D initially by starting a Phase 2a combination trial in NASH before progressing to T2D.
- Explore various avenues to advance DA-1241 to FDA approval, including, if the Phase 2 clinical trials are successful, securing a pharmaceutical partner to advance work on a global Phase 3 program.
- Advance DA-1726 through IND and initiation of human clinical trials with the initial goal of have DA-1726 be IND-ready by the first quarter of 2023.
- Pursue ANA001 as a treatment and/or prophylaxis for COVID-19.
- Explore alternatives for the future of NB-01, including assessing whether to pursue NB-01 as an orphan drug and/or as a nutraceutical product.
- Explore out licensing opportunities for NB-02.
- Explore additional acute therapeutic indications for gemcabene that may strengthen our pipeline of assets.
- Extend the pipeline of drugs as NeuroBo continues to build and develop its product portfolio by opportunistically pursue strategic partnerships.
- Continue to hire highly qualified management and personnel in advancing drug development, achieving marketing approval, and implementing its corporate growth strategy.

### Market Opportunity

#### *NASH*

Non-alcoholic steatohepatitis (NASH) is a severe form of NAFLD, characterized by inflammation and fibrosis in the liver that can progress to cirrhosis, liver failure, hepatocellular carcinoma ("HCC") and death. There are currently no approved products for the treatment of NASH.

The prevalence of NAFLD, which affects approximately 25% of the global population, and NASH, which develops in approximately 20% to 25% of NAFLD patients, is growing and is driven primarily by the worldwide obesity epidemic. The critical pathophysiologic mechanisms underlying the development and progression of NASH include reduced ability to handle lipids, increased insulin resistance, injury to hepatocytes and liver fibrosis in response to hepatocyte injury. Patients with NASH frequently have other significant metabolic co-morbidities such as obesity, hyperglycemia, dyslipidemia and systemic hypertension (a constellation of which is commonly referred to as metabolic syndrome) and these further contribute to the risk of cardiovascular disease. A report from the Center for Disease Analysis indicates, the number of NAFLD cases in the United States is projected to expand from 83.1 million in 2015 to 100.9 million in 2030 and NASH cases from 16.5 million to 27 million in that period. A similar prevalence growth is expected in Europe. Diet and exercise are currently the standard of care for NAFLD and NASH, but adherence to this treatment regimen is poor and there remains a high unmet need in the treatment of NASH.

### ***Obesity***

Obesity is a major health crisis in the U.S. and has become a worldwide epidemic. According to the World Health Organization (“WHO”), there are as many as 1.9 billion people worldwide considered to be overweight, 650 million of whom are estimated to be obese. The National Center for Health Statistics published data from the National Health and Nutrition Examination Survey (NHANES) indicating from 1999 – 2018 the prevalence of obesity in U.S. adults has increased from 30.5% to 42.4%, with another 30.7% considered overweight and 9.2% being classified as severely obese. The Centers for Disease Control and Prevention (“CDC”) and the WHO consider excessive body weight to be associated with a host of complications, including diabetes, hypertension, high cholesterol, coronary artery disease, cancer, liver and pulmonary disease which are often precipitated or exacerbated by the obese condition.

According to the CDC, in 2019 the estimated annual medical costs of obesity in the U.S. was \$173 billion. Despite the vast number of patients affected by this disease, until recently the pharmaceutical market to treat obesity has been relatively small with few effective therapies available. Current therapies are poorly effective and or poorly tolerated by patients. While some patients are candidates for gastric bypass or reduction surgery, the potential complications, including mortality, and the substantial costs and recovery time make it a realistic option only for those patients characterized as morbidly obese. A measure of the urgency of this medical need in the U.S. is the growing success of semaglutide (WEGOVY®), a drug recently approved for the treatment of chronic weight management in adults with obesity. With the success of semaglutide, researchers have developed second generation drugs that not only interact with the same receptor as semaglutide (GLP-1) but other targets as well that affect weight and metabolism. These second generation drugs have the potential benefit of maintaining or increasing the weight loss targets of semaglutide, but also to decrease the side effects associated with treatment.

### ***Type 2 Diabetes (T2D)***

As with obesity, the incidence of T2D is growing at an alarming rate. In the last 20 years, the number of adults diagnosed with diabetes has more than doubled as the American population has aged and become more overweight or obese. Current data (2021) from the International Diabetes Federation indicate 537 million adults (20-79 years) are living with diabetes with this number predicted to rise to 643 million by 2030. An aging population, poor dietary habits and increasing obesity rates are all driving the increasing incidence of T2D. The association between NAFLD/NASH, obesity, and diabetes is striking. Approximately 70% of those with T2D have NAFLD (30% to 40% classified as NASH) and in obesity the prevalence of NASH is between 25% and 30%. While obesity does not directly cause the hyperglycemic condition associated with diabetes, the correlation is striking as CDC statistics indicate that 90% of type 2 diabetics are overweight or obese.

In the U.S., the CDC reports that the total prevalence of diabetes in 2022 was estimated to be 37.3 million people, or 11.3% of the population, with another 96 million considered to have prediabetes at risk to develop T2D. T2D accounts for up to 95% of all diagnosed cases of diabetes. T2D is frequently not diagnosed until complications appear, and approximately one-quarter of all people with diabetes are undiagnosed. Type 2 diabetes is a complicated metabolic disorder that involves multiple factors including loss of sensitivity to the effects of insulin, a decrease in the body’s ability to produce insulin and the overproduction of



glucose by the liver. Uncontrolled diabetes results in abnormally high blood sugar levels, a condition known as hyperglycemia. The long-term adverse effects of hyperglycemia include blindness and loss of kidney function as well as nerve damage, loss of sensation and poor circulation in the extremities, each of which may eventually necessitate amputation. According to the CDC and WHO, diabetes is currently the seventh leading cause of death by disease and is a leading cause of kidney disease, heart attacks and lower limb amputations and blindness.

## **Product Candidates**

### *New Product Candidates*

#### **DA-1241**

DA-1241 is a new drug candidate with therapeutic potential for NASH and T2D that can be orally administered once a day. Two phase 1 clinical trials for the treatment of T2D have been completed in the United States.

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, stimulates the secretion of insulin and incretin hormones such as glucagon-like peptide-1 (GLP-1), and thereby reduces plasma glucose levels without hypoglycemia risk and lowers plasma lipids levels of both triglycerides and cholesterol. 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. Extensive non-clinical studies have shown DA-1241 has therapeutic potential for the reduction in hepatic steatosis, inflammation, and fibrosis regardless of body weight reduction.

#### **DA-1726**

DA-1726 is a long-acting, novel peptide drug candidate in preclinical development with therapeutic potential for obesity and NASH.

DA-1726 is a dual agonist that activates both GLP-1 receptors (“GLP-1R”) and glucagon receptors (“GCGR”). Activation of GLP-1R or GCGR contributes to central anorexic effect (appetite suppression) and activation of GCGR peripherally enhances basal metabolic rate. Accordingly, non-clinical studies have shown that 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 mice and rats. DA-1726 directly lowers blood glucose and lipid levels in addition to the accompanying metabolic improvement by weight loss. Weight reduction is closely related to the alleviation of fatty liver. Having stabilized the fragile peptide through several unique modifications, DA-1726 is predicted to be available as a once-weekly regimen to humans.

### *Current Product Candidates*

#### **ANA001**

ANA001 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. At

the time of closure 48 participants had been enrolled which is statistically sufficient for us to analyze 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, 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***

NB-01 is a novel therapeutic that has been studied in a 128-subject Phase 2 clinical trial conducted in the United States.

In extensive preclinical studies performed in mice and rats, NB-01 has shown multiple mechanistic and therapeutic effects. NB-01 addresses a range of mechanisms that contribute to neuropathic pain and nerve degeneration in diabetic and other peripheral neuropathies. These include a decrease in key inflammatory markers, restoration of nerve growth factor (NGF) to normal levels, and reduction of advanced glycation end products (AGEs). Inflammation is a central factor in pain generation and other peripheral neurodegenerative diseases. NB-01 reduces levels of TNF- $\alpha$  and IL-6, both of which are markers of inflammation. NB-01 also reduces AGEs, which are implicated in diabetes-related complications. AGE inhibitors have been clinically tested as potential treatments for these complications. NB-01 also restores the neurotrophin NGF, which is involved in nerve growth, maintenance and repair.

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 evaluating alternative development pathways such as orphan drug or nutraceutical (non-pharmaceutical) product.

### ***NB-02***

NB-02 is a product candidate for the symptomatic and disease modifying treatment of neurodegenerative diseases, including Alzheimer's disease and tauopathies. In preclinical studies, NeuroBo has observed the mechanisms of action of NB-02 to include inhibition of tau phosphorylation, acetylcholinesterase (AChE) inhibition, inhibition of A $\beta$  toxicity and amyloid plaque formation, and anti-inflammatory effects.

Specifically, in both *in vitro* and *in vivo* models, NB-02 has demonstrated inhibition of AChE, as is the case with three of the current drugs on the market to treat the symptoms of Alzheimer's disease. It has also demonstrated inhibition of tau phosphorylation and of amyloid plaque formation, both mechanisms believed to contribute to the progression of neurodegenerative diseases.

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***

Gemcabene is currently being assessed as for additional indications including COVID-19 in combination with ANA001. Gemcabene was previously being developed for the treatment of dyslipidemia, a serious medical condition that increases the risk of life-threatening cardiovascular disease, and was focused on orphan indications such as homozygous familial hypercholesterolemia (HoFH), as well as severe hypertriglyceridemia (SHTG).

## **New Development Programs**

### ***DA-1241: Treatment of T2D and NASH***

#### ***Background***

Type 2 diabetes (T2D), previously referred to as “noninsulin-dependent diabetes” or “adult-onset diabetes,” accounts for 95% of all diabetes worldwide. This form encompasses individuals who have relative insulin deficiency and have peripheral insulin resistance. Based on CDC data, the U.S. population with diabetes

is estimated to be 37.3 million in 2022, which accounts for 11.3% of the population. Approximately one-quarter of these people are undiagnosed. Accordingly, GlobalData Plc estimated global anti-diabetic drug sales to be \$48.1 billion in nine major markets in 2019 and projected that the global antidiabetic market will continue to grow to \$91.9 billion by 2029 at a compound annual growth rate (CAGR) of 6.7%, with the US market accounting for 58% of the global market due to high drug prices.

Patients with T2D have an increased prevalence of lipid abnormalities, contributing to their high risk of atherosclerotic cardiovascular diseases (ASCVD). According to the CDC, the prevalence of high cholesterol (non-HDL  $\geq$ 130 mg/dL) among patients with T2D is 44.3%. ADA recommends the use of moderate-intensity statin therapy in addition to lifestyle therapy for patients with diabetes aged 40 – 75 years regardless of ASCVD.

Despite several classes of anti-diabetic pharmacotherapy, there remains an unmet need for additional pre-insulin options. Metformin remains an anchor therapy, but the use of sulfonylureas (“SUs”), thiazolidinediones (“TZDs”), and DPP4 inhibitors continues to decline. SUs and TZDs are now only prescribed for patients with major affordability issues. DPP4 inhibitors have ceded share to the sodium-glucose cotransporter 2 (“SGLT2”) inhibitors and GLP-1 classes, because of lower A1c and weight loss efficacy, and the lack of compelling outcomes data. SGLT2 inhibitors and GLP-1s have shown efficacy by providing “glucose plus” effects (strong A1c, weight, and cardiovascular benefits) and cardiovascular and renal outcomes data in multiple clinical trials. Based on the third party’s report, an estimated 10% to 15% of T2D patients are still at risk of progressing to insulin. These patients are contraindicated for or unable to tolerate SGLT2 inhibitors and GLP-1 therapies. There is a further unmet need for T2D/dyslipidemia comorbid patients, as 5% of these patients are intolerant to statins, requiring alternative therapies to control their lipid levels. PCSK9 inhibitors are the existing alternative for these patients today, but patients struggle with the injection route of administration and high cost. Beyond oral hypoglycemic agents with a novel mechanism, there is an unmet need for an effective drug therapy to improve lipid metabolism in diabetic patients.

#### *DA-1241 Preclinical Development*

Extensive preclinical pharmacology, Absorption, Distribution, Metabolism and Excretion (“ADME”), safety and toxicology studies have been completed. The pharmacokinetic characteristics of DA-1241 were identified through the full set of preclinical ADME package. The safety and toxicology studies completed are: (i) central nervous system (CNS), cardiovascular (CV), and respiratory safety in rats and dogs; (ii) a single-dose, 4-week, 13-week and 26-week oral toxicity studies in rats; (iii) 4-week, 13-week and 39-week oral toxicity studies in dogs; (iv) pre-natal development studies in rats and rabbits; and (v) genotoxicity tests of in vitro bacterial reverse mutation, chromosome aberration, and in vivo micronucleus.

Comprehensive non-clinical studies demonstrated DA-1241 distinctively activates GPR119 across species, stimulates the secretion of insulin and GLP-1, a gut peptide hormone with various metabolic benefits, from the pancreas and intestine, respectively, and thereby reduces postprandial glucose and lipid levels after single administration to mice. The postprandial hypoglycemic response by DA-1241 observed in wild type mice disappeared in GPR119-deficient mice, demonstrating target engagement. Notably, DA-1241 treatment did not cause hypoglycemia  $<$  50 mg/dl in overnight fasted mice.

In diabetic mice with hypertriglyceridemia, chronic treatment with DA-1241 lowered fasting and non-fasting blood glucose levels, in which DA-1241 prevented the pancreatic beta cell loss and preserved pancreatic function. Moreover, DA-1241 treatment decreased hepatic lipid accumulation in addition to plasma triglycerides levels at the same dose levels. When a DPP4 inhibitor was cotreated with DA-1241 to prolong the biological half-life of plasma GLP-1, plasma concentrations of active GLP-1 increased more than those due to degradation blockade with DPP4 inhibitors, and thereby potentiation of GLP-1 action further improved glucose and lipid metabolism compared to each treatment alone.

In a non-diabetic mouse model with pre-established dyslipidemia, DA-1241 completely reduced plasma and hepatic triglycerides to normal control levels and also decreased plasma LDL-cholesterol, independent of glycemic control. Comprehensive mechanism studies have shown that the lipid-lowering effects of DA-1241 are due in part to inhibiting lipid synthesis in the liver and interfering with dietary lipid transport in the intestine.

With regard to the NASH indication, DA-1241 has shown to improve fatty liver in various types of mouse models with metabolic diseases. Thereafter, therapeutic potential for treating NASH has been evaluated in several NASH mice models with different pathophysiology. Among them, the STAM-NASH mouse model exhibits mild fatty liver and moderate liver inflammation/fibrosis and is rapidly chemically induced. DA-1241 improved hepatic inflammation and fibrosis, showing a decrease in NAFLD activity score (NAS) and relative fibrotic area of the liver compared to the vehicle-treated control. Diet-induced obesity (DIO)-NASH mice are chronically induced through a Western diet and are characterized by marked fatty liver and mild to moderate hepatic inflammation/fibrosis. In DIO-NASH mice, DA-1241 improved hepatic steatosis, inflammation, and fibrosis assessed by histological and biochemical methods regardless of body weight reduction. Of note, DA-1241 improved systemic inflammatory status with reduced plasma inflammatory cytokines (TNF $\alpha$ , IL6) and chemokines (CCL2, CXCL1, CXCL2, CXCL10) contributing to tissue damage. Therefore, DA-1241 treatment reduced the levels of plasma liver enzymes (ALT, AST), which were increased due to liver tissue damage in DIO-NASH mice. In mice with metabolic diseases, the effects of DA-1241 on the NASH phenotypes (steatosis, inflammation, and fibrosis in the liver) are enhanced by the co-treatment with a DPP4 inhibitor compared to each treatment alone due to potentiated GLP-1 actions.

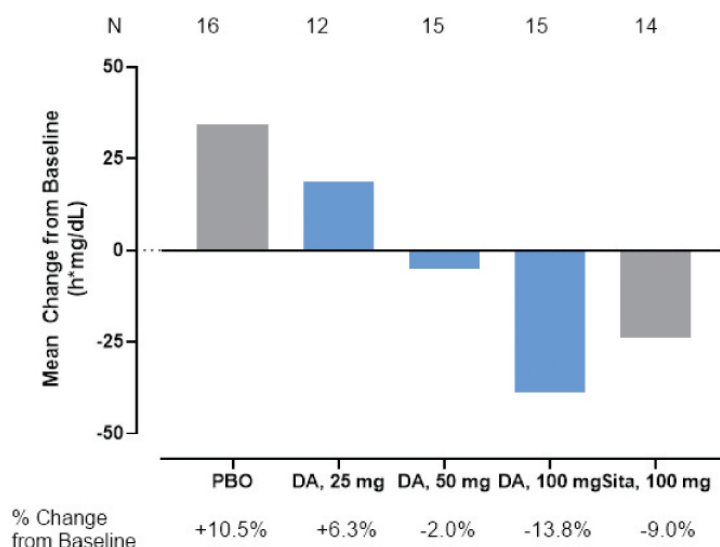
#### *Result of Phase 1 U.S. Clinical Trial for DA-1241*

**Completed Phase 1a and 1b trials in the US healthy subjects.** The first-in-humans Phase 1a study, which was a double-blind, placebo controlled, single ascending dose (“SAD”), single-center study in 60 healthy male volunteers to evaluate the safety, tolerability, pharmacokinetics (“PK”), pharmacodynamics (“PD”), and interaction effect with metformin. Each cohort was given a single oral dose of 12.5, 25, 50, 100, 200, and 400 mg DA-1241 or placebo tablets. The dose level of DA-1241 for the interaction effect (IE) assessment of metformin on the PK of DA-1241 was 100 mg. Therefore, the IE cohort had 2 separate treatment periods. Subjects in the IE cohort received DA-1241 100 mg or placebo alone in Treatment Period 1, and DA-1241 100 mg or placebo with 500 mg metformin (IR formulation) in Treatment Period 2. DA-1241 was well tolerated over a dose range of 12.5 mg to 400 mg. There was no effect of concomitant administration of metformin on DA-1241 PK parameters.

In Phase 1b, Part 1 was a double-blind placebo-controlled, multiple-ascending dose (MAD), single-center study of DA-1241 in healthy subjects. Overall 24 male subjects were blinded and randomized to receive DA-1241: 50, 100 or 200 mg or placebo, as single daily oral doses for 28 days. Safety data reviews and dose escalation decisions between cohorts took place after all subjects of an ongoing cohort had completed procedures through day 14. All doses tested were well tolerated. There were no Serious Adverse Events (SAEs) and no discontinuations due to Adverse Events (AEs).

**Completed Phase 1b trial in the US T2D patients.** The Phase 1b study was designed as a placebo and active comparator (sitagliptin 100 mg)-controlled, double-blind, randomized, multi-center study with an objective of evaluating whether DA-1241 delivers improved glucose-lowering efficacy in 83 diabetic patients. Patients were treated with placebo, sitagliptin 100 mg or DA-1241 25 mg, 50 mg and 100 mg once daily for 8 weeks, in combination with stable doses of metformin (13~19 patients/group). In the mixed meal tolerance test to evaluate the ability to reduce postprandial glucose through GPR119 activation, the incremental AUE<sub>0-4h</sub> of plasma glucose (“iAUE”) upon nutrient ingestion was measured and compared. Eight-week treatment of DA-1241 25 mg, 50 mg and 100 mg showed the changes of +6.3%, -2.0% and -13.8% in iAUE levels from the baseline and DA-1241 100 mg showed similar blood glucose improvement with that of sitagliptin 100 mg (-9.0%), and it outperformed placebo (+10.5%).

**Exploratory P1b Study in the U.S.: Glucose-Lowering Effects**

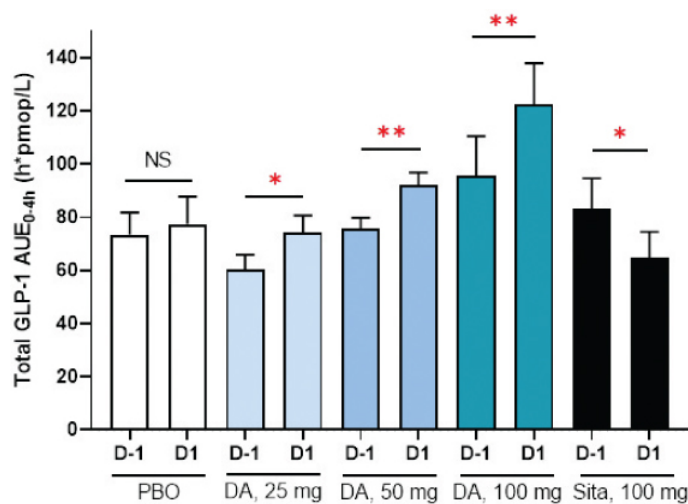


**Mean Change in Postprandial Glucose Excursion at Week 8**

In the parameters of glycemic variability measured with a Continuous Glucose Monitoring (CGM) system and fasting plasma glucose, the glucose-lowering efficacy by DA-1241 was similar to that of sitagliptin. Moreover, the time-in-range, the percentage of how long blood glucose value is within 70~180mg/dL, was increased by mitigating the hypoglycemia risk and duration of hyperglycemia whereas such time-in-range was reduced in the placebo group.

Single administration or 8-week repeated administration of DA-1241 increased secretion of gut peptide hormones such as glucagon-like peptide-1 (GLP-1), glucose-dependent insulinotropic polypeptide (GIP) and peptide YY (PYY) in gastrointestinal tracts after taking meals. The amount of secretion of such hormones increased in proportion to the extent of exposure to DA-1241.

**Exploratory P1b Study in the U.S.: Target-related Biomarker Change**



**Total GLP-1 Secretion during Mixed Meal Tolerance Test**

\* & \*\* P<0.05 & P<0.01 versus corresponding baseline values; DA, DA-1241; Sita, Sitagliptin

In terms of safety, no clinically significant adverse events were observed following the 8-week treatment, confirming the tolerability of DA-1241, and the bodyweight showed a tendency to decrease.

**DA-1241 Phase 2 Trial Design.** If this offering is consummated and the 2022 License Agreement becomes effective, we currently intend to perform three Phase 2 clinical trials in the United States;

**Combined T2D/NASH Phase 2a:** One clinical trial is expected to be a 24-week, double-blinded, randomized, placebo-controlled clinical trial to establish safety and an early signal of efficacy in NAFLD as surrogate for NASH and T2D as a next-generation competitive oral agent. Approximately 150 adult NAFLD patients diagnosed by a MRI-PDFF imaging method with or without T2D will be randomized, in which the planned Phase 2a treatment group will be various doses of DA-1241, DA-1241 plus sitagliptin 100 mg and their matching placebo, as an oral once-daily regimen. The primary pharmacodynamic endpoint for the planned study will be the change from baseline to Week 24 in the liver fat reduction rate will be assessed by MRI-PDFF. As the secondary pharmacodynamic parameter glycated hemoglobin (“HbA1c”) as a surrogate marker for T2D, and subgroup analyses will be performed.

**T2D Phase 2b:** One Phase 2b clinical trial is a dose range finding study to establish efficacy expectations similar to Phase 3 for the treatment of T2D. This planned study is a 12-week, double-blinded, randomized, placebo-controlled clinical trial in approximately 300 subjects with T2D on oral antidiabetic drugs. There are four treatment groups and the three dose levels for the planned treatment groups will be determined based on the results of Phase 2a study. The primary endpoint is the change from baseline to Week 12 in HbA1c and various glycemic outcomes such as continuous glucose monitoring for 7 days in addition to fed and fasting lipid levels will be determined. The Phase 2b trial is planned to be conducted internationally.

**NASH Phase 2b:** The other Phase 2b study is a dose range finding trial to establish clinical efficacy in histological improvement for NASH treatment similar to Phase 3. This planned Phase 2b trial is 52-week, double-blinded, randomized, placebo-controlled clinical study in approximately 400 biopsy confirmed NASH patients with F2-F3 fibrosis. There are four treatment groups and the three dose levels for the planned treatment groups will be determined based on the results of Phase 2a study. This study will be conducted as a multi-center internal study. The primary endpoint is the proportion of patients whose NAFLD activity score (NAS) or fibrosis score (or fibrotic area) are improved by one or more stage from the baseline to Week 24 and Week 52. Various plasma biomarkers that were improved in the preclinical studies performed in mice will also be evaluated to assess changes in systemic inflammatory (TNF $\alpha$ , CCL2, CXCLs) and fibrotic (TIMP-2, type IV collagen) status.

### ***DA-1726: Treatment of Obesity and NASH***

#### *Background*

Obesity is a disease caused by abnormal or excessive fat accumulation due to an imbalance in energy intake and consumption over a long period of time. According to the World Health Organization (WHO), more than 1.9 billion people worldwide are overweight with 650 million considered to be obese. The comorbidities of obesity include type 2 diabetes, cardiovascular disease, hypertension, NASH, etc., and the risk of these diseases is higher in obese people than in non-obese people.

The treatment of obesity can be divided into three mechanisms: (i) appetite control, (ii) absorption inhibition, and (iii) increase of energy expenditure. Currently, there are a total of five approved anti-obesity medications on the market, of which liraglutide (SAXENDA<sup>®</sup>), semaglutide (WEGOVY<sup>®</sup>), phentermine/topiramate (QSYMIA<sup>®</sup>), and naltrexone/bupropion (CONTRAVE<sup>®</sup>) have an appetite suppression mechanism. Another medication, orlistat (XENICAL<sup>®</sup>/ ALLI<sup>®</sup>), controls body weight by inhibiting fat absorption. However, there is still an unmet need in the market as there are no agents with a mechanism to reduce body weight by increasing energy expenditure in peripheral tissue.

Nonalcoholic fatty liver disease refers to a spectrum of liver damage that includes a wide range of liver diseases, from steatosis to cirrhosis. NAFLD is one of the most common diseases accompanying obesity and T2D, and obesity and T2D are known to exacerbate the progression of NAFLD to HCC. Although there is still no therapeutic agent on the market, clinical results of treatment improvement by GLP-1 and oxyntomodulin analogues have been reported and are in the spotlight.



Oxyntomodulin is a gut hormone released from intestinal L-cells after meal ingestion and represents dual agonism of the GLP-1 receptor and glucagon receptor. It increases energy expenditure through glucagon receptors and increases appetite suppression and insulin secretion through GLP-1 receptor activation, ultimately inducing weight loss and glycemic control. The furthest stage of development of any oxyntomodulin analogue is Phase 2, with five drugs (cotadutide, efinopegdutide, BI-456906, mazdutide, and pemvidutide) being prepared or in progress for Phase 2 trials for the treatment of obesity, NASH, or T2D.

#### *DA-1726 Preclinical Development*

Animal toxicity studies of DA-1726 for the Phase 1 clinical trial have been completed and the results are in various stages of analysis and reporting. The toxicity studies included safety pharmacology studies and general toxicity studies.

The mode of action and pharmacological effects of DA-1726 were evaluated in various disease models. In high-fat diet-induced obese mice, DA-1726 showed more body weight loss and increasing energy expenditure than a pair-fed group. In comparison with GLP-1 analogue, DA-1726 represented superior body weight loss compared to semaglutide in obese mice. At the end of the study, DA-1726 significantly increased the expression of thermogenic genes (*Ucp-1* and *Ppargc1a*) in epididymal fat and increased white adipose tissue browning was histologically confirmed. In addition, DA-1726 inhibited adipocyte differentiation *in vitro*. Taken together, it suggests the GCGR action of DA-1726 contributes to reduced adiposity by enhancing fat burning and inhibiting adipogenesis. DA-1726 effectively reduced postprandial glucose excursion in acute oral glucose tolerance test in normal mice. Notably, DA-1726 showed similar glycemic control and excellent weight loss to semaglutide in obese mice with hyperglycemia. Simultaneously, DA-1726 enhanced insulin sensitivity by significantly reducing fasting plasma insulin and glucose levels. Meanwhile, DA-1726 showed no hypoglycemia risk in overnight fasted normal mice, unlike semaglutide.

In obese NASH mice, DA-1726 significantly reduced plasma clinical chemistry parameters (ALT, AST, ALP, T-BIL, glucose, and cholesterol) and hepatic fat accumulation. In histopathological analysis of steatosis, lobular inflammation, and ballooning in the liver, DA-1726 showed an excellent improvement effect compared to semaglutide. Improvement of liver fibrosis was also observed with DA-1726. In the liver tissue, the expression of inflammation (*Tnfa*, *Il-1 $\beta$* , and *Ccl2*) and fibrosis (*Acta2*, *Timp1*, *Colla1*, *Col3a1*, and *Mmp9*) related genes were significantly decreased. Taken together, the findings from the pre-clinical trials suggest DA-1726 has therapeutic potential for NASH in addition to obesity.

**DA-1726 Phase 1 Trial Design:** The first-in-human Phase 1 study in the United States is being planned to establish safety, tolerability and pharmacokinetics of DA-1726 in total approximately 100 healthy subjects, which is a double-blind and placebo-controlled trial. Doses to be applied in the planned clinical trial will be determined based on the predicted human effective dose assessed by preclinical ADME and repeated toxicity studies at the end of 2022. For a MAD trial under the same IND, DA-1726 will be injected subcutaneously once weekly for 12 weeks.

**DA-1726 Phase 2a Trial Design:** A combined Phase 2a clinical trial in the United States is being planned to follow the completion of the Phase 1 clinical trial. The Phase 2a clinical trial is expected to explore a proof-of-concept at the highest tolerated dose to assess the effects of DA-1726 on weight loss as a primary endpoint and on liver fat reduction for a secondary endpoint in approximately 120 obese subjects, including a subset of subjects with NAFLD diagnosed by a MRI-PDFF image method. This study is a double-blind, placebo-controlled, randomized, multi-center trial and DA-1726 will be injected subcutaneously once weekly for 6 months at the highest tolerate dose from Phase 1. The primary endpoint for the planned study will be the change from baseline to Week 2 in body weight. As the secondary pharmacodynamic parameter, the liver fat reduction rate will be assessed by MRI-PDFF and a subgroup analysis will be performed.

#### **License Agreement**

On September 14, 2022, we entered into the 2022 License Agreement with Dong-A pursuant to which, subject to the conditions set forth therein, we would receive an exclusive license (other than in the Republic of Korea) to two proprietary compounds for specified indications. The 2022 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 effectiveness of the 2022 License Agreement is contingent upon our closing the Qualified Financing.

Under the terms of the 2022 License Agreement, Dong-A will (i) receive an upfront payment of \$22,000,000, which will be paid in shares of Series A Convertible Preferred Stock under the terms of the Securities Purchase Agreement, which will be convertible into common stock upon Stockholder Approval; (ii) be 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) be eligible to receive commercial-based milestone payments, payable in cash or our common stock dependent upon the achievement of specific commercial developments and (iv) be eligible to receive regulatory milestone payments of up to \$178 million for DA-1726 and \$138 million for DA-1241, payable in cash or our common stock, dependent upon the achievement of specific regulatory developments.

Our obligation to pay royalties to Dong-A under the 2022 License Agreement continues on a product-by-product and country-by country basis until the later 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 we or Dong-A may terminate the 2022 License Agreement (i) 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, (ii) 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) or (iii) if we fail to complete the offering of units by December 31, 2022 (or January 31, 2023 under specified circumstances set forth in the 2022 License Agreement).

#### **Shared Services Agreement**

On September 14, 2022, in connection with the 2022 License Agreement, we and Dong-A entered into a shared services agreement (the “Shared Services Agreement”). The Shared Services Agreement provides that Dong-A will provide technical support, pre-clinical development, and clinical trials support services in exchange for payment to Dong-A as set forth in the Shared Services Agreement. In addition, the Shared Services Agreement provides that Dong-A will manufacture all of our clinical requirements of DA-1241 and DA-1726 under the terms provided in the Shared Services Agreement.

Either party may terminate the Shared Services Agreement for the other party’s material breach that is not cured within 30 days of notice. Dong-A may also terminate the Shared Services Agreement in part on a service-by-service or product-by-product basis upon a breach by us which is not cured within 30 days.

#### **Securities Purchase Agreement**

On September 14, 2022, in connection with the License Agreement, we entered into the Securities Purchase Agreement. Pursuant to the Securities Purchase Agreement, upon the consummation of the 2022 License Agreement and a Qualified Financing (i) Dong-A will receive the Upfront License Payment and (ii) Dong-A will purchase from us \$15 million in value of shares of Series A Convertible Preferred Stock 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 is 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.

At such time as we obtain the requisite stockholder approval under Nasdaq listing rule 5635 (or its successor) for the issuance of the common stock underlying the Series A Convertible Preferred Stock (the “Stockholder Approval”), such shares of the Series A Convertible Preferred Stock will automatically convert into shares of our common stock at a conversion price equal to the price per share in the Qualified Financing. The Warrants may not be exercised by Dong-A prior to our receipt of the Stockholder Approval.

Pursuant to the Securities Purchase Agreement, we have agreed to call a special meeting of stockholders not later than 60 days after the closing under the Securities Purchase Agreement to obtain the Stockholder Approval, with respect to the shares of our common stock issuable upon the conversion of the Series A Convertible Preferred Stock and the exercise of the Warrants issued under the Securities Purchase Agreement. We agreed to prepare and file a proxy statement with respect to such special meeting of stockholders within 10 days after the closing under the Securities Purchase Agreement. In the event that we do not obtain the Stockholder Approval at the first stockholder meeting, we are obligated to hold a meeting every four months thereafter.

### **Registration Rights Agreement**

In connection with the Securities Purchase Agreement, on September 14, 2022, we entered into a registration rights agreement with Dong-A and certain other stockholders (the “Registration Rights Agreement”). The Registration Rights Agreement provides Dong-A with demand and piggyback registration rights, including the right to two long-form registration statements. In addition, we agreed to file, within 30 days following the Stockholder Approval, a registration statement to register the shares of common stock issuable upon: (i) the conversion of the Series A Convertible Preferred Stock; (ii) shares of our common stock issuable upon the exercise of the Warrants; and (iii) any other common stock held by the parties to the Registration Rights Agreement (the “Registrable Securities”); and to use commercially reasonable efforts to cause each registration statement to be declared effective under the Securities Act as promptly as possible after the filing thereof, but in any event no later than the 60<sup>th</sup> day after Stockholder Approval (or in case the Securities and Exchange Commission reviews the registration statement, the 90<sup>th</sup> date after Stockholder Approval); provided that if we are notified that the registration statement is not being reviewed or is no longer subject to comment, we are required to make the registration statement effective by the fourth trading day after such date. We agreed to use our commercially reasonable efforts to keep such registration statement continuously effective under the Securities Act until the date that all Registrable Securities covered by such registration statement have been sold or are otherwise able to be sold pursuant to Rule 144.

### **Investor Rights Agreement**

On September 14, 2022, we entered into an investor rights agreement with Dong-A (the “Investor Rights Agreement”) pursuant to which, following our receipt of the Stockholder Approval, Dong-A will have the right, subject to the terms thereof, to designate for appointment to our board of directors (the “Board”) that number of directors commensurate with Dong-A’s and its affiliates’ beneficial ownership of our common stock, with the number of directors that Dong-A is entitled to designate rounded up to the nearest whole number (the “DA Designees”). Upon obtaining the Stockholder Approval, to the extent necessary to permit the designation of the DA Designees, the size of the Board shall be increased to that number of directors that would permit Dong-A to designate a number of directors to fill the vacancies created thereby that is commensurate with Dong-A’s and its affiliates’ collective beneficial ownership of the common stock outstanding at such time (taking into account any DA Designees already serving on the Board at such time). The compensation (including equity-based compensation) and rights to indemnity of, and reimbursement of expenses incurred by, the DA Designees that are members of the Board will be the same as those provided to other non-employee directors generally. When evaluating a prospective DA Designee for membership on the Board, the Board and the Nominating and Governance Committee shall apply the same review processes and standards as each of them, respectively, applies to other prospective non-employee directors generally.

In addition, the Investor Rights Agreement provides that Dong-A will be subject to a customary standstill for nine (9) months following our receipt of the Stockholder Approval. Furthermore, for so long as Dong-A has the right to designate any DA Designee to the Board, Dong-A will vote their shares of our common stock in favor of any Company Director (as defined in the Investor Rights Agreement) or any nominee designated by the Nominating and Corporate Governance Committee of the Board and against the removal of any Company Director, in each case, at any meeting of the stockholders of the Company.

### **Existing Development Programs**

Please see the information set forth in *Item 1. Business — Product Candidates* in our [Annual Report on Form 10-K for the year ended December 31, 2021](#) and in *Management’s Discussion and Analysis of Financing*

*Condition and Result of Operations — Current Scientific Activity* in our [Quarterly Report on Form 10-Q for the quarter ended June 30, 2022](#), which is incorporated herein by reference.

### **Manufacturing**

NeuroBo will use third-party manufacturers, including Dong-A in South Korea, to manufacture clinical quantities of DA-1241, DA-1726, ANA001 and NB-01. As NeuroBo advance the product candidates through clinical development and greater quantities are required, we plan to continue to use third parties including Dong-A ST to manufacture the product candidates.

NeuroBo also plan to rely on third parties to manufacture commercial quantities of any products we successfully develop. Among the conditions for FDA approval of a pharmaceutical product is the requirement that the manufacturer's quality control and manufacturing procedures conform to cGMP, which must be followed at all times. The FDA typically inspects manufacturing facilities every two years. In complying with cGMP regulations, pharmaceutical manufacturers must expend resources and time to ensure compliance with product specifications as well as production, record keeping, quality control, reporting and other requirements.

### **Competition**

The pharmaceutical and biotechnology industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. NeuroBo faces potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions. Any product candidates that NeuroBo successfully develops and commercializes will compete with existing therapies and new therapies that may become available in the future.

Some of NeuroBo's competitors may have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than NeuroBo does. Other firms may also compete with NeuroBo in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient enrollment for clinical trials, as well as in acquiring technologies complementary to, or necessary for, NeuroBo's programs. Mergers and acquisitions in the pharmaceutical, biotechnology and diagnostic industries may result in even more resources being concentrated among a smaller number of NeuroBo's competitors. Smaller or early-stage companies may also prove to be significant competitors with NeuroBo, particularly through collaborative arrangements with large and established companies.

NeuroBo's commercial opportunity could be reduced or eliminated if its competitors develop and commercialize therapeutics that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that NeuroBo may develop. NeuroBo's competitors also may obtain marketing approvals for their products more rapidly than NeuroBo may obtain approval for its products, which could result in its competitors establishing a strong market position before NeuroBo is able to enter the market. In addition, NeuroBo's ability to compete may be affected because in some cases insurers or other third-party payors, including government programs, seek to encourage the use of generic products. This may have the effect of making branded products less attractive, from a cost perspective, to buyers.

#### *DA-1241 and DA-1726-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).

Additional pharmaceutical and biotechnology companies with product candidates in development for the treatment of NASH include AstraZeneca plc, Altimmune Inc., Boehringer Ingelheim GmbH, Bristol-Myers Squibb Company, Durect Corporation, Galectin Therapeutics Inc., Galmed Pharmaceuticals Ltd., Immuron Ltd., Ionis Pharmaceuticals, Inc., Islet Sciences, Inc., MediciNova, Inc., MiNA Therapeutics, NGM Biopharmaceuticals, Inc., NuSirt Sciences Inc., Pfizer Inc., Viking Therapeutics, Inc. and Zydus Pharmaceuticals (USA) Inc. NASH is a complex disease and we believe that it is unlikely that any one therapeutic option will be optimal for every NASH patient.

#### *DA-1726-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 Wegovy (semaglutide), liraglutide (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. 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 than our clinical programs or have already received regulatory approval.

#### *DA-1241-T2D*

The market for T2D treatments is competitive and if DA-1241 is approved for T2D it will compete with several classes of drugs for T2D that are approved to improve glucose control, including DPP4 inhibitors, SGLT2 inhibitors, and oral GLP1 analogues as the second or third line therapy for pre-insulin status. Further competition could arise from products currently in development, including: aldose reductase inhibitors (Applied Therapeutics); and GPR40 agonists (Hyundai Pharm.); and small molecule GLP-1 receptor agonists (Pfizer). Some of the agents approved to treat T2D are not generic, are oral once-daily pills and are effective in lowering glucose and A1C. In addition, there are several investigational drugs being studied to treat T2D, and if these investigational therapies were approved, they would also compete with DA-1241.

#### *ANA001 — COVID-19*

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. Currently, multiple treatment options have been approved or given emergency use authorization by the FDA. For hospitalized patients treatments include remdesivir (VEKLURY<sup>®</sup>), dexamethasone, baricitinib (OLUMIANT<sup>®</sup>), and tocilizumab (ACTEMRA<sup>®</sup>). Of these, only remdesivir (VEKLURY<sup>®</sup>) is considered to be an antiviral. For outpatients at high-risk for progression to severe COVID-19, antiviral treatment options include remdesivir (VEKLURY<sup>®</sup>), nirmatrelvir/ritonavir (PAXLOVID<sup>™</sup>) and molnupiravir. In addition, several monoclonal antibody preparations have been approved for use for the outpatient treatment of mild to moderate COVID-19; sotrovimab, bebtelovimab, casirivimab/imdevimab (REGEN-COV<sup>®</sup>), and bamlanivimab/etesevimab. However, at the time of preparation of this document only bebtelovimab is currently authorized for use within the United States. This is because the widely circulating Omicron strain (B.1.1.529) is resistant to casirivimab/imdevimab (REGEN-COV<sup>®</sup>), sotrovimab, and bamlanivimab/etesevimab. With regard to pre-exposure prophylaxis for prevention of COVID-19, the monoclonal antibody combination of tixagevimab/cilgavimab (Evusheld<sup>™</sup>) is approved for use in certain individuals who are immunocompromised or have contraindications to an approved SARS-CoV-2 vaccine.

While vaccines and the aforementioned approved products do provide a clear benefit, there are still many unmet needs regarding therapeutics for the treatment and prevention of COVID-19. There are no



drugs currently approved for the post-exposure prophylaxis of SARS-CoV-2. Changing SARS-CoV-2 variants evade the protective effects of vaccines and monoclonal antibodies. With all direct acting antivirals there is the concern for the emergence of resistance in addition to product specific concerns. Remdesivir (VEKLURY®) must be given in the healthcare setting as it only comes in an intravenous formulation. Molnupiravir is not recommended in children  $\leq 18$  years as well as pregnant women and those trying to become pregnant. Nirmatrelvir/ritonavir (PAXLOVID™) has many contraindications secondary to a multitude of drug-drug interactions. There is still a clear clinical need for an oral antiviral that can be given to a wider group of individuals including children.

#### *NB-01 — Painful Diabetic Neuropathy*

NeuroBo expects that, if approved, NB-01 will compete with currently approved drug therapies for painful diabetic neuropathy, including pregabalin, duloxetine, and tapentadol HCl. NeuroBo is also aware of a number of therapies that are approved to treat other types of neuropathic pain, and that various therapies are used off-label to treat neuropathic pain. In addition to the marketed therapies, NeuroBo is aware of several companies currently developing therapies for neuropathic pain, including Biogen Inc., Cara Therapeutics, Inc., Daiichi Sankyo Company, Eliem Therapeutics Inc, Immune Pharmaceuticals Inc., Novartis AG, and Xenoport Inc.

#### *NB-02 — Cognitive disease and Tauopathies*

NeuroBo expects that, if approved, NB-02 will compete with the currently approved therapies for management of cognitive disease including Alzheimer's disease. In Alzheimer's disease, four drugs are currently approved by the FDA for the treatment of symptoms of Alzheimer's disease, based on acetylcholinesterase (AChE) inhibition (three drugs) and NMDA receptor antagonism (one drug). In addition to the marketed therapies, NeuroBo is aware of several companies currently developing therapies for Alzheimer's disease, including Eisai Co., Ltd., Hoffman-LaRoche, Otsuka Pharmaceuticals, Inc., Novartis AG, Avanir Pharmaceuticals, and Biohaven Pharmaceuticals.

### **Intellectual Property**

Our ability to commercialize its product candidates depends in large part on our ability to obtain and maintain intellectual property protection for our current and potential product candidates, including ANA001, NB-01, NB-02 and gemcabene, and if the 2022 License Agreement is consummated, DA-1241 and DA-1726. NeuroBo's policy is to seek to protect its intellectual property position by, among other methods, filing U.S. and non-U.S. patent applications related to the technology, inventions and improvements that are important to the development and implementation of its business strategy. NeuroBo also relies on trade secrets, know-how and continuing technological innovation to develop and maintain its proprietary position.

We have licensed or acquired rights to patent applications directed to its product candidates, preclinical compounds and related technologies to establish intellectual property positions on these compounds and their uses in disease.

As of September 13, 2022, our intellectual property portfolio for NB-01 included four issued U.S. patents, comprised of two patents directed to composition of matter and two patents directed to use of the composition and two pending applications directed to composition of matter and use of the composition, and 66 granted non-U.S. patents, comprised of composition of matter and use of the composition; these patents and applications are related to our NB-01 clinical programs in peripheral neuropathy and neurological conditions. The issued patents would be expected to expire between 2026 and 2031, excluding any additional term for patent term adjustments or patent term extensions. The patents issuing from these applications, if any, are expected to expire between 2026 and 2031, excluding any additional term for patent term adjustments or patent term extensions. One patent family including some of the above patents and patent applications for NB-01 is assigned to University-Industry Cooperation Group of Kyung Hee University, and is exclusively licensed from Kyung Hee University to Dong-A and then from Dong-A to NeuroBo pursuant to the terms of the corresponding agreements. The other two patent families including the other above patents and patent applications for NB-01 are assigned to Dong-A ST and exclusively licensed to NeuroBo. The jurisdictions for the non-U.S. patents and applications include: Canada, China, the European Patent



Convention (including Austria, Belgium, Finland, France, Germany, Greece, Hungary, Italy, Netherlands, Poland, Portugal, Romania, Spain, Switzerland, Turkey, and the United Kingdom), India, Japan, Mexico, the Republic of Korea, and Russia.

As of September 13, 2022, our intellectual property portfolio for NB-02 included three issued U.S. patents, one patent directed to composition of matter and two patents directed to use of the composition and two pending U.S. patent applications, 82 non-U.S. granted patents, and 4 non-U.S. patent applications, all of which are directed to compositions of matter and use thereof. The issued patents and patents issuing from these applications, if any, are expected to expire around 2035, excluding any additional term for patent term adjustments or patent term extensions. The jurisdictions for the non-U.S. patents and applications include: Brazil, China, the European Patent Convention (including Albania, Austria, Belgium, Bulgaria, Croatia, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Monaco, North Macedonia, Netherlands, Norway, Poland, Portugal, Romania, San Marino, Serbia, Slovenia, Slovakia, Spain, Sweden, Switzerland, Turkey, and the United Kingdom), India, Japan, the Republic of Korea, and Russia.

As of September 13, 2022, our intellectual property portfolio relating to gemcabene included six issued U.S. patents, three pending U.S. patent applications, 38 non-U.S. granted patents and 25 non-U.S. patent applications directed to formulations, compositions, methods of use and methods of manufacturing. The Gemcabene intellectual property includes both owned and Pfizer-licensed issued and pending patents in the United States and non-U.S. jurisdictions. The issued patents in the United States and non-U.S. countries have expiration dates between December 2031 and November 2036. The patents in the United States and non-U.S. countries that may be issued from pending applications, if any, are expected to expire between December 2031 and October 2039. The jurisdictions for the non-U.S. countries include: Argentina, Australia, Brazil, Canada, China, Europe, Hong Kong, India, Israel, Japan, Mexico, New Zealand, Philippines, Korea, Russia, Singapore, South Africa, Taiwan and Thailand.

As of September 13, 2022, our intellectual property portfolio relating to ANA-001 included two pending U.S. patent applications, two PCT applications, and two non-U.S. patent applications directed to formulations and methods of use. The ANA-001 intellectual property includes both owned and YourChoice Therapeutics-licensed pending applications in the United States and PCT. The patents in the United States and non-U.S. countries that may be issued from pending applications, if any, are expected to expire between February 2041 to January 2042. The jurisdictions for the non-U.S. countries include: Argentina and Taiwan.

As of September 13, 2022, our exclusively licensed intellectual property portfolio under the 2022 License Agreement, assuming it becomes effective, for DA-1241 includes one U.S. patent directed to both composition of matter and a process of making the composition and one U.S. non-provisional patent application directed to both composition of matter and use of the composition. The issued U.S. patent would be expected to expire in July 2035, excluding any additional term for patent term adjustments or patent term extensions. NeuroBo's intellectual property portfolio for DA-1241 also includes approximately 17 non-U.S. patents and 14 non-U.S. patent applications directed to composition of matter and/or use of the composition. The issued non-U.S. patents would be expected to expire between 2035 and 2039, excluding any additional term for patent term adjustments or patent term extensions. The jurisdictions for the non-U.S. patents and applications include: Australia, Brazil, Canada, China, the European Patent Convention, Hong Kong, India, Israel, Japan, Mexico, New Zealand, Philippines, Republic of Korea, Russia, Saudi Arabia, and Singapore.

As of September 13, 2022, our exclusively licensed intellectual property portfolio for DA-1726 under the 2022 License Agreement, assuming it becomes effective, would include one U.S. patent directed to both composition of matter and use of the composition and one U.S. non-provisional patent application directed to both composition of matter and use of the composition. The issued U.S. patent would be expected to expire in 2038, excluding any additional term for patent term adjustments or patent term extensions. Our intellectual property portfolio for DA-1726 would also include (i) a PCT application that would enter national phases in October 2022 and (ii) approximately five non-U.S. patents directed to composition of matter and eight non-U.S. patent applications directed to composition of matter and/or use. The issued non-U.S. patents would be expected to expire between 2038 and 2040, excluding any additional term for patent term

adjustments or patent term extensions. The jurisdictions for the non-U.S. patents and applications include: Australia, Brazil, Canada, China, the European Patent Convention, Japan, Philippines, Republic of Korea, Russia, and Singapore.

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries, including the United States, the patent term is 20 years from the earliest filing date of a non-provisional patent application. In the United States, a patent's term may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the U.S. Patent and Trademark Office, or the USPTO, in examining and granting a patent, or may be shortened if a patent is terminally disclaimed over an earlier filed patent. The term of a U.S. patent that covers a drug or biological product may also be eligible for patent term extension when approval from the FDA is granted, provided statutory and regulatory requirements are met. In the future, if our product candidates receive approval from the FDA or foreign regulatory authorities, we expect to apply for patent term extensions on issued patents covering those products, depending upon the length of the clinical trials for each drug and/or other factors. There can be no assurance that any of our pending patent applications will issue or that we will benefit from any patent term extension or other favorable adjustment to the term of any of its patents.

As with other biotechnology and pharmaceutical companies, our ability to maintain and solidify its proprietary and intellectual property position for its current and potential product candidates, including ANA001, NB-01, NB-02 and gemcabene and, if the 2022 License Agreement is consummated, DA-1241 and DA-1726, our preclinical compounds, and our core technologies will depend on its success in obtaining effective patent claims and enforcing those claims if granted. However, patent applications that we may file or license from third parties may not result in the issuance of patents. NeuroBo also cannot predict the breadth of claims that may be allowed or enforced in its patents. Any issued patents that we may receive in the future may be challenged, invalidated or circumvented. For example, prior to March 16, 2013, in the United States, patent applications were subject to a "first to invent" rule of law. Applications filed after March 16, 2013, except for certain applications claiming the benefit of earlier-filed applications, are subject to a "first to file" rule of law.

Discoveries reported in the scientific literature often lag the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. We cannot be certain that any existing or future application will be subject to the "first to file" or "first to invent" rule of law, that we or our licensor were the first to make the inventions claimed in our existing or future patent portfolio subject to the prior laws, or that we or our licensor were the first to file for patent protection of such inventions subject to the new laws. If third parties prepare and file patent applications in the United States that also claim technology we have claimed in our patents or patent applications, we may have to participate in interference proceedings in the USPTO to determine priority of invention, which could result in substantial costs to us, even if the eventual outcome is favorable to NeuroBo. In addition, because of the extensive time required for clinical development and regulatory review of a product candidate NeuroBo may develop, it is possible that, before any of our product candidates can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantage of any such patent.

In addition to patents, we rely upon unpatented trade secrets, know-how, and continuing technological innovation to develop and maintain its competitive position. We seek to protect our proprietary information, in part, by using confidentiality agreements with its collaborators, scientific advisors, employees and consultants, and invention assignment agreements with its employees. We also have agreements requiring assignment of inventions with selected consultants, scientific advisors and collaborators. The confidentiality agreements are designed to protect our proprietary information and, in the case of agreements or clauses requiring invention assignment, to grant us ownership of technologies that are developed under those agreements.

## BENEFICIAL OWNERSHIP

The following table sets forth certain information with respect to the beneficial ownership of our common stock as of August 31, 2022 by:

- each person, or group of affiliated persons, who we know to beneficially own more than 5% of our common stock;
- each of our Named Executive Officers;
- each of our directors; and
- all of our executive officers and directors as a group.

The percentage beneficial ownership information prior to the offering shown in the table is based on an aggregate of 888,693 shares of our common stock outstanding as of August 31, 2022. The percentage of beneficial ownership after this offering shown in the table is based on \_\_\_\_\_ shares of common stock outstanding after the closing of this offering, assuming no sale of Class B Units, no exercise of outstanding options issued under our equity incentive plans, no exercise of any warrants issued in this offering. The percentage of beneficial ownership also does not include the Series A Convertible Preferred Stock which are not currently convertible into common stock.

We have determined beneficial ownership in accordance with the rules of the SEC. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting power or investment power with respect to those securities. In addition, the rules include shares of common stock issuable pursuant to: (i) the exercise of stock options that are either immediately exercisable or exercisable on or before October 30, 2022, which is 60 days after August 31, 2022 and (ii) outstanding warrants to purchase common stock held by that person that is either immediately exercisable or exercisable on or before October 30, 2022, which is 60 days after August 31, 2022. These shares are deemed to be outstanding and beneficially owned by the person holding those options and warrants for the purpose of computing the percentage ownership of that person, but they are not treated as outstanding for the purpose of computing the percentage ownership of any other person.

Unless otherwise noted below, the address of each of the individuals and entities named in the table below is c/o NeuroBo Pharmaceuticals, Inc., 200 Berkeley Street, Office 19th Floor, Boston, Massachusetts 02116. Beneficial ownership representing less than 1% is denoted with an asterisk (\*).

Unless otherwise indicated, the persons or entities identified in this table have sole voting and investment power with respect to all shares shown as beneficially owned by them, subject to applicable community property laws.

	Number of Shares of Common Stock Beneficially Owned Prior to this Offering		Number of Shares of Common Stock Beneficially Owned After this Offering	
	Shares	Percentage	Shares	Percentage
<b>5% Stockholders:</b>	—	—	—	—
JK BioPharma Solutions, Inc. <sup>(1)</sup>	60,571	6.8%		
Dong-A ST Co., Ltd. <sup>(2)</sup>	96,020	10.8%		
E&Investment, Inc. <sup>(3)</sup>	200,554	22.6%		
Roy Lester Freeman <sup>(4)</sup>	48,538	5.5%		
<b>Other Directors and Named Executive Officers:</b>				
Andrew Koven <sup>(5)</sup>	722	*0%		
Na Yeon (Irene) Kim <sup>(3)(6)</sup>	203,846	22.9%		
Jason Groves <sup>(7)</sup>	1,833	*		
Michael Salisbury <sup>(8)</sup>	1,833	*		
Hyung Heon Kim	—	—		

	Number of Shares of Common Stock Beneficially Owned Prior to this Offering		Number of Shares of Common Stock Beneficially Owned After this Offering	
	Shares	Percentage	Shares	Percentage
Richard Kang	—	—		
D. Gordon Strickland <sup>(9)</sup>	333	*		
Gil Price	—	—		
All directors and executive officers as a group (8 persons)	208,567	23.5%		%

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- (1) Represents shares held by JK BioPharma Solutions, Inc. (“JK”). The address of the principal executive offices of JK is 1 Research Court, Suite 370, Rockville, MD 20850.
  - (2) Represents shares held by Dong-A ST Co., Ltd. (“Dong-A”). Dong-A is a South Korean corporation. The address of Dong-A ST Co., Ltd. is 64, Cheonho-daero, Dongdaemun-gu, Seoul, Republic of Korea.
  - (3) Includes 96,351 shares of common stock held by The E&Healthcare Investment Fund II (“Fund II”), 37,373 shares of common stock held by The E&Healthcare Investment Fund No. 6 (“Fund 6”), 62,159 shares of common stock held by The E&Healthcare Investment Fund No. 7 (“Fund 7”) and 4,671 shares of common stock held by E&Investment, Inc. (“GP”). GP is the general partner of each of Fund II, Fund 6 and Fund 7 and may be deemed to beneficially own 200,554 shares of common stock. Na Yeon Kim as the Chief Executive Officer of GP, may be deemed to hold shared voting and dispositive power over a total of 202,387 shares of common stock. Ms. Kim has been granted stock options to purchase up to 2,666 shares of common stock in respect of her service on the Board, of which 1,833 are exercisable within 60 days of August 31, 2022. The business address of Ms. Kim and the address of the principal office of the person and entities noted in this footnote is 16th floor, Yeoksam I-Tower, 326, Teheran-ro, Gangnam-gu, Seoul, Republic of Korea 06211.
  - (4) Represents shares held by Roy Lester Freeman. The address of Mr. Freeman is 200 Berkeley Street, 19th Floor, Boston, Massachusetts, 02116.
  - (5) Includes 722 shares of common stock issuable upon the exercise of stock options.
  - (6) Includes 202,013 shares of common stock and 1,833 shares of common stock issuable upon the exercise of stock options.
  - (7) Includes 1,833 shares of common stock issuable upon the exercise of stock options.
  - (8) Includes 1,833 shares of common stock issuable upon the exercise of stock options.
  - (9) Includes 333 shares of common stock issuable upon the exercise of stock options.

**CERTAIN RELATIONSHIPS AND RELATED PERSON TRANSACTIONS**

Other than compensation arrangements, including employment, termination of employment and change in control arrangements, with our directors and executive officers, and the other transactions discussed in the sections titled “Executive Compensation” and “Certain Relationships and Related Party Transactions” in our [Definitive Proxy Statement on Schedule 14A filed with the SEC on May 18, 2022](#) and incorporated by reference herein, the following is a description of each transaction since January 1, 2019 and each currently proposed transaction in which:

- the amounts involved exceeded or will exceed the lesser of (a) \$120,000 or (b) 1% of the average of our total assets for the fiscal years ended December 31, 2021 or 2020; and
- any of our directors, executive officers or holders of more than 5% of our capital stock, or any member of the immediate family of, or person sharing the household with, the foregoing persons, had or will have a direct or indirect material interest.

On September 14, 2022, we entered into a series of agreements with Dong-A, including the 2022 License Agreement, the Shared Services Agreement, the Securities Purchase Agreement and the Investor Rights Agreement. The disclosure regarding such agreements under “Business” above is incorporated by reference herein.

In addition, on September 14, 2022, we entered into a Registration Rights Agreement with Dong-A and affiliates of E&Investment, Inc., which is the holder of 22.6% of our outstanding stock on the date hereof and Na Yeon (Irene) Kim, who is the chief executive officer of E&Investment, Inc., is a member of our Board. The disclosure regarding the Registration Rights Agreement under “Business” above is incorporated by reference herein.

## DESCRIPTION OF SECURITIES WE ARE OFFERING

The following description summarizes certain terms of the Series B Convertible Preferred Stock and warrants included in this offering. The material terms and provisions of our common stock and our Series B Convertible Preferred Stock are described under the caption “*Description of Capital Stock*”. This summary does not purport to be complete and is qualified in its entirety by the provisions of our certificate of incorporation and bylaws and the provisions of the Series B Preferred Stock and warrants, copies of which are filed with the SEC as exhibits to the Registration Statement on Form S-1 of which this prospectus forms a part, and to the applicable provisions of Delaware law.

We are offering (i) Class A Units, each unit consisting of one share of common stock and one warrant, and (ii) Class B Units, consisting of one share of Series B Convertible Preferred Stock and one warrant.

Each share of common stock and Series B Convertible Preferred Stock and accompanying warrant included in each unit will be immediately separable upon issuance and will be issued separately will be immediately separable upon issuance and will be issued separately. The units will not be issued or certificated. We are also registering the shares of common stock included in the Class A Units and the shares of common stock issuable upon conversion of the Series B Convertible Preferred Stock and shares of common stock issuable from time to time upon exercise of the warrants included in the units offered hereby.

### **Warrants**

*The following description of the warrants we are offering is a summary and is qualified in its entirety by reference to the provisions of the warrant, the form of which is filed as an exhibit to the registration statement of which this prospectus forms a part.*

#### ***Duration and Exercise Price.***

Each warrant offered hereby will have an initial exercise price per share equal to \$ . The warrant will be immediately exercisable upon issuance and will expire on the fifth anniversary of the original issuance date. The exercise price and number of shares of common stock issuable upon exercise is subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting our shares of common stock and the exercise price. Pursuant to a warrant agency agreement between us and American Stock Transfer & Trust Company, as warrant agent, the warrants will be issued in book-entry form and shall initially be represented only by one or more global warrants deposited with the warrant agent, as custodian on behalf of The Depository Trust Company (“DTC”), and registered in the name of Cede & Co., a nominee of DTC, or as otherwise directed by DTC.

#### ***Exercisability.***

The warrants will be exercisable, at the option of the holder, in whole or in part, by delivering to us a duly executed exercise notice accompanied by payment in full for the number of shares of common stock purchased upon such exercise (except in the case of a cashless exercise, as discussed below). A holder (together with its affiliates) may not exercise any portion of the warrant to the extent that the holder would own more than 4.99% (or, at the election of the holder, 9.99%) of the outstanding shares of common stock immediately after exercise. However, upon notice from the holder to us, the holder may decrease or increase the holder’s beneficial ownership limitation, which may not exceed 9.99% of the number of outstanding shares of common stock immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the warrants, provided that any increase in the beneficial ownership limitation will not take effect until 61 days following notice to us. Purchasers in this offering may also elect, prior to the issuance of the warrants, to have the initial exercise limitation set at 9.99% of our outstanding shares of common stock. No fractional shares will be issued in connection with the exercise of a warrant. In lieu of fractional shares, we will either pay the holder an amount in cash equal to the fractional amount multiplied by the exercise price or round down to the next whole share.

#### ***Cashless Exercise.***

If, at the time a holder exercises its warrants, a registration statement registering the issuance of the shares of common stock underlying the warrants under the Securities Act is not then effective or available

and an exemption from registration under the Securities Act is not available for the issuance of such shares, then in lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, the holder may elect instead to receive upon such exercise (either in whole or in part) the net number of shares of common stock determined according to a formula set forth in the common warrants.

***Transferability.***

Subject to applicable laws, a warrant may be transferred at the option of the holder upon surrender of the warrant to us together with the appropriate instruments of transfer.

***Exchange Listing.***

There is no trading market available for the warrants on any securities exchange or nationally recognized trading system. We do not intend to list the warrants on any securities exchange or nationally recognized trading system.

***Right as a Stockholder.***

Except as otherwise provided in the warrants or by virtue of such holder's ownership of our shares of common stock, the holders of the warrants do not have the rights or privileges of holders of our shares of common stock, including any voting rights, until they exercise their warrants.

***Fundamental Transaction.***

In the event of a fundamental transaction, as described in the warrants and generally including any reorganization, recapitalization or reclassification of our shares of common stock, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, the acquisition of more than 50% of our outstanding shares of common stock, or any person or group becoming the beneficial owner of more than 50% of the voting power represented by our outstanding shares of common stock, the holders of the warrants will be entitled to receive upon exercise of the warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised the warrants immediately prior to such fundamental transaction. Additionally, as more fully described in the warrant, in the event of certain fundamental transactions, the holders of the warrants will be entitled to receive consideration in an amount equal to the Black Scholes value of the warrants on the date of consummation of the transaction.

***Call Feature.***

The warrants are callable by us in certain circumstances. Subject to certain exceptions, in the event that the warrants are outstanding, if, after the closing date, (i) the volume weighted average price of our common stock for 30 consecutive trading days (the "Measurement Period"), which Measurement Period commences on the closing date, exceeds 300% of the exercise price (subject to adjustment for forward and reverse stock splits, recapitalizations, stock dividends and similar transactions after the initial exercise date), (ii) the average daily trading volume for such Measurement Period exceeds \$500,000 per trading day, and (iii) the warrant holder is not in possession of any information that constitutes or might constitute, material non-public information which was provided by the Company, and subject to the applicable beneficial ownership limitation, then we may, within one trading day of the end of such Measurement Period, upon notice (a "Call Notice"), call for cancellation of all or any portion of the warrants for which a notice of exercise has not yet been delivered (a "Call") for consideration equal to \$0.001 per warrant share. Any portion of a warrant subject to such Call Notice for which a notice of exercise shall not have been received by the Call Date (as hereinafter defined) will be canceled at 6:30 p.m. (New York City time) on the tenth trading day after the date the Call Notice is sent by the Company (such date and time, the "Call Date"). Our right to call the warrants shall be exercised ratably among the holders based on the then outstanding warrants.



## UNDERWRITING

We are offering the Class A Units and Class B Units described in this prospectus through the underwriters named below. Ladenburg Thalmann & Co. Inc. is acting as the representative of the underwriters in this offering. Subject to the terms and conditions of the underwriting agreement, dated as of \_\_\_\_\_, the underwriters have agreed to purchase the number of our securities set forth opposite its name below.

Underwriters	Number of Class A Units	Number of Class B Units
Ladenburg Thalmann & Co. Inc.	—	
Total		

A copy of the underwriting agreement will be filed as an exhibit to the registration statement of which this prospectus is part.

We have been advised by the underwriters that they propose to offer the Class A Units and Class B Units, if any, directly to the public at the public offering price set forth on the cover page of this prospectus. Any securities sold by the underwriters to securities dealers will be sold at the public offering price less a selling concession not in excess of \$ \_\_\_\_\_ per share (or per share of common stock underlying the Series B Convertible Preferred Stock), \$ \_\_\_\_\_ per warrant.

The underwriting agreement provides that the underwriters' obligation to purchase the securities we are offering is subject to conditions contained in the underwriting agreement.

No action has been taken by us or the underwriters that would permit a public offering of the Class A Units or Class B Units, or the shares of common stock, shares of Series B Convertible Preferred Stock and warrants included in the Class A Units or Class B Units in any jurisdiction outside the United States where action for that purpose is required. None of our securities included in this offering may be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sales of any of the securities offering hereby be distributed or published in any jurisdiction except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons who receive this prospectus are advised to inform themselves about and to observe any restrictions relating to this offering of securities and the distribution of this prospectus. This prospectus is neither an offer to sell nor a solicitation of any offer to buy the securities in any jurisdiction where that would not be permitted or legal.

The underwriters have advised us that they do not intend to confirm sales to any account over which they exercise discretionary authority.

### Underwriting Discount and Expenses

The following table summarizes the underwriting discount and commission to be paid to the underwriters by us.

	Per Class A Unit <sup>(1)</sup>	Per Class B Unit <sup>(2)</sup>	Total Without Over- Allotment	Total With Full Over- Allotment
Public offering price	\$	\$	\$	\$
Underwriting discounts and commissions to be paid to underwriters by us <sup>(3)(4)</sup>	\$	\$	\$	\$
Proceeds, before expenses, to us	\$	\$	\$	\$

- (1) The public offering price and underwriting discount corresponds to, in respect of the Class A Units, (i) a public offering price per share of common stock of \$ \_\_\_\_\_ (\$ \_\_\_\_\_ net of the underwriting discount) and (ii) a public offering price per warrant of \$ \_\_\_\_\_ (\$ \_\_\_\_\_ net of the underwriting discount).

- (2) The public offering price and underwriting discount in respect of the Class B Units corresponds to (i) a public offering price per Series B Convertible Preferred Stock convertible into shares of common stock of \$ \_\_\_\_\_ (\$ \_\_\_\_\_ net of the underwriting discount) and (ii) a public offering price per warrant of \$ \_\_\_\_\_ (\$ \_\_\_\_\_ net of the underwriting discount).
- (3) We have also agreed to pay the representative a management fee of 0.5% of the gross proceeds from the offering and to reimburse the accountable expenses of the representative, including a pre-closing expense allowance of up to a maximum of \$35,000 and an additional closing expense allowance up to a maximum of \$110,000.
- (4) We have granted a 45-day option to the underwriters to purchase up to \_\_\_\_\_ additional shares of common stock, additional \_\_\_\_\_ warrants to purchase an additional \_\_\_\_\_ shares of common stock at the assumed public offering price per share of common stock and the assumed public offering price per warrant set forth above less the underwriting discounts and commissions solely to cover over-allotments, if any.

We estimate the total expenses payable by us for this offering to be approximately \$ \_\_\_\_\_, which amount includes (i) the underwriting discount of \$ \_\_\_\_\_, (ii) reimbursement of the accountable expenses of the underwriters, including the legal fees of the representative, in an amount not to exceed \$35,000 for pre-closing expenses plus \$110,000 for closing expenses, (iii) a management fee of approximately \$ \_\_\_\_\_ which represents 0.5% of the total gross proceeds payable to the representative, and (iv) other estimated company expenses of approximately \$ \_\_\_\_\_, which includes legal, accounting, printing costs, and various fees associated with the registration and listing of our shares.

### **Over-allotment Option**

We have granted to the underwriters an option exercisable not later than 45 days after the date of this prospectus to purchase up to an additional \_\_\_\_\_ shares and \_\_\_\_\_ warrants at the assumed public offering price per share of common stock and the public offering price per warrant set forth on the cover page hereto less the underwriting discounts and commissions. The underwriters may exercise the option solely to cover over-allotments, if any, made in connection with this offering. If any additional shares of common stock, and/or warrants are purchased, the underwriters will offer these shares of common stock and/or warrants on the same terms as those on which the other securities are being offered.

### **Determination of Offering Price**

Our common stock is currently traded on The Nasdaq Capital Market under the symbol "NRBO." On \_\_\_\_\_, 2022, the closing price of our common stock was \$ \_\_\_\_\_ per share.

The public offering price of the securities offered by this prospectus will be determined by negotiation between us and the underwriters. Among the factors that will be considered in determining the public offering price of the shares:

- Our history and our prospects;
- The industry in which we operate;
- Our past and present operating results; and
- The general condition of the securities markets at this time of this offering.

The offering price stated on the cover page of this prospectus should not be considered an indication of the actual value of the shares of common stock sold in this offering. That price is subject to change as a result of market conditions and other factors and we cannot assure you that the shares of common stock sold in this offering can be resold at or above the public offering price.

### **Right of First Refusal**

We have granted to Ladenburg Thalmann & Co. Inc. the right of first refusal for a period of twelve (12) months following the closing of this offering to act as sole bookrunner, exclusive placement agent or exclusive sales agent in connection with any financing of the Company.

**Listing**

Our shares of common stock are listed on the Nasdaq Capital Market under the symbol “NRBO.”

The last reported sales price of our shares of common stock on \_\_\_\_\_, 2022 was \$ \_\_\_\_\_ per share. The actual public offering price per Class A Unit or Class B Unit, as the case may be, will be determined between us, the underwriters and the investors in the offering, and may be at a discount to the current market price of our common stock. Therefore, the assumed public offering price used throughout this prospectus may not be indicative of the final offering price. There is no established public trading market for the warrants or the Series B Convertible Preferred Stock, and we do not expect such a market to develop. In addition, we do not intend to apply for listing of the Series B Convertible Preferred Stock or the warrants on any securities exchange or other trading system.

**Lock-up Agreements**

Our officers, directors and each of their respective affiliates and associated partners, Dong-A (and its respective affiliates), and certain other stockholders have agreed with the underwriters to be subject to a lock-up period of 90 days following the date of this prospectus. This means that, during the applicable lock-up period, such persons may not offer for sale, contract to sell, sell, distribute, grant any option, right or warrant to purchase, pledge, hypothecate or otherwise dispose of, directly or indirectly, any shares of our common stock or any securities convertible into, or exercisable or exchangeable for, shares of our common stock. Certain limited transfers are permitted during the lock-up period if the transferee agrees to these lock-up restrictions. We have also agreed, in the underwriting agreement, to similar lock-up restrictions on the issuance and sale of our securities for 90 days following the closing of this offering, although we will be permitted to issue stock options or stock awards to directors, officers and employees under our existing plans. Ladenburg Thalmann & Co. Inc. may, in their sole discretion and without notice, waive the terms of any of these lock-up agreements.

**Other Relationships**

From time to time, certain of the underwriters and their affiliates may provide in the future, various advisory, investment and commercial banking and other services to us in the ordinary course of business, for which they will receive customary fees and commissions. The representative has received compensation in connection with advisory services provided to the company in connection with a licensing transaction and will receive an additional cash fee upon closing of the licensing transaction and will receive a cash commission of 3% on the \$15 million private placement transaction with Dong-A.

**Transfer Agent, Warrant Agent and Registrar**

The transfer agent, warrant agent and registrar for our common stock is American Stock Transfer & Trust Company, LLC.

**Stabilization, Short Positions and Penalty Bids**

The underwriters may engage in syndicate covering transactions stabilizing transactions and penalty bids or purchases for the purpose of pegging, fixing or maintaining the price of our common stock;

- Syndicate covering transactions involve purchases of securities in the open market after the distribution has been completed in order to cover syndicate short positions. Such a naked short position would be closed out by buying securities in the open market. A naked short position is more likely to be created if the underwriters are concerned that there could be downward pressure on the price of the securities in the open market after pricing that could adversely affect investors who purchase in the offering.
- Stabilizing transactions permit bids to purchase the underlying security so long as the stabilizing bids do not exceed a specific maximum.
- Penalty bids permit the underwriters to reclaim a selling concession from a syndicate member when the securities originally sold by the syndicate member are purchased in a stabilizing or syndicate covering transaction to cover syndicate short positions.

These syndicate covering transactions, stabilizing transactions, and penalty bids may have the effect of raising or maintaining the market prices of our securities or preventing or retarding a decline in the market prices of our securities. As a result the price of our common stock may be higher than the price that might otherwise exist in the open market. Neither we nor the underwriters make any representation or prediction as to the effect that the transactions described above may have on the price of our common stock. These transactions may be effected on the Nasdaq Capital Market, in the over-the-counter market or on any other trading market and, if commenced, may be discontinued at any time.

In connection with this offering, the underwriters also may engage in passive market making transactions in our common stock in accordance with Regulation M during a period before the commencement of offers or sales of shares of our common stock in this offering and extending through the completion of the distribution. In general, a passive market maker must display its bid at a price not in excess of the highest independent bid for that security. However, if all independent bids are lowered below the passive market maker's bid that bid must then be lowered when specific purchase limits are exceeded. Passive market making may stabilize the market price of the securities at a level above that which might otherwise prevail in the open market and, if commenced, may be discontinued at any time.

Neither we, nor the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the prices of our securities. In addition, neither we nor the underwriters make any representation that the underwriters will engage in these transactions or that any transactions, once commenced will not be discontinued without notice.

#### **Indemnification**

We have agreed to indemnify the underwriters against certain liabilities, including certain liabilities arising under the Securities Act, or to contribute to payments that the underwriters may be required to make for these liabilities.

## DESCRIPTION OF CAPITAL STOCK

*The following description of our capital stock and provisions of our Third Amended and Restated Certificate of Incorporation, as amended ("Certificate of Incorporation") and Second Amended and Restated Bylaws ("Amended and Restated Bylaws") are summaries. You should also refer to the Certificate of Incorporation and the Amended and Restated Bylaws, which are filed as exhibits to the registration statement of which this prospectus is a part.*

### **General**

Our Certificate of Incorporation authorizes us to issue up to 100,000,000 shares of common stock and 10,000,000 shares of preferred stock, par value \$0.001 per share, all of which shares of preferred stock are currently undesignated. Our board of directors may establish the rights and preferences of the preferred stock from time to time.

As of August 31, 2022, there were (i) 888,693 shares of common stock outstanding; (ii) no outstanding shares of preferred stock; (iii) 36,493 shares of common stock issuable upon the exercise of outstanding stock options; and (iv) 228,235 shares of common stock issuable upon the exercise of outstanding warrants.

### **Common Stock**

#### ***Voting***

Each holder of our common stock is entitled to one vote for each share on all matters submitted to a vote of the stockholders, including the election of directors. Our stockholders do not have cumulative voting rights. Because of this, the holders of a majority of the shares of common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they should so choose.

#### ***Dividends***

Subject to preferences that may be applicable to any then-outstanding preferred stock, holders of our common stock are entitled to receive ratably those dividends, if any, as may be declared from time to time by the board of directors out of legally available funds.

#### ***Liquidation***

In the event of our liquidation, dissolution or winding up, holders of our common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities and the satisfaction of any liquidation preference granted to the holders of any then-outstanding shares of preferred stock.

#### ***Rights and Preferences***

Holders of our common stock have no preemptive, conversion or subscription rights and there are no redemption or sinking fund provisions applicable to the common stock. The rights, preferences and privileges of the holders of our common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of preferred stock that we may designate in the future.

### **Preferred Stock**

Our board of directors has the authority under our Certificate of Incorporation, without further action by our stockholders, to issue up to 10,000,000 shares of preferred stock in one or more series, to establish from time to time the number of shares to be included in each such series, to fix the rights, preferences and privileges of the shares of each wholly unissued series and any qualifications, limitations or restrictions thereon, and to increase or decrease the number of shares of any such series, but not below the number of shares of such series then outstanding.

Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of our common stock. The purpose

of authorizing our board of directors to issue preferred stock and determine its rights and preferences is to eliminate delays associated with a stockholder vote on specific issuances. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in control of us and may adversely affect the market price of our common stock and the voting and other rights of the holders of our common stock. It is not possible to state the actual effect of the issuance of any shares of preferred stock on the rights of holders of common stock until the board of directors determines the specific rights attached to that preferred stock.

### ***Series A Convertible Preferred Stock***

Prior to the closing of this offering and the private offering and the issuance of the Upfront License Payment, we will designate 3,700 shares of our authorized and unissued preferred stock as Series A Convertible Preferred Stock by filing the Series A Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock (the “Series A Certificate of Designation”) with the Delaware Secretary of State.

Each share of Series A Convertible Preferred Stock will be convertible into \_\_\_\_\_ shares of our common stock, subject to adjustment as provided in the Series A Certificate of Designation. Each share of Series A Convertible Preferred Stock will be automatically converted into shares of common stock issued as part of the units in this offering on the first trading day after the approval by our stockholders of the issuance of voting shares upon conversion of the Series A Convertible Preferred Stock issued in connection with the Upfront License Payment and issued in the private offering (the “Stockholder Approval”). We will not undertake any conversion of the Series A Convertible Preferred Stock, and no stockholder will have the right to convert any portion of its Series A Convertible Preferred Stock, until after we obtain Stockholder Approval. The holder of Series A Convertible Preferred Stock may elect to exchange the Series A Convertible Preferred Stock following the nine-month anniversary of the issuance thereof for the cash value of such shares as calculated based on the volume-weighted average price per share of our common stock on the day immediately prior to the date of conversion, in lieu of delivery of shares of common stock (if the shares deliverable upon conversion would otherwise violate listing rules of the Nasdaq Stock Market).

The Series A Convertible Preferred Stock shall be:

- Senior to all of our other equity securities;
- The liquidation preference per share of Series A Convertible Preferred Stock will be the amount such holders would receive if such holders had converted the Series A Convertible Preferred Stock into shares of common stock immediately prior to such liquidation.

The Series A Convertible Preferred Stock will have no voting rights, except as required by law and except that the consent of the holders of a majority of the then outstanding Series Convertible Preferred Stock is required to amend the terms of the Series A Certificate of Designation. The holders of the Series A Convertible Preferred Stock are entitled to receive dividends on an as-converted basis with the holders of the Company’s common stock, when, as and if such dividends are paid on our common stock. In the event of any liquidation, dissolution or winding-up of the Company, the holders of the Series A Convertible Preferred Stock will participate *pari passu* with the holders of our common stock, on an as-converted basis.

### ***Series B Convertible Preferred Stock***

In connection with this offering, we will designate shares of our preferred stock as Series B Convertible Preferred Stock by filing the Series B Certificate of Designation (as defined below) with the Delaware Secretary of State.

Each share of Series B Convertible Preferred Stock will be convertible at any time at the holder’s option into shares of common stock, subject to adjustment as provided in the Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock (the “Series B Certificate of Designation”). Notwithstanding the foregoing, the Series B Certificate of Designation will further provide

that we shall not effect any conversion of the Series B Convertible Preferred Stock, with certain exceptions, to the extent that, after giving effect to an attempted conversion, the holder of Series B Convertible Preferred Stock (together with such holder's affiliates, and any persons acting as a group together with such holder or any of such holder's affiliates) would beneficially own a number of shares of Common Stock in excess of 4.99% (or, at the election of the purchaser prior to the date of issuance, 9.99%) of the shares of our common stock then outstanding after giving effect to such exercise (the "Series B Convertible Preferred Stock Beneficial Ownership Limitation").

Subject to certain limitations, if the volume weighted average price of our stock during any 30 consecutive trading day period exceeds 300% of the conversion price, the average daily dollar trading volume for such 30 consecutive trading period \$500,000 per trading day and the holder is not in possession of any material non-public information, we may force each holder of Series B Convertible Preferred Stock to convert all of their shares of Series Convertible B Preferred Stock.

In the event of a liquidation, the holders of Series B Convertible Preferred Stock will be entitled to participate on an as-converted-to-common-stock basis with holders of the common stock in any distribution of assets of the Company to the holders of the common stock.

The Series B Convertible Preferred Stock will have no voting rights, except as required by law and except as described in the Series B Certificate of Designation. However, as long as any shares of Series B Convertible Preferred Stock remain outstanding, the Series B Certificate of Designation will provide that we shall not, without the affirmative vote of holders of a majority of the then-outstanding shares of Series B Convertible Preferred Stock: (a) alter or change adversely the powers, preferences or rights given to the Series B Convertible Preferred Stock or alter or amend the Series B Certificate of Designation, (b) increase the number of authorized shares of Series B Convertible Preferred Stock or (c) effect a stock split or reverse stock split of the Series Convertible B Preferred Stock or any like event.

The Series B Certificate of Designation will provide, among other things, that we shall not pay any dividends on shares of common stock (other than dividends in the form of common stock) unless and until such time as we pay dividends on each share of Series B Convertible Preferred Stock on an as-converted basis. Other than as set forth in the previous sentence, the Series B Certificate of Designation will provide that no other dividends shall be paid on shares of Series B Convertible Preferred Stock and that we shall pay no dividends (other than dividends in the form of common stock) on shares of common stock unless we simultaneously comply with the previous sentence.

The Series B Certificate of Designation will not provide for any restriction on the repurchase of Series B Convertible Preferred Stock by us while there is any arrearage in the payment of dividends on the Series B Convertible Preferred Stock. There will be no sinking fund provisions applicable to the Series B Convertible Preferred Stock.

We will not be obligated to redeem or repurchase any shares of Series B Convertible Preferred Stock. Shares of Series B Convertible Preferred Stock will not otherwise be entitled to any redemption rights or mandatory sinking fund or analogous fund provisions. Furthermore, Series B Convertible Preferred Stock does not have a termination date and can therefore be held perpetually.

There is no established public trading market for the Series B Convertible Preferred Stock, and we do not expect a market to develop. In addition, we do not intend to list the Series B Convertible Preferred Stock on any securities exchange or nationally recognized trading system. Without an active trading market, the liquidity will be limited.

The transfer agent for our Series B Convertible Preferred Stock to be issued in this offering is American Stock Transfer & Trust Company, LLC.

#### **Description of Outstanding Warrants**

As of August 31, 2022, there were warrants outstanding to purchase 228,235 shares of common stock issuable upon the exercise of warrants at a weighted-average exercise price of \$140.07. Certain of these warrants have a net exercise provision under which its holder may, in lieu of payment of the exercise price in cash, surrender the warrant and receive a net amount of shares based on the fair market value of our



common stock at the time of exercise of the warrant after deduction of the aggregate exercise price. Each of these warrants also contains provisions for the adjustment of the exercise price and the aggregate number of shares issuable upon the exercise of the warrant in the event of dividends, share splits, reorganizations and reclassifications and consolidations. Certain of these warrants provide that, subject to limited exceptions, a holder will not have the right to exercise any portion of its warrants if the holder, together with its affiliates, would beneficially own over 4.99% of our then outstanding common stock following such exercise; provided, however, that upon prior notice to us, the warrant holder may increase its ownership, provided that in no event will the ownership exceed 9.99%.

### **Anti-Takeover Provisions**

#### ***Section 203 of the Delaware General Corporation Law***

We are subject to Section 203 of the Delaware General Corporation Law, which prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years after the date that such stockholder became an interested stockholder, with the following exceptions:

- before such date, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;
- upon completion of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction began, excluding for purposes of determining the voting stock outstanding, but not the outstanding voting stock owned by the interested stockholder, those shares owned (1) by persons who are directors and also officers and (2) employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- on or after such date, the business combination is approved by the board of directors and authorized at an annual or special meeting of the stockholders, and not by written consent, by the affirmative vote of at least 66 $\frac{2}{3}$ % of the outstanding voting stock that is not owned by the interested stockholder.

In general, Section 203 defines a “business combination” to include the following:

- merger or consolidation involving the corporation or any direct or indirect majority-owned subsidiary of the corporation and the interested stockholder;
- any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder (in one transaction or a series of transactions);
- subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation or by any direct or indirect majority-owned subsidiary of the corporation of any stock of the corporation or of such subsidiary to the interested stockholder;
- any transaction involving the corporation or any direct or indirect majority-owned subsidiary of the corporation that has the effect of increasing the proportionate share of the stock or any class or series of the corporation beneficially owned by the interested stockholder; or
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits by or through the corporation.

In general, Section 203 defines an “interested stockholder” as an entity or person who, together with the person’s affiliates and associates, beneficially owns, or within three years prior to the time of determination of interested stockholder status did own, 15% or more of the outstanding voting stock of the corporation.

#### **Certificate of Incorporation and Amended and Restated Bylaws**

Our Certificate of Incorporation provides that the authorized number of directors may be changed only by resolution of the board of directors, and vacancies and newly created directorships on the board of

directors may, except as otherwise required by law or determined by the board of directors, only be filled by a majority vote of the directors then serving on the board of directors, even though less than a quorum.

Our Amended and Restated Bylaws provide that all stockholder actions must be effected at a duly called meeting of stockholders and eliminate the right of stockholders to act by written consent without a meeting. Our Amended and Restated Bylaws also provide that only our Chairman of the board of directors, Chief Executive Officer or the board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors may call a special meeting of stockholders.

Our Amended and Restated Bylaws also provide that stockholders seeking to present proposals before a meeting of stockholders to nominate candidates for election as directors at a meeting of stockholders must provide timely advance notice in writing, and specify requirements as to the form and content of a stockholder's notice. At any meeting of stockholders for the election of directors at which a quorum is present, the election will be determined by a plurality of the votes cast by the stockholders entitled to vote at the election.

Our Certificate of Incorporation and Amended and Restated Bylaws provide that the stockholders cannot amend many of the provisions described above except by a vote of 66 $\frac{2}{3}$ % or more of our outstanding common stock. As described above, our Certificate of Incorporation gives our board of directors the authority, without further action by our stockholders, to issue up to 10,000,000 shares of preferred stock in one or more series.

The combination of these provisions will make it more difficult for our existing stockholders to replace our board of directors as well as for another party to obtain control of us by replacing our board of directors. Since our board of directors has the power to retain and discharge our officers, these provisions could also make it more difficult for existing stockholders or another party to effect a change in management. In addition, the authorization of undesignated preferred stock makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change our control.

These provisions are intended to enhance the likelihood of continued stability in the composition of our board of directors and its policies and to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to reduce our vulnerability to hostile takeovers and to discourage certain tactics that may be used in proxy fights. However, such provisions could have the effect of discouraging others from making tender offers for our shares and may have the effect of delaying changes in our control or management. As a consequence, these provisions may also inhibit fluctuations in the market price of our stock that could result from actual or rumored takeover attempts. We believe that the benefits of these provisions, including increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure our Company, outweigh the disadvantages of discouraging takeover proposals, because negotiation of takeover proposals could result in an improvement of their terms.

#### **Choice of Forum**

Our Amended and Restated Bylaws provide that the Court of Chancery of the State of Delaware will be the exclusive forum for:

- any derivative action or proceeding brought on our behalf;
- any action asserting a breach of fiduciary duty;
- any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our Certificate of Incorporation or our Amended and Restated Bylaws; or
- any action asserting a claim against us that is governed by the internal affairs doctrine.

The provision does not apply to suits brought to enforce a duty or liability created by the Exchange Act.

The enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that, in connection with any action, a court could

find the choice of forum provisions contained in our Certificate of Incorporation to be inapplicable or unenforceable in such action. Our Amended and Restated Bylaws further provides that the federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, subject to and contingent upon a final adjudication in the State of Delaware of the enforceability of such exclusive forum provision.

**Registration Rights**

See Business — Registration Rights Agreement for a summary of the terms of the Registration Rights Agreement between Dong-A and us.

**Transfer Agent and Registrar**

The transfer agent and the registrar for the Company is American Stock Transfer and Trust Company, 6201 15<sup>th</sup> Avenue, Brooklyn, New York 11219.

**Common Stock Listing**

Our common stock is listed on the Nasdaq Capital Market under the symbol “NRBO”.

## LEGAL MATTERS

Honigman LLP, Kalamazoo, Michigan, will issue a legal opinion as to the validity of the securities offered by this prospectus. The representative of the underwriters is being represented by Ellenoff, Grossman & Schole, LLP, New York, New York.

## EXPERTS

The consolidated financial statements as of December 31, 2021 and 2020 and for each of the years then ended incorporated by reference in this Prospectus and in the Registration Statement have been so incorporated in reliance on the report of BDO USA, LLP, an independent registered public accounting firm, incorporated herein by reference, given on the authority of said firm as experts in auditing and accounting. The report on the consolidated financial statements contains an explanatory paragraph regarding the Company's ability to continue as a going concern.

## WHERE YOU CAN FIND MORE INFORMATION

We file annual, quarterly and other reports, proxy statements and other information with the SEC. Our SEC filings are available to the public over the Internet at the SEC's website at <http://www.sec.gov>. Our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, and Current Reports on Form 8-K, including any amendments to those reports, and other information that we file with or furnish to the SEC pursuant to Section 13(a) or 15(d) of the Exchange Act can also be accessed free of charge through the Internet. These filings will be available as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. You may also access these filings through our website at [www.neurobopharma.com](http://www.neurobopharma.com).

We have filed with the SEC a registration statement under the Securities Act relating to the offering of these securities. The registration statement, including the attached exhibits, contains additional relevant information about us and the securities. This prospectus does not contain all of the information set forth in the registration statement. You can obtain a copy of the registration statement, at prescribed rates, from the SEC at the address listed above. The registration statement, along with our most recent annual report on Form 10-K, subsequent reports on Form 10-Q and current reports on Form 8-K, as well as other filings that we make with the SEC, are also available on our Internet website, [www.neurobopharma.com](http://www.neurobopharma.com). We have not incorporated by reference into this prospectus the information on our website, and you should not consider it to be a part of this prospectus.

## INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE

The SEC allows us to "incorporate by reference" in this prospectus much of the information we file with the SEC, which means that we can disclose important information to you by referring you to those publicly available documents. The information we incorporate by reference is an important part of this prospectus, and certain information that we will later file with the SEC will automatically update and supersede this information. Later information that we file with the SEC will automatically update and supersede the information that is either contained, or incorporated by reference, in this prospectus, and will be considered to be a part of this prospectus from the date those documents are filed.

We incorporate by reference into this prospectus and the registration statement of which this prospectus forms a part the information or documents listed below that we have filed with the SEC, and any future filings we will make with the SEC under Sections 13(a), 13(c), 14, or 15(d) of the Exchange Act (other than information furnished under Item 2.02 or Item 7.01 of Form 8-K or Schedule 14A), including all filings filed pursuant to the Exchange Act after the date of the registration statement and prior to effectiveness of the registration statement, and following effectiveness of the registration statement and until the termination or completion of the offering of the securities covered by this prospectus:

- Our [Annual Report on Form 10-K for the fiscal year ended December 31, 2021, filed with the SEC on March 31, 2022](#), including the information specifically incorporated by reference into such Annual Report on Form 10-K from our [definitive proxy statement for our 2022 Annual Meeting of Stockholders filed with the SEC on May 18, 2022](#);

- Our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2022 and June 30, 2022, filed with the SEC on [May 13, 2022](#) and [August 12, 2022](#);
- Our Current Reports on Form 8-K filed with the SEC on [January 14, 2022](#), [January 28, 2022](#), [March 21, 2022](#), [June 10, 2022](#), [September 12, 2022](#) and [September 14, 2022](#); and
- [The description of the Registrant's Common Stock contained in the Registrant's Form 8-A \(File No. 001-37809\) filed with the Commission on June 20, 2016, as further amended by any subsequent amendment or report filed for the purpose of updating such description.](#)

We will furnish without charge to you, on written or oral request, a copy of any or all of the documents incorporated by reference in this prospectus including exhibits to these documents. You should direct any requests for documents to NeuroBo Pharmaceuticals, Inc., Attn: Secretary, 200 Berkeley Street, 19<sup>th</sup> Floor, Boston, Massachusetts 02116, or via e-mail at [info@neurobopharma.com](mailto:info@neurobopharma.com). Our phone number is (800) 736-3001.

You also may access these filings on our website at <http://ir.neurobopharma.com>. We do not incorporate the information on our website into this prospectus and you should not consider any information on, or that can be accessed through, our website as part of this prospectus (other than those filings with the SEC that we specifically incorporate by reference into this prospectus).



## **NeuroBo Pharmaceuticals, Inc.**

**Class A Units consisting of shares of common stock and warrants and  
Class B Units consisting of shares of Series B Convertible Preferred Stock and warrants  
(and shares of common stock underlying shares of Series B Convertible Preferred Stock and warrants)**

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**PRELIMINARY PROSPECTUS**

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**, 2022**

*Sole Book Running Manager*

**Ladenburg Thalmann**

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**PART II**  
**INFORMATION NOT REQUIRED IN THE PROSPECTUS**

**Item 13. Other Expenses of Issuance and Distribution.**

The following table sets forth all expenses paid or payable by the registrant in connection with this offering. All amounts shown are estimates except for the SEC registration fee and the FINRA filing fee.

	Amount Paid or to Be Paid
SEC registration fee	\$
FINRA filing fee	
Printing expenses	
Legal fees and expenses	
Accounting fees and expenses	
Other fees and expenses	
Total	\$

\* To be completed by amendment.

**Item 14. Indemnification of Directors and Officers.**

We are incorporated under the laws of the State of Delaware. Section 102 of the Delaware General Corporation Law permits a corporation to eliminate the personal liability of directors of a corporation to the corporation or its stockholders for monetary damages for a breach of fiduciary duty as a director, except where the director breached his or her duty of loyalty, failed to act in good faith, engaged in intentional misconduct or knowingly violated a law, authorized the payment of a dividend or approved a stock repurchase in violation of Delaware corporate law or obtained an improper personal benefit.

Section 145 of the Delaware General Corporation Law provides that a corporation has the power to indemnify a director, officer, employee or agent of the corporation and certain other persons serving at the request of the corporation in related capacities against expenses (including attorneys' fees), judgments, fines and amounts paid in settlements actually and reasonably incurred by the person in connection with an action, suit or proceeding to which he or she is or is threatened to be made a party by reason of such position, if such person acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the best interests of the corporation, and, in any criminal action or proceeding, had no reasonable cause to believe his or her conduct was unlawful, except that, in the case of actions brought by or in the right of the corporation, no indemnification shall be made with respect to any claim, issue or matter as to which such person shall have been adjudged to be liable to the corporation unless and only to the extent that the Court of Chancery or other adjudicating court determines that, despite the adjudication of liability but in view of all of the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses which the Court of Chancery or such other court shall deem proper.

As permitted by the Delaware General Corporation Law, our amended and restated bylaws provide that: (1) we are required to indemnify our directors and executive officers to the fullest extent permitted by the Delaware General Corporation Law; (2) we may, in our discretion, indemnify our other officers, employees and agents as set forth in the Delaware General Corporation Law; (3) we are required, upon satisfaction of certain conditions, to advance all expenses incurred by our directors and executive officers in connection with certain legal proceedings; (4) the rights conferred in the bylaws are not exclusive; (5) we are authorized to enter into indemnification agreements with our directors, officers, employees and agents; and (6) we may secure insurance on behalf of any director, officer, employee or other agent for any liability arising out of his or her actions in that capacity regardless of whether we would otherwise be permitted to indemnify him or her under the provisions of Delaware law.



We have entered into indemnification agreements with our directors and officers. These agreements provide broader indemnity rights than those provided under the Delaware General Corporation Law and our Certificate of Incorporation. The indemnification agreements are not intended to deny or otherwise limit third-party or derivative suits against us or our directors or officers, but to the extent a director or officer were entitled to indemnity or contribution under the indemnification agreement, the financial burden of a third-party suit would be borne by us, and we would not benefit from derivative recoveries against the director or officer. Such recoveries would accrue to our benefit but would be offset by our obligations to the director or officer under the indemnification agreement.

We maintain a directors' and officers' liability insurance policy. The policy insures directors and officers against unindemnified losses arising from certain wrongful acts in their capacities as directors and officers and reimburses us for those losses for which we have lawfully indemnified the directors and officers. The policy contains various exclusions.

**Item 15. Recent Sales of Unregistered Securities.**

The following sets forth information regarding all unregistered securities we sold in the three years preceding the date of this registration statement. The information below does not reflect the 1-for-30 reverse stock split effective September 12, 2022.

On April 16, 2020, in connection with a registered direct offering, we issued to H.C. Wainwright & Co., LLC, as compensation for its serving as our exclusive placement agent for such registered direct offering warrants to purchase up to 37,500 shares of our common stock with an exercise price of \$12.50 per share.

On October 1, 2021, we entered into a securities purchase agreement (the "October 2021 Securities Purchase Agreement") with several institutional investors for the purchase and sale in a registered direct offering of 4,307,693 shares of our common stock, at a purchase price of \$3.25 per share for gross proceeds of approximately \$14.0 million. The October 2021 Securities Purchase Agreement also provided for a concurrent private placement of warrants to purchase our common stock with the purchasers in the registered direct offering for no additional consideration.

On January 18, 2021, we entered into a securities purchase agreement with certain institutional and accredited investors, pursuant to which we, in a private placement, sold an aggregate of 2,500,000 shares of our common stock at a purchase price of \$4.00 per share for gross proceeds of \$10.0 million, and warrants to purchase an aggregate of 2,500,000 shares of common stock.

On December 31, 2020, we acquired 80% of ANA Therapeutics, Inc., a Delaware corporation ("ANA"), pursuant to an Agreement and Plan of Merger, dated December 31, 2020 (the "2020 Merger Agreement"). Pursuant to the 2020 Merger Agreement, we issued to the stockholders of ANA 3,243,875 shares of our common stock.

Unless otherwise noted, the transactions described in Item 15 were exempt from registration under the Securities Act pursuant to Section 4(a)(2) of the Securities Act in that such sales did not involve a public offering or under Rule 506 of Regulation D promulgated under the Securities Act, based on written representations provided to the Registrant.

**Item 16. Exhibits and Financial Statement Schedules.**

- (a) Reference is made to the attached Exhibit Index.
- (b) No financial statement schedules are provided because the information called for is not required or is shown in the financial statements or the notes thereto.

**Item 17. Undertakings.**

- (a) The undersigned Registrant hereby undertakes:
  - (1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

- (i) To include any prospectus required by Section 10(a)(3) of the Securities Act;
- (ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20 percent change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement; and
- (iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;

*provided, however*, that paragraphs (a)(1)(i), (ii) and (iii) do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the Commission by the Registrant pursuant to Section 13 or Section 15(d) of the Exchange Act, that are incorporated by reference in the registration statement.

- (2) That, for the purpose of determining any liability under the Securities Act, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.
- (3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.
- (4) That, for the purpose of determining liability under the Securities Act of 1933 to any purchaser: each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness; provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.
- (5) That, for the purpose of determining liability under the Securities Act to any purchaser,
  - (i) each prospectus filed by the Registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and
  - (ii) each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5), or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii) or (x) for the purpose of providing the information required by Section 10(a) of the Securities Act shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof; *provided, however*, that no statement made in a registration statement or

prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such effective date.

- (b) The Registrant hereby undertakes that, for purposes of determining any liability under the Securities Act, each filing of the Registrant's annual report pursuant to Section 13(a) or 15(d) of the Exchange Act (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Exchange Act) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.
- (c) Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the Registrant pursuant to the indemnification provisions described herein, or otherwise, the Registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer or controlling person of the Registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

## EXHIBIT INDEX

Exhibit Number	Description	Incorporated by Reference			
		Form	File No.	Exhibit	Filing Date
1.1**	Form of Underwriting Agreement between the Registrant and Ladenburg Thalmann & Co. Inc.				
2.1++	<a href="#">Agreement and Plan of Merger, dated as of July 24, 2019, by and among Registrant, GR Merger Sub Inc. and NeuroBo Pharmaceuticals, Inc.</a>	S-4	333-233588	2.1	11/4/2019
2.2	<a href="#">First Amendment to Agreement and Plan of Merger, dated as of July 24, 2019, by and among Registrant, GR Merger Sub Inc. and NeuroBo Pharmaceuticals, Inc.</a>	S-4	001-37809		11/4/2019
2.3	<a href="#">Agreement and Plan of Merger, dated as of December 31, 2020, by and among the Registrant, Shelby Merger Sub 1, Inc., Shelby Merger Sub 2, LLC, ANA Therapeutics, Inc. and Akash Bakshi</a>	8-K	001-37809	2.1	1/1/2021
3.1	<a href="#">Third Amended and Restated Certificate of Incorporation of Registrant.</a>	8-K	001-37809	3.1	8/10/2016
3.2	<a href="#">Certificate of Amendment (Reverse Stock Split) to the Third Amended and Restated Certificate of Incorporation of the Company.</a>	8-K	001-37809	3.1	12/31/2019
3.3	<a href="#">Certificate of Amendment (Name Change) to the Third Amended and Restated Certificate of Incorporation of the Company.</a>	8-K	001-37809	3.2	12/31/2019
3.4	<a href="#">Certificate of Amendment (Reverse Stock Split) to the Third Amended and Restated Certificate of Incorporation of the Company.</a>	8-K	001-37809	3.1	9/12/2022
3.5**	Form of Certificate of Designation of Series A Convertible Preferred Stock				
3.6**	Form of Certificate of Designation of Series B Convertible Preferred Stock				
3.7	<a href="#">Second Amended and Restated Bylaws of Registrant.</a>	10-K	001-37809	3.4	3/30/2020
4.1	<a href="#">Form of Common Stock Certificate of the Registrant.</a>	S-1	333-210815	4.1	6/13/2016
4.2**	Form of Warrant Agency Agreement between the Registrant and American Stock Transfer & Trust Company.	8-K	001-37809		
4.3**	Form of Warrant offered hereby.	8-K	001-37809		
4.4	<a href="#">Form of Warrant to Purchase Common Stock</a>	8-K	001-37809	4.1	3/13/2017
4.5	<a href="#">Warrant to Purchase Stock, dated July 31, 2018, by and between the Registrant and Silicon Valley Bank</a>	8-K	001-37809	4.1	8/6/2018
4.6	<a href="#">Form of Placement Agent's Warrant to Purchase Common Stock</a>	8-K	001-37809	4.1	4/15/2020
4.7	<a href="#">Form of Warrant to Purchase Common Stock</a>	8-K	001-37809	4.1	1/21/2021
4.8	<a href="#">Form of Warrant to Purchase shares of Common Stock</a>	8-K	001-37809	4.1	10/4/2021
5.1**	Opinion of Honigman LLP.				
10.1+	<a href="#">Form of Indemnification Agreement.</a>	S-1	333-210815	10.1	4/18/2016

Exhibit Number	Description	Incorporated by Reference			
		Form	File No.	Exhibit	Filing Date
10.2†	<a href="#">Amended and Restated License Agreement, effective as of August 2, 2018, by and between the Registrant and Pfizer Inc..</a>	8-K	001-37809	10.1	8/6/2018
10.3+	<a href="#">2019 Equity Incentive Plan.</a>	8-K	001-37809	10.2	12/31/2019
10.4+	<a href="#">Form of Restricted Stock Grant Notice and Restricted Stock Agreement under the Amended and Restated 2015 Equity Incentive Plan (Employees).</a>	8-K	001-37809	10.4	7/25/2019
10.5+	<a href="#">Form of Restricted Stock Grant Notice and Restricted Stock Agreement under the Amended and Restated 2015 Equity Incentive Plan (Directors).</a>	8-K	001-37809	10.5	7/25/2019
10.6^	<a href="#">License and Collaboration Agreement, dated as of July 23, 2019, by and between the Registrant and Beijing SL Pharmaceutical Co., Ltd.</a>	8-K	001-37809	10.6	7/25/2019
10.7	<a href="#">Membership Agreement, dated as of November 11, 2020, by and between WeWork and the Registrant.</a>	10-K	001-37809	10.15	3/30/2020
10.7	<a href="#">Amendment to Membership Agreement, dated December 23, 2021, by and between WeWork and the Registrant.</a>	10-K	001-37809	10.47	3/31/2022
10.8	<a href="#">Amendment to Membership Agreement, dated February 9, 2022, by and between WeWork and the Registrant.</a>	10-K	001-37809	10.48	3/31/2022
10.9^	<a href="#">Manufacturing and Supply Agreement, dated as of September 28, 2018, between Dong-A ST Co., Lt. and the Registrant.</a>	S-4	333-233588	10.36	9/3/2019
10.10	<a href="#">Lease Agreement, dated as of May 2, 2019, by and between Gyeonggi Urban Innovation Corporation and NeuroBo Co., Ltd.</a>	S-4	333-233588	10.40	9/3/2019
10.11^	<a href="#">License Agreement, dated as of January 18, 2018, as amended on April 18, 2018 and July 24, 2019, by and between Dong-A ST Co., Ltd. and the Registrant.</a>	S-4	333-233588	10.42	9/3/2019
10.12^	<a href="#">Acquisition Agreement, dated January 18, 2018, as amended on April 18, 2018 and July 24, 2019, by and between Dong-A ST Co., Ltd. and the Registrant.</a>	S-4	333-233588	10.43	9/3/2019
10.13+	<a href="#">2018 Stock Plan for the Registrant.</a>	S-4	333-233588	10.44	9/3/2019
10.14+	<a href="#">Form of Stock Option Agreement for the 2018 Stock Plan for the Registrant.</a>	S-4	333-233588	10.45	9/3/2019
10.15+	<a href="#">Form of Notice of Grant of Restricted Stock Purchase Right for the 2018 Stock Plan for the Registrant.</a>	S-4	333-233588	10.46	9/3/2019
10.16+	<a href="#">Form of Notice of Grant of Stock Option to the 2018 Stock Plan for the Registrant.</a>	S-4	333-233588	10.47	9/3/2019
10.17+	<a href="#">Form of Notice of Grant of Restricted Stock Bonus for the 2018 Stock Plan for the Registrant.</a>	S-4	333-233588	10.48	9/3/2019
10.18++	<a href="#">Contingent Value Rights Agreement, dated as of December 30, 2019, by and among the Registrant, Grand Rapids Holders Representative, LLC, Computershare Inc. and Computershare Trust Company, N.A..</a>	8-K	001-37809	10.1	12/31/2019

Exhibit Number	Description	Incorporated by Reference			
		Form	File No.	Exhibit	Filing Date
10.19	<a href="#">First Amendment to Contingent Value Rights Agreement, dated as of December 30, 2019, by and among the Registrant, Grand Rapids Holders Representative, LLC, Computershare Inc. and Computershare Trust Company, N.A., dated as of March 23, 2021.</a>	8-K	001-37809	10.1	3/24/2021
10.20+	<a href="#">Employment Agreement, dated February 11, 2020, by and between the Registrant and Richard Kang.</a>	8-K	001-37809	10.1	2/13/2020
10.21+	<a href="#">Form of Incentive Stock Option Agreement for 2019 Equity Incentive Plan.</a>	10-K	001-37809	10.31	3/30/2020
10.22+	<a href="#">Form of Restricted Stock Agreement for 2019 Equity Incentive Plan.</a>	10-K	001-37809	10.32	3/30/2020
10.23+	<a href="#">Form of Non-Qualified Stock Option Agreement for 2019 Equity Incentive Plan.</a>	10-K	001-37809	10.33	3/30/2020
10.24+	<a href="#">Form of Stock Unit Agreement for 2019 Equity Incentive Plan.</a>	10-K	001-37809	10.34	3/30/2020
10.25	<a href="#">Form of Securities Purchase Agreement.</a>	8-K	001-37809	10.1	4/15/2020
10.26	<a href="#">Manufacturing and Supply Agreement (NB-02 formerly DA-9803), dated as of June 7, 2020, by and between Dong-A ST Co., Ltd. and the Registrant.</a>	10-Q	001-37809	10.2	8/11/2020
10.27	<a href="#">Form of Support Agreement.</a>	8-K	001-37809	10.1	1/6/2021
10.28	<a href="#">Form of Lock-Up Agreement.</a>	8-K	001-37809	10.2	1/6/2021
10.29+	<a href="#">Employment Agreement, dated as of December 31, 2020, by and between the Registrant and Akash Bakshi.</a>	10-K	001-37809	10.40	4/15/2021
10.30	<a href="#">Form of Securities Purchase Agreement, dated as of October 1, 2021, by and among NeuroBo Pharmaceuticals, Inc. and the purchasers identified on the signature pages thereto.</a>	8-K	001-37809	10.1	10/4/2021
10.31+	<a href="#">NeuroBo Pharmaceuticals, Inc. 2021 Inducement Plan.</a>	8-K	001-37809	10.1	11/4/2021
10.32+	<a href="#">Form of Stock Option Grant Notice, Option Agreement and Notice of Exercise under the NeuroBo Pharmaceuticals, Inc. 2021 Inducement Plan.</a>	8-K	001-37809	10.2	11/4/2021
10.33+	<a href="#">Separation Agreement entered into on November 3, 2021 by and between NeuroBo Pharmaceuticals, Inc. and Richard Kang.</a>	8-K	001-37809	10.3	11/4/2021
10.34+	<a href="#">Employment Agreement entered into on November 3, 2021 by and between NeuroBo Pharmaceuticals, Inc. and Ben Gil Price.</a>	8-K	001-37809	10.4	11/4/2021
10.35+	<a href="#">Amended and Restated Non-Employee Director Compensation Policy, dated January 14, 2022.</a>	8-K	001-37809	10.1	1/28/2022
10.36	<a href="#">Amendment to Membership Agreement, dated April 19, 2022, by and between WeWork and the Registrant.</a>	10-Q	001-37809	10.1	8/12/2022
10.37^	<a href="#">License Agreement by and between Dong-A ST Co., Ltd. and the Registrant, dated September 14, 2022</a>	8-K	001-37809	10.1	9/14/2022
10.38++	<a href="#">Securities Purchase Agreement by and between Dong-A ST Co., Ltd. and the Registrant, dated September 14, 2022</a>	8-K	001-37809	10.3	9/14/2022

Exhibit Number	Description	Incorporated by Reference			
		Form	File No.	Exhibit	Filing Date
10.39	<a href="#">Registration Rights Agreement by and among Dong-A ST Co., Ltd., The E&amp;Healthcare Investment Fund II, The E&amp;Healthcare Investment Fund No. 6, The E&amp;Healthcare Investment Fund No. 7 and the Registrant, dated September 14, 2022</a>	8-K	001-37809	10.4	9/14/2022
10.40	<a href="#">Shared Services Agreement by and between Dong-A ST Co., Ltd. and the Registrant, dated September 14, 2022</a>	8-K	001-37809	10.2	9/14/2022
10.41	<a href="#">Investor Rights Agreement by and between Dong-A ST Co., Ltd. and the Registrant, dated September 14, 2022</a>	8-K	001-37809	10.5	9/14/2022
21.1*	<a href="#">Subsidiaries of the Registrant</a>				
23.1*	<a href="#">Consent of BDO USA, LLP, Independent Registered Public Accounting Firm.</a>				
23.2**	Consent of Honigman, LLP (included in Exhibit 5.1).				
24.1*	<a href="#">Power of Attorney of certain directors and officers of the Registrant (contained on signature page).</a>				
107*	<a href="#">Calculation of Registration Fee</a>				

\* Filed herewith.

\*\* To be filed by amendment

† Registrant has omitted and filed separately with the SEC portions of the exhibit pursuant to a confidential treatment request under Rule 406 promulgated under the Securities Act.

+ Indicates a management contract or compensatory plan.

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

^ 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. Certain portions of the exhibits that are not material and would be competitively harmful if publicly disclosed have been redacted pursuant to Item 601(b)(10)(iv) of Regulation S-K. Copies of the unredacted exhibits will be furnished to the SEC upon request.

^^ Previously filed.



**SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933, as amended, the Registrant has duly caused this Registration Statement on Form S-1 to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Boston, Commonwealth of Massachusetts, on September 16, 2022.

**NEUROBO PHARMACEUTICALS, INC.**

By: /s/ Gil Price, M.D.

Name: Gil Price, M.D.

Title: President and Chief Executive Officer

KNOW ALL MEN BY THESE PRESENTS, that the undersigned officers and directors of NeuroBo Pharmaceuticals, Inc., a Delaware corporation, do hereby constitute and appoint each of Gil Price, M.D. and Andrew Koven as his or her true and lawful attorney-in-fact and agent, with full power of substitution and re-substitution, for him and in his name, place, and stead, in any and all capacities, to sign any and all amendments (including post-effective amendments, exhibits thereto and other documents in connection therewith) to this Registration Statement and any subsequent registration statement filed by the Registrant pursuant to Rule 462(b) of the Securities Act of 1933, as amended, which relates to this Registration Statement, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent, or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof

Pursuant to the requirements of the Securities Act of 1933, this registration statement has been signed by the following persons in the capacities and on the dates indicated:

Signature	Title of Capacities	Date
/s/ Gil Price, M.D. Gil Price, M.D.	President and Chief Executive Officer (Principal Executive Officer, Principal Financial Officer and Principal Accounting Officer)	September 16, 2022
/s/ Andrew Koven Andrew Koven	Chair of the Board of Directors	September 16, 2022
/s/ Jason L. Groves Jason L. Groves	Director	September 16, 2022
/s/ Richard J. Kang Richard J. Kang	Director	September 16, 2022
/s/ Hyung Heon Kim Hyung Heon Kim	Director	September 16, 2022
/s/ Na Yeon (Irene) Kim Na Yeon (Irene) Kim	Director	September 16, 2022
/s/ Michael Salsbury Michael Salsbury	Director	September 16, 2022
/s/ D. Gordon Strickland D. Gordon Strickland	Director	September 16, 2022

## SUBSIDIARIES OF NEUROBO PHARMACEUTICALS, INC.

<b>Name</b>	<b>Jurisdiction of Organization</b>
NeuroBo Therapeutics, Inc.	Delaware
NeuroBo Co., Ltd.	A Korean limited company
ANA Therapeutics, LLC	Delaware

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Consent of Independent Registered Public Accounting Firm

NeuroBo Pharmaceuticals, Inc.  
Boston, MA

We hereby consent to the incorporation by reference in the Prospectus constituting a part of this Registration Statement of our report dated March 31, 2022, relating to the consolidated financial statements of NeuroBo Pharmaceuticals, Inc. appearing in the Company's Annual Report on Form 10-K for the year ended December 31, 2021. Our report contains an explanatory paragraph regarding the Company's ability to continue as a going concern.

We also consent to the reference to us under the caption "Experts" in the Prospectus.

/s/ BDO USA, LLP  
Boston, Massachusetts

September 16, 2022

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## Calculation of Filing Fee Table

FORM S-1  
(Form Type)NeuroBo Pharmaceuticals, Inc.  
(Exact Name of Registrant as Specified in its Charter)

## Newly Registered Securities

Security Type	Security Class Title	Fee Calculation or Carry Forward Rule	Amount Registered	Proposed Maximum Offering price Maximum Aggregate Offering Price Per Unit	Maximum Aggregate Offering Price (1)(3)	Fee Rate	Amount of Registration Fee
<b>Fees to Be Paid</b>							
Equity	Class A Units, consisting of (i) shares of Common Stock, par value \$0.001 per share and (ii) Warrants to purchase Common Stock						
Equity	Common Stock, par value \$0.001 per share (2)	Rule 457(o)				\$92.70 per \$1,000,000	
Equity	Warrants to purchase Common Stock included in the Class A Units (2)(4)						
Equity	Class B Units, consisting of (i) shares of Series B Convertible Preferred Stock, par value \$0.001 per share, (ii) Common Stock issuable on conversion of Series B Convertible Preferred Stock, and (iii) Warrants to purchase Common Stock	Rule 457(o)				\$92.70 per \$1,000,000	
Equity	Series B Convertible Preferred Stock, par value \$0.001 per share (2)						
Equity	Common Stock issuable upon conversion of Series B Convertible Preferred Stock (2)(5)						
Equity	Warrants to purchase Common Stock included in the Class B Units (2)(4)						
Equity	Shares of Common Stock issuable upon exercise of Warrants (2)						
<b>Total Offering Amounts</b>					\$ 15,000,000.00		\$ 1,390.50
<b>Total Fees Previously Paid</b>							\$ 0.00
<b>Total Fee Offsets</b>							\$ 0.00
<b>Net Fee Due</b>							\$ 1,390.50

- (1) Estimated solely for the purpose of calculating the amount of the registration fee in accordance with Rule 457(i) and Rule 457(o) under the Securities Act of 1933 (the "Securities Act").
- (2) Pursuant to Rule 416 under the Securities Act, the securities registered hereby also include an indeterminate number of additional securities as may from time to time become issuable by reason of stock splits, stock dividends, recapitalizations, or other similar transactions.
- (3) Includes the price of additional shares of Common Stock and/or Warrants that may be issued upon exercise of the option granted to the underwriter to cover over-allotments, if any.
- (4) No registration fee required pursuant to Rule 457(g).
- (5) No registration fee required pursuant to Rule 457(i).

