As filed with the Securities and Exchange Commission on January 23, 2023

Registration No. 333-

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

FORM S-3

REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

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

Delaware	**47-2389984**
(State or other jurisdiction of incorporation or organization)	(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)

Joseph Hooker
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)

Copy to:
Phillip D. Torrence, Esq.
Honigman LLP
650 Trade Centre Way, Suite 200
Kalamazoo, Michigan 49002
(269) 337-7700

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

If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box: ☐

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, other than securities offered only in connection with dividend or interest reinvestment plans, 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 registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box. ☐

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box. ☐

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☐

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

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.

Subject to completion, dated January 23, 2023

PROSPECTUS

NEUROBO PHARMACEUTICALS, INC.

22,629,907 shares of common stock, including 10,000,000 shares of common stock underlying warrants

This prospectus ("prospectus") relates to the resale from time to time of up to 22,629,907 shares of common stock of NeuroBo Pharmaceuticals, Inc. by the selling stockholders identified in this prospectus under the caption "Selling Stockholders" (the "selling stockholders"), including their pledgees, assignees, donees, transferees or successor-in-interest, comprised of 12,629,907 shares of common stock and 10,000,000 shares of common stock underlying warrants issued to the selling stockholder.

We issued 12,333,333 shares of the common stock pursuant to a securities purchase agreement with one of the selling stockholders, Dong-A ST Co. Ltd. ("Dong-A"), pursuant to which, concurrently with our public offering of units which was consummated on November 8, 2022, (i) we issued to Dong-A shares of our Series A Convertible Preferred Stock with a value of $22 million, which converted following stockholder approval of such conversion into 7,333,333 shares of common stock as an upfront payment in respect of the license agreement between us and Dong-A, dated as of September 14, 2022, and (ii) we issued to Dong-A, in a private offering, shares of our Series A Convertible Preferred Stock with a value of $15 million, which converted following stockholder approval of such conversion into 5,000,000 shares of common stock together with warrants to purchase 10,000,000 shares of our common stock at an exercise price of $3.00 per share which are exercisable on "cashless" basis for shares without any cash payment. The remaining 296,574 shares were previously issued to Dong-A and the other selling stockholders.

The selling stockholders may, from time to time, sell, transfer or otherwise dispose of any or all of their shares of common stock or interests in their shares of common stock on any stock exchange, market or trading facility on which the shares of common stock are traded or in private transactions. These dispositions may be at fixed prices, at prevailing market prices at the time of sale, at prices related to the prevailing market price, at varying prices determined at the time of sale, or at negotiated prices. See "Plan of Distribution" on page 50 of this prospectus for more information. We will not receive any proceeds from the resale or other disposition of the common stock by the selling stockholders.

Our Common Stock is listed on the Nasdaq Capital Market under the symbol "NRBO." On January 20, 2023, the last reported sale price of our Common Stock as reported on the Nasdaq Capital Market was $0.82 per share.

You should read this prospectus, together with additional information described under the headings "Information Incorporated by Reference" and "Where You Can Find More Information," carefully before you invest in any of our securities.

This prospectus contains or incorporates by reference summaries of certain provisions contained in some of the documents described herein, but reference is made to the actual documents for complete information. All the summaries are qualified in their entirety by the actual documents. Copies of some of the documents referred to herein have been filed or have been incorporated by reference as exhibits to the registration statement of which this prospectus forms a part, and you may obtain copies of those documents as described in this prospectus under the heading "Where You Can Find More Information."

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

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 9 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.

The date of this prospectus is , 2023

TABLE OF CONTENTS

ABOUT THIS PROSPECTUS

This prospectus relates to the resale, from time to time, by the selling stockholders identified in this prospectus under "Selling Stockholders" beginning on page 47, of up to 22,629,907 shares of our common stock, $0.001 par value per share comprised of 12,629,907 shares of common stock owned by the selling stockholders and 10,000,000 shares of common stock underlying warrants issued to one of the selling stockholders. We are not selling any securities under this prospectus, and we will not receive any proceeds from the sale of shares of our common stock by the selling stockholders under 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.

We have not 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.

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

We are a clinical-stage biotechnology company with two primary programs focused on treatment of nonalcoholic steatohepatitis ("***NASH***"), obesity and type 2 diabetes ("***T2D***"):

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

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

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

- ANA001 is a proprietary oral niclosamide formulation is being developed as a treatment for patients with moderate coronavirus disease (COVID-19). Enrollment in the Phase 2 clinical trial of ANA001 for treatment of moderate COVID-19 in hospitalized patients was closed in July 2022 and the clinical trial moved to the data analysis phase. Following an analysis of the clinical trial data, which is expected in the first quarter of 2023, we will be able to begin discussions with the Food and Drug Administration regarding the next steps in the clinical development of ANA001 for treatment of COVID-19.

- NB-01 was primarily focused on the development of a treatment for painful diabetic neuropathy (PDN). We are currently exploring alternatives with respect to the future of NB-01, including bringing the NB-01 asset to the market through a different regulatory pathway, such as with an orphan drug indication or as a nutraceutical.

- NB-02 has the potential to treat the symptoms of cognitive impairment and modify the progression of neurodegenerative diseases associated with the malfunction of a protein called tau, and with amyloid beta plaque deposition. We have postponed continued work on the Investigation New Drug application to the FDA for NB-02 and the first human clinical trials for NB-02 until global health and macroeconomic conditions improve. We are also considering engaging with a strategic partner with respect to further development of NB-02.

- Gemcabene is currently being assessed as an acute indication for COVID-19 in combination with ANA001. Gemcabene was previously focused on developing and commercializing therapies for the treatment of dyslipidemia, a serious medical condition that increases the risk of life-threatening cardiovascular disease, focused on orphan indications such as homozygous familial hypercholesterolemia, as well as NAFLD/NASH.

Recent Developments

Transactions with Dong-A ST Co., Ltd.

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

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

On September 14, 2022, in connection with the License Agreement, we entered into a Securities Purchase Agreement with Dong-A (the "***Securities Purchase Agreement***"). Pursuant to the Securities Purchase Agreement, upon the consummation of the License Agreement and a Qualified Financing (as defined in the Securities Purchase Agreement), which occurred on November 8, 2022, (i) Dong-A received the Upfront License Payment and (ii) Dong-A purchased 1,500 shares of Series A Preferred Stock and warrants to purchase 10,000,000 shares of our common stock substantially equivalent to those issued to investors in respect of the Qualified Financing (the "***warrants***") for a purchase price of $15 million (the "***Dong-A Financing***").

On December 22, 2022, our stockholders approved the conversion of the Series A Preferred Stock and the exercise of the warrants and all of the Series A Preferred Stock converted into 12,333,333 shares of our common stock.

Public Offering

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

On November 8, 2022, the Public Offering closed, and we issued and sold (i) 3,147,003 Class A Units which included 3,147,003 shares of common stock, 3,147,003 Series A Warrants and 3,147,003 Series B Warrants and (ii) 2,692,997 Class B Units which included 2,692,997 shares of Series B Convertible Preferred Stock, 2,692,997 Class A Warrants and 2,692,997 Class B Warrants. We received gross proceeds of approximately $17.3 million. The exercise price for the Series A Warrants and Series B Warrants was $3.00 per share. Following the closing of the Public Offering, all of the 2,692,997 shares of Series B Preferred Stock were converted into common stock on a one-for-one basis.

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. 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.

The Offering	
Securities to be offered by the selling stockholders	Up to 22,629,907 shares of common stock, including 10,000,000 shares of common stock underlying warrants.
Use of proceeds	The common stock to be offered and sold using this prospectus will be offered and sold by the selling stockholders named in this prospectus. Accordingly, we will not receive any proceeds from any sale of shares of our common stock in this offering. A portion of the shares covered by this prospectus may be issued upon exercise of the warrants. Upon any cash exercise of the warrants, the selling stockholders will pay us the applicable exercise price. We anticipate that proceeds that we receive from the cash exercise of such warrants, if any, will be used for working capital and general corporate purposes, including, without limitation, development of our product candidates, and general and administrative expenses. It is possible that, pending their use, we may invest the net proceeds in a way that does not yield a favorable, or any, return for us. See the section entitled "Use of Proceeds" in this prospectus.
Risk factors	You should carefully consider the risk factors described in the section of this prospectus titled "Risk Factors," together with all of the other information included and incorporated by reference in this prospectus, before deciding to invest in our securities.
Market and trading symbol	Our common stock is listed on the Nasdaq Capital Market under the symbol "NRBO".

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

- We have incurred losses since inception, we anticipate that we will incur continued losses for the foreseeable future;
- 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 will need additional financings to fund operations and such additional financings may cause dilution to existing stockholders, restrict our operations or require us to relinquish our technologies;
- The timing and costs related to the clinical development of our products are difficult to predict, particularly due to our developing products to treat NASH, for which there are currently no approved products, and any delays in our clinical trials may lead to a delay in the submission of marketing approval applications;
- We may be required to make significant payments under the License Agreement;
- We may not be able to successfully obtain regulatory or marketing approval for, or successfully commercialize, any of our product candidates.
- The regulatory review and approval processes of the FDA and comparable foreign regulatory authorities are lengthy, time-consuming and inherently unpredictable;
- Our pursuit of potential therapeutic and prophylactic treatments for COVID-19 is in an early stage and subject to many risks, and our 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 our 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 us to additional risks;
- 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.
- 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 our control;
- We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do;
- Our commercial success depends upon attaining significant market acceptance of its product candidates, if approved, among hospitals, physicians, patients and healthcare payors;

- We rely on third parties to develop our preclinical studies, clinical trials, research programs and product candidates and to manufacture our 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 we are unable to engage with these third parties, it could have a material adverse effect on our business and our obtaining of regulatory approval and commercialization of our product candidates;

- 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.

- Our relationships with healthcare providers and third-party payors will be subject to applicable healthcare laws and regulations, which could expose us to certain penalties and consequences;

- Certain tax matters, including our ability to use our NOLs to offset future taxable income may be subject to certain limitations, could impact its results of operations and financial conditions;

- If we are unable to obtain, maintain and protect sufficient intellectual property rights, its competitive position could be harmed;

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

- We may become involved in lawsuits to protect or enforce our intellectual property, which could be expensive, time consuming, unsuccessful and could distract our personnel from their normal responsibilities;

- Dong-A has a significant interest in and controls our Company, and as a result, Dong-A's interests may conflict with ours or our other stockholders' interests in the future;

- We are 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.

- Provisions in our corporate charter documents and under Delaware law could make an acquisition of our Company more difficult and may prevent attempts by our stockholders to replace or remove our current management;

- We are a "smaller reporting company", which could make our common stock less attractive to investors;

- We have identified material weaknesses in our 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;

- Any failure, inadequacy, interruption or security lapse of our information technology could prevent us from accessing critical information or expose us to liability;

- An active trading market for our common stock may not be maintained;

- We incur increased costs as a result of operating as a public company and its management is required to devote substantial time to compliance initiatives;

- 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;

- 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 the ability of our stockholders to obtain a favorable judicial forum for disputes with our Company or our directors, officers or employees;

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

- The liquidity and trading volume of our common stock could be low, its ownership will be concentrated and the market price of its common stock may be highly volatile; and

- Our common stock may be delisted from the Nasdaq Capital Market if it fails to comply with the continued listing requirements.

Risks Related to the Business

We have incurred losses since inception, we anticipate that we will incur continued losses for the foreseeable future. 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 $91.1 million as of September 30, 2022. It is possible we will never generate revenue or profit.

As of September 30, 2022, we had cash and cash equivalents of $6.4 million. In November 2022, we completed our public offering and concurrent private placement which resulted in net proceeds to us of approximately $29.3 million. We expect that our cash and cash equivalents will be adequate to fund operations into the second quarter of 2024.

We expect that our costs will increase significantly as we advance the development of our 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.

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.

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

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

We have acquired exclusive rights (other than in the Republic of Korea) to DA-1241 and DA-1726 for the specific indications provided in the License Agreement. Under the License Agreement, in consideration for the license, we have made an upfront payment of $22.0 million in Series A Convertible Preferred Stock which converted into 7,333,333 shares of common stock upon stockholder approval of conversion of the 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 process the data from our 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 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 are not 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 ma y 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 COVID-19, we ceased development of NB-01 on the prior regulatory pathway and determined 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.

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

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

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

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

Factors that may generally affect patient enrollment include:

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

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

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

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

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

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

T2D

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

NASH

There are currently no medications approved for the treatment of NASH. However, various therapeutics are used off-label for the treatment of NASH, including vitamin E (an antioxidant), insulin sensitizers (e.g., metformin, pioglitazone), antihyperlipidemic agents (e.g., gemfibrozil), pentoxifylline and ursodeoxycholic acid (UDCA). There are several product candidates in Phase 3 or earlier clinical or preclinical development for the treatment of NASH, including Madrigal Pharmaceuticals, Inc.'s THR beta agonist (resmetirom), Novo Nordisk's GLP1 agonist (semaglutide), and Inventiva's pan-PPAR agonist (lanifibranor), as well as FXR agonists from Intercept Pharmaceuticals Inc. (obeticholic acid), Novartis AG (tropifexor, nidufexor), Metacrine (MET409, MET642), Terns Pharmaceuticals (TERN-101), Gilead Sciences, Inc. (cilofexor) and Enanta Pharmaceuticals, Inc. (EDP-305).

Obesity

Due to the growing overweight and obesity epidemic and consumer demand, there are many competitors in the field of obesity treatment. Obesity treatments range from behavioral modification, to drugs and medical devices, and surgery, generally as a last resort. If DA-1726 were approved for obesity, our primary competition in the obesity treatment market would currently be from approved and marketed products, including, liragluitde (SAXENDA®), semaglutide (WEGOVY®), phentermine/topiramate (QSYMIA®), naltrexone/bupropion (CONTRAVE®) and orlistat (XENICAL®/ ALLI®). 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®], nirmatrelvir/ritonavir [PAXLOVID™] and molnupiravir), and several antibody treatments have received emergency use authorization from the FDA (sotrovimab, bebtelovimab, casirivimab/imdevimab [REGEN-COV®], tixagevimab/cilgavimab [EVUSHELD™] 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. For example, pursuant to the terms of the License Agreement and the Shared Services Agreement (as described below under "Transactions with Dong-A"), we collaborate with Dong-A on the development of DA-1241 and DA-1726.

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, 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.

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.

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 have undergone an additional ownership change upon the closing of the 2022 License Agreement and private placement, 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 as our sole third party manufacturer for the manufacture of DA-1241, DA-1726 and 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.

To meet our projected needs for clinical supplies to support our activities through regulatory approval and commercial manufacturing, Dong-A 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 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 our 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 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 DA-1241, DA-1726, ANA001, NB-01 and NB-02, 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 DA-1241, DA-1726, ANA001, NB-01, NB-02 and gemcabene, 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

Dong-A has a significant interest in and controls our Company, and its interests may conflict with ours or those of our other stockholders in the future.

Dong-A currently owns approximately 48.87% of our outstanding common stock. In addition, pursuant to the Investor Rights Agreement between us and Dong-A, Dong-A has the right to appoint a number of our directors commensurate with its percentage holding of our common stock and, as a result, Dong-A controls both the determinations of the Board 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 stockholders. The interests of Dong-A may not always coincide with our interests or the interests of our other stockholders. 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, Dong-A is 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. 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.

We are 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.

Dong-A owns more than 50% of our outstanding common stock. Thus, we 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 are 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 currently rely on the "*controlled company*" exemptions under the Nasdaq listing rules even though 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 a 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 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 smaller reporting companies, including, but not limited to, for smaller reporting companies, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act. Once we are no longer a "smaller reporting 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 of 1933, as amended (the "***Securities Act***") and the Securities Exchange Act of 1934, as amended (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.

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.

As of December 31, 2022, Dong-A holds approximately % of our outstanding common stock. As a result, Dong-A is 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 results in Dong-A having the ability to determine whether there would be a change in 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 may also contribute to the low trading volume and volatility of our common stock.

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 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.

If we do not meet 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. On September 27, 2022, we were notified by Nasdaq that we were in compliance with all listing requirements, including the minimum closing bid price requirement.

There can be no assurance that we will be able to remain in compliance with the minimum bid price requirement and other Nasdaq listing criteria. If we fail meet the applicable continued listing requirements for the Nasdaq Capital Market in the future, 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).

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)).

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

The common stock to be offered and sold using this prospectus will be offered and sold by the selling stockholders named in this prospectus. Accordingly, we will not receive any proceeds from any sale of shares of our common stock in this offering. A portion of the shares covered by this prospectus may be issued upon exercise of the warrants. Upon any cash exercise of the warrants, the selling stockholder that exercises the warrant will pay us the applicable exercise price. We anticipate that proceeds that we receive from the cash exercise of such warrants, if any, will be used for working capital and general corporate purposes, including, without limitation, development of our product candidates, and general and administrative expenses. We will pay all of the fees and expenses incurred by us in connection with this registration. We will not be responsible for fees and expenses incurred by the selling stockholders or any underwriting discounts or agent's commissions.

TRANSACTIONS WITH DONG-A

On September 14, 2022, we entered into a series of agreements with Dong-A described below, including the License Agreement, the Shared Services Agreement, the Securities Purchase Agreement, the Registration Rights Agreement and the Investor Rights Agreement (the "***Dong-A Agreements***"). On November 8, 2022, the transactions contemplated by the Dong-A Agreements (the "***Dong-A Transactions***") were consummated, the License Agreement became effective and the Series A Preferred Stock and warrants were issued to Dong-A.

License Agreement

On September 14, 2022, we entered into the 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 and certain other Asian countries) to two proprietary compounds for specified indications. The 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 Mellius.

Under the terms of the License Agreement, Dong-A (i) received an upfront payment of $22,000,000, which was paid in shares of Series A Preferred Stock, which was converted into 7,333,333 shares of common stock on December 22, 2022; (ii) is eligible to receive single digit royalties on net sales received by the Company from the commercial sale of products covering DA-1241 or DA-1726; (iii) is eligible to receive commercial-based milestone payments, dependent upon the achievement of specific commercial developments, which commercial milestone payments may be paid in shares of our common stock, with the price per share determined based on the VWAP (as defined in the License Agreement) for the 30 trading days ending on the trading day prior to the date on which achievement of such milestone is announced (the "***30-day VWAP***"); and (iv) be eligible to receive regulatory milestone payments of up to $178 million for DA-1726 and $138 million for DA-1241, dependent upon the achievement of specific regulatory developments, which regulatory milestone payments may be paid in shares of our common stock, based on the 30-day VWAP.

The term of the License Agreement will continue 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 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 or (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).

Shared Services Agreement

On September 14, 2022, in connection with the 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 therein. 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 a Securities Purchase Agreement with Dong-A (the "***Securities Purchase Agreement***"). Pursuant to the Securities Purchase Agreement, upon the consummation of the License Agreement and our raising at least $15 million from outside investors, (i) Dong-A received the Upfront License Payment and (ii) Dong-A purchased from us $15 million in value of shares of Series A Convertible Preferred Stock and warrants to purchase 10,000,000 shares of our common stock. On December 22, 2022, the Series A Preferred Stock issued pursuant to the Securities Purchase Agreement was converted into 5,000,000 shares of common stock.

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 the other selling 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 of the conversion of the Series A Preferred Stock ("***Stockholder Approval***"), which occurred on December 22, 2022, a registration statement to (i) register the shares of common stock issuable upon the conversion of the Series A 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 of 1933, as amended (the "***Securities Act***"), as promptly as possible after the filing thereof, but in any event no later than the 60th day after Stockholder Approval (or in case the SEC reviews the registration statement, the 90th 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 the conversion of the Series A Preferred Stock into common stock, Dong-A will have the right, subject to the terms thereof, to designate for appointment to our 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***"). To the extent necessary to permit the designation of the DA Designees, the size of our Board of Directors 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 our Board of Directors 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 our Board will be the same as those provided to other non-employee directors generally. When evaluating a prospective DA Designee for membership on our Board, our Board and the Nominating and Corporate 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 for a customary standstill for nine months following the conversion of the Series A Preferred Stock to common stock. Furthermore, for so long as Dong-A has the right to designate any DA Designee to our Board of Directors, 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 Director, in each case, at any meeting of the stockholders.

SELLING STOCKHOLDERS

The shares of common stock being offered by the selling stockholders are those previously issued to the selling stockholders or will be issued upon exercise of the warrants. For additional information regarding the issuances of certain of those shares of common stock and warrants, see "Prospectus Summary— Recent Developments – Transactions with Dong-A ST Co. Ltd." above. We are registering the shares of common stock in order to permit the selling stockholders to offer the shares for resale from time to time.

The table below lists the selling stockholders and other information regarding the beneficial ownership of the shares of common stock by the selling stockholders. The second column lists the number of shares of common stock beneficially owned by the selling stockholders, based on its ownership of the shares of common stock and warrants, as of December 31, 2022, assuming exercise of the warrants held by the selling stockholders on that date, without regard to any limitations on exercises.

The third column lists the shares of common stock being offered by this prospectus by the selling stockholders.

In accordance with the terms of the Registration Rights Agreement with the selling stockholders, this prospectus generally covers the resale the shares of common stock owned by the selling stockholders or issuable to the selling stockholders upon exercise of the warrants, in each case as described under "Transactions with Dong-A— Registration Rights Agreement" above, determined as if such securities were converted or exercised in full, each as of the trading day immediately preceding the applicable date of determination, and all subject to adjustment as provided in the Registration Rights Agreement, without regard to any limitations on the conversion or exercise thereof. The fourth column assumes the sale of all of the shares offered by the selling stockholders pursuant to this prospectus.

The terms of the warrants prevent the holder thereof from acquiring shares of common stock upon conversion that would result in the number of shares beneficially owned by such holder and its affiliates exceeding 9.99% of the total number of shares of Common Stock outstanding immediately after giving effect to the conversion. Further, holders of the warrants may not exercise any portion of such holder's warrants to the extent that the holder would own more than 4.99% (or, at the election of the holder, 9.99%) of our outstanding shares of common stock immediately after giving effect to the exercise. The numbers of shares reported below do not reflect these limitations. The selling stockholder may sell all, some or none of its shares in this offering. See "Plan of Distribution."

Name of Selling Stockholder:	Number of Shares of Common Stock Owned Prior to Offering	Maximum Number of Shares of Common Stock to be Sold Pursuant to this Prospectus Offered	Number of Shares of Common Stock Owned after Offering
Dong-A ST Co., Ltd.(1)	22,429,353	22,429,353	-
The E&Healthcare Investment Fund II(2)	96,351	96,351	-
The E&Healthcare Investment Fund No. 6(2)	37,373	37,373	-
The E&Healthcare Investment Fund No. 7(2)	62,159	62,159	-
E&Investment, Inc. (2)	4,671	4,671	

(1) Represents 12,429,353 shares of common stock and warrants to purchase 10,000,000 shares of common stock 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.

(2) E&Investment, Inc. ("***GP***"), is the general partner of The E&Healthcare Investment Fund II ("***Fund II***"), ,E&Healthcare Investment Fund No. 6 ("***Fund 6***") and The E&Healthcare Investment Fund No. 7 ("***Fund 7***")(GP, Fund II, Fund 6 and Fund 7 are referred to herein as the "***E&H Funds***"). As a result of being the general partner, GP may be deemed to hold shared voting and dispositive power over the shares held by Each of Fund II, Fund 6 and Fund 7, Na Yeon Kim is the Chief Executive Officer of the GP and as a result may be deemed to hold shared voting and dispositive power over the shares held by each of GP, Fund II, Fund 6 and Fund 7. Ms. Kim also is currently service as a director on the Company's board of directors. The business 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.

Relationships with Selling Stockholders

As discussed in greater detail above under "Transactions with Dong-A", in September 2022, we entered into the Dong-A Agreements, including a Securities Purchase Agreement, pursuant to which we sold and issued shares of our Series A Convertible Preferred Stock. We also entered into the Registration Rights Agreement with Dong-A and the E&H Funds pursuant to which we are filing the registration statement of which this prospectus forms a part. On December 22, 2022, our stockholders approved the conversion of the Series A Convertible Preferred Stock into 12,333,333 shares of common stock and the exercise of the warrants to purchase 10,000,000 shares of common stock, the resale of which is being registered hereunder.

In addition to the foregoing transactions, we are party to a License Agreement with Dong-A for NB-01, as described under "Item 1. Business – Licensing Agreements – License Agreement with Dong-A for NB-01" in our Annual Report on Form 10-K for the year ended December 31, 2021 and a Manufacturing Agreement with Dong-A as described under "Item 13. Certain Relationships and Related Transactions and Director Independence – Manufacturing Agreement with Dong-A ST" in our Annual Report on Form 10-K for the year ended December 31, 2021.

Mr. Hyung Heon Kim, a member of our Board, is the General Counsel and a Vice President of Dong-A.

Ms. Na Yeon Kim, a member of our Board, is the Chief Executive Officer of the GP.

PLAN OF DISTRIBUTION

We are registering the shares of the common stock (i) issued to or currently held by the selling stockholders and (ii) issuable upon exercise of the warrants issued to the selling stockholders to permit the resale of these shares of common stock by the holders of the shares of the common stock and the warrants from time to time after the date of this prospectus. We will not receive any of the proceeds from the sale by the selling stockholders of the shares of the common stock. We will bear all fees and expenses incident to our obligation to register the shares of the common stock.

The selling stockholders may sell all or a portion of the shares of common stock beneficially owned by it and offered hereby from time to time directly or through one or more underwriters, broker-dealers or agents. If the shares of the common stock are sold through underwriters or broker-dealers, the selling stockholders will be responsible for underwriting discounts or commissions or agent's commissions. The shares of the common stock may be sold on any national securities exchange or quotation service on which the securities may be listed or quoted at the time of sale, in the over-the-counter market or in transactions otherwise than on these exchanges or systems or in the over-the-counter market and in one or more transactions at fixed prices, at prevailing market prices at the time of the sale, at varying prices determined at the time of sale, or at negotiated prices. These sales may be effected in transactions, which may involve crosses or block transactions. The selling stockholders may use any one or more of the following methods when selling shares:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- settlement of short sales entered into after the effective date of the registration statement of which this prospectus is a part;
- broker-dealers may agree with the selling stockholders to sell a specified number of such shares at a stipulated price per share;
- through the writing or settlement of options or other hedging transactions, whether such options are listed on an options exchange or otherwise;
- a combination of any such methods of sale; and
- any other method permitted pursuant to applicable law.

The selling stockholders also may resell all or a portion of the shares in open market transactions in reliance upon Rule 144 under the Securities Act, as permitted by that rule, or Section 4(a)(1) under the Securities Act, if available, rather than under this prospectus, provided that they meet the criteria and conform to the requirements of those provisions.

Broker-dealers engaged by the selling stockholders may arrange for other broker-dealers to participate in sales. If the selling stockholders effect such transactions by selling shares of common stock to or through underwriters, broker-dealers or agents, such underwriters, broker-dealers or agents may receive commissions in the form of discounts, concessions or commissions from the selling stockholders or commissions from purchasers of the shares of common stock for whom they may act as agent or to whom they may sell as principal. Such commissions will be in amounts to be negotiated, but, except as set forth in a supplement to this prospectus, in the case of an agency transaction will not be in excess of a customary brokerage commission in compliance with FINRA Rule 2121; and in the case of a principal transaction a markup or markdown in compliance with FINRA Rule 2121.01.

In connection with sales of the shares of common stock or otherwise, the selling stockholders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the shares of the common stock in the course of hedging in positions they assume. The selling stockholders may also sell the shares of common stock short and if such short sale shall take place after the date that this registration statement is declared effective by the Commission, the selling stockholders may deliver shares of common stock covered by this prospectus to close out short positions and to return borrowed shares in connection with such short sales. The selling stockholders may also loan or pledge shares of common stock to broker-dealers that in turn may sell such shares, to the extent permitted by applicable law. The selling stockholders may also enter into option or other transactions with broker-dealers or other financial institutions or the creation of one or more derivative securities which require the delivery to such broker-dealer or other financial institution of shares offered by this prospectus, which shares such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction). Notwithstanding the foregoing, the selling stockholders have been advised that they may not use shares registered on this registration statement to cover short sales of our common stock made prior to the date the registration statement, of which this prospectus forms a part, has been declared effective by the SEC.

The selling stockholders may, from time to time, pledge or grant a security interest in some or all of the shares of common stock or the warrants owned by them and, if they default in the performance of their secured obligations, the pledgees or secured parties may offer and sell the shares of the common stock from time to time pursuant to this prospectus or any amendment to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act, amending, if necessary, the list of selling stockholders to include the pledgees, transferees or other successors in interest as selling stockholders under this prospectus. The selling stockholders also may transfer and donate the shares of the common stock in other circumstances in which case the transferees, donees, pledgees or other successors in interest will be the selling beneficial owners for purposes of this prospectus.

The selling stockholders and any broker-dealer or agent participating in the distribution of the shares of common stock may be deemed to be "underwriters" within the meaning of Section 2(a)(11) of the Securities Act in connection with such sales. In such event, any commissions paid, or any discounts or concessions allowed to, any such broker-dealer or agent and any profit on the resale of the shares purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. If a selling stockholder is an "underwriter" within the meaning of Section 2(a)(11) of the Securities Act, the selling stockholder will be subject to the applicable prospectus delivery requirements of the Securities Act including Rule 172 thereunder and may be subject to certain statutory liabilities of, including but not limited to, Sections 11, 12 and 17 of the Securities Act and Rule 10b-5 under the Exchange Act.

The selling stockholders have informed us that it is not a registered broker-dealer and does not have any written or oral agreement or understanding, directly or indirectly, with any person to distribute the common stock. Upon our being notified in writing by a selling stockholder that any material arrangement has been entered into with a broker-dealer for the sale of common stock through a block trade, special offering, exchange distribution or secondary distribution or a purchase by a broker or dealer, a supplement to this prospectus will be filed, if required, pursuant to Rule 424(b) under the Securities Act, disclosing (i) the name of each such selling stockholder and of the participating broker-dealer(s), (ii) the number of shares involved, (iii) the price at which such the shares of the Common Stock were sold, (iv) the commissions paid or discounts or concessions allowed to such broker-dealer(s), where applicable, (v) that such broker-dealer(s) did not conduct any investigation to verify the information set out or incorporated by reference in this prospectus, and (vi) other facts material to the transaction.

Under the securities laws of some states, the shares of common stock may be sold in such states only through registered or licensed brokers or dealers. In addition, in some states the shares of common stock may not be sold unless such shares have been registered or qualified for sale in such state or an exemption from registration or qualification is available and is complied with.

There can be no assurance that any selling stockholder will sell any or all of the shares of common stock registered pursuant to the registration statement of which this prospectus forms a part.

The selling stockholders and any other person participating in such distribution will be subject to applicable provisions of the Exchange Act and the rules and regulations thereunder, including, without limitation, to the extent applicable, Regulation M of the Exchange Act, which may limit the timing of purchases and sales of any of the shares of common stock by the selling stockholder and any other participating person. To the extent applicable, Regulation M may also restrict the ability of any person engaged in the distribution of the shares of common stock to engage in market-making activities with respect to the shares of common stock. All of the foregoing may affect the marketability of the shares of common stock and the ability of any person or entity to engage in market-making activities with respect to the shares of common stock.

We will pay all expenses of the registration of the shares of common stock pursuant to the Registration Rights Agreement, including, without limitation, SEC filing fees and expenses of compliance with state securities or "blue sky" laws; provided, however, that the selling stockholder will pay all underwriting discounts and selling commissions, if any and any related legal expenses incurred by it. We will indemnify the selling stockholder against certain liabilities, including some liabilities under the Securities Act, in accordance with the registration rights agreement, or the selling stockholder will be entitled to contribution. We may be indemnified by the selling stockholder against civil liabilities, including liabilities under the Securities Act, that may arise from any written information furnished to us by the selling stockholder specifically for use in this prospectus, in accordance with the Registration Rights Agreement, or we may be entitled to contribution.

LEGAL MATTERS

Honigman LLP, Kalamazoo, Michigan, has issued a legal opinion as to the validity of the securities offered by this prospectus.

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.

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. 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, June 30, 2022 and September 30, 2022, filed with the SEC on May 13, 2022, August 12, 2022 and November 14, 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, September 14, 2022, September 15, 2022, September 29, 2022, November 4, 2022, November 8, 2022 and December 22, 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 any person, including any beneficial owner, to whom a prospectus is delivered, 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 that are specifically incorporated by reference. You should direct any requests for documents to NeuroBo Pharmaceuticals, Inc., Attn: Secretary, 200 Berkeley Street, 19th Floor, Boston, Massachusetts 02116, or via e-mail at 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.

22,629,907 shares of common stock,
including 10,000,000 shares of common stock underlying warrants

PROSPECTUS

, 2023

PART II

INFORMATION NOT REQUIRED IN THE PROSPECTUS

Item 14. Other Expenses of Issuance and Distribution.

The following table sets forth all expenses paid or payable by the registrant in connection with this offering (except any underwriting discounts and commissions and expenses incurred by the selling stockholders for brokerage, accounting, tax or legal services or any other expenses incurred by the selling stockholders in disposing of the shares). All amounts shown are estimates except for the SEC registration fee.

	Amount Paid or to Be Paid
SEC registration fee	$ 1,895.30
Printing expenses	$ 10,000.00
Legal fees and expenses	$ 45,000.00
Accounting fees and expenses	$ 25,000.00
Other fees and expenses	$ 5,000.00
Total	$ 86,895.30

Item 15. 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 16. Exhibits.

Exhibit Number	Description	Incorporated by Reference			
		Form	File No.	Exhibit	Filing Date
3.1	Third Amended and Restated Certificate of Incorporation of Registrant.	8-K	001-37809	3.1	8/10/2016
3.2	Certificate of Amendment (Reverse Stock Split) to the Third Amended and Restated Certificate of Incorporation of the Company.	8-K	001-37809	3.1	12/31/2019
3.3	Certificate of Amendment (Name Change) to the Third Amended and Restated Certificate of Incorporation of the Company.	8-K	001-37809	3.2	12/31/2019
3.4	Certificate of Amendment (Reverse Stock Split) to the Third Amended and Restated Certificate of Incorporation of the Company.	8-K	001-37809	3.1	9/12/2022
3.5	Second Amended and Restated By-Laws of the Registrant	10-K	001-37809	3.4	3/30/2020
4.1	Form of Common Stock Certificate of the Registrant.	S-1	333-210815	4.1	6/13/2016
5.1*	Opinion of Honigman LLP.				
10.1	Registration Rights Agreement by and among Dong-A ST Co., Ltd., The E&Healthcare Investment Fund II, The E&Healthcare Investment Fund No. 6, The E&Healthcare Investment Fund No. 7 and the Registrant, dated September 14, 2022.	8-K	001-37809	10.4	9/14/2022
23.1*	Consent of BDO USA, LLP, Independent Registered Public Accounting Firm.				
23.2*	Consent of Honigman, LLP (included in Exhibit 5.1).				
24.1*	Power of Attorney of certain directors and officers of the Registrant (contained on signature page).				
107*	Calculation of Registration Fee				

* Filed herewith.

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 of 1933;

(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 Securities Exchange Act of 1934 that are incorporated by reference in the registration statement or is contained in a form of prospectus filed pursuant to §230.424(b) of this chapter that is part of the registration statement.

(2) That, for the purpose of determining any liability under the Securities Act of 1933, 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 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 of 1933 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 of 1933, each filing of the Registrant's annual report pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Securities Exchange Act of 1934) 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 of 1933 may be permitted to directors, officers and controlling persons of the Registrant pursuant to the foregoing provisions, 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 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 Act and will be governed by the final adjudication of such issue.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Boston, Commonwealth of Massachusetts, on January 23, 2023.

NEUROBO PHARMACEUTICALS, INC.

By: /s/ Joseph Hooker
Name: Joseph Hooker
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 Joseph Hooker 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/ Joseph Hooker Joseph Hooker	President and Chief Executive Officer (Principal Executive Officer, Principal Financial Officer and Principal Accounting Officer)	January 23, 2023
/s/ Andrew Koven Andrew Koven	Chair of the Board of Directors	January 23, 2023
/s/ Jason L. Groves Jason L. Groves	Director	January 23, 2023
/s/ Richard J. Kang Richard J. Kang	Director	January 23, 2023
 Hyung Heon Kim	Director	
 Na Yeon (Irene) Kim	Director	
/s/ Michael Salsbury Michael Salsbury	Director	January 23, 2023
/s/ D. Gordon Strickland D. Gordon Strickland	Director	January 23, 2023

Exhibit 5.1

January 23, 2023

NeuroBo Pharmaceuticals, Inc.
200 Berkeley Street, Office 19th Floor
Boston, Massachusetts 02116

Re: Registration Statement on Form S-3

Ladies and Gentlemen:

We have acted as counsel to NeuroBo Pharmaceuticals, Inc., a Delaware corporation (the "***Company***"), in connection with preparing and filing with the Securities and Exchange Commission (the "***Commission***") pursuant to the Securities Act of 1933, as amended (the "***Securities Act***"), of a Registration Statement on Form S-3 (such registration statement as amended or supplemented from time to time, the "***Registration Statement***"), in connection with the registration under the Securities Act of the resale from time to time by selling stockholders of an aggregate of 22,629,907 shares of the Company's common stock, par value $0.001 per share (the "***Common Stock***"), including (i) 12,629,907 shares of Common Stock (the "***Shares***") and (ii) 10,000,000 shares of Common Stock ("***Warrant Shares***") issuable upon exercise of certain outstanding warrants to purchase shares of Common Stock (the "***Warrants***"). A portion of the Shares were issued pursuant to the Agreement and Plan of Merger and Reorganization, dated as of July 24, 2019, as amended on October 29, 2019, by and among the Company, a private entity formerly known as NeuroBo Pharmaceuticals, Inc. and GR Merger Sub, Inc., a portion of the Shares were issued pursuant to the License Agreement, dated September 14, 2022, by and between the Company and Dong-A ST Co. Ltd. (*"**Dong-A**"*) and the remaining Shares and all of the Warrants were issued pursuant to a Securities Purchase Agreement, dated September 14, 2022, by and between the Company and Dong-A.

For the purpose of rendering this opinion, we examined originals or copies of such documents as we deemed relevant. In conducting our examination, we assumed, without investigation, the genuineness of all signatures, the correctness of all certificates, the authenticity of all documents submitted to us as originals, the conformity to original documents of all documents submitted as copies, and the authenticity of the originals of such copies, and the accuracy and completeness of all records made available to us by the Company. In addition, in rendering this opinion, we have assumed that the Common Stock will be offered in the manner and on the terms identified or referred to in the Registration Statement, the accompanying prospectus, including all supplements and amendments thereto.

In addition, in rendering this opinion, we have assumed (i) that the Warrants will be exercised in accordance with their terms and applicable securities laws, in the manner and on the terms identified or referred to in the Registration Statement and the related prospectus, including all supplements and amendments thereto, and before the resale of the Warrant Shares, and (ii) that the Warrant Shares will duly registered on the books of the transfer agent and registrar therefore in the name and on behalf of the persons exercising the Warrants upon exercise of the Warrants. With respect to the Warrant Shares, we express no opinion to the extent that future issuances of securities of the Company, including the Warrant Shares, and/or antidilution adjustments to outstanding securities of the Company, including the Warrants, may cause the Warrants to be exercisable for more shares of Common Stock than the number that then remain authorized, unissued unreserved, and available for issuance.

Our opinion is limited solely to matters set forth herein. The law covered by the opinions expressed herein is limited to the Delaware General Corporation Law. We are not rendering any opinion with respect to federal law, including federal securities laws, or state blue sky securities laws.

Based upon our examination of such documents and other matters as we deem relevant, we are of the opinion that (i) the Shares are validly issued, fully paid and non-assessable, and (ii) upon the valid exercise of the Warrants in accordance with their terms, including proper issuance and delivery to the persons exercising such Warrants of the underlying Warrant Shares duly registered on the books of the transfer agent and registrar therefor in the name of or on behalf of the holder of such Warrants, the Warrant Shares issued will be validly issued, fully paid and non-assessable.

We hereby consent to the filing of this opinion with the Commission as Exhibit 5.1 to the Registration Statement and to the reference to our firm under the caption "Legal Matters" in the Registration Statement and the related prospectus. In giving such consent, we do not admit that we are within the category of persons whose consent is required by Section 7 of the Securities Act or the rules and regulations promulgated thereunder by the Commission. This opinion letter is given as of its date, and we disclaim any undertaking to advise you of any subsequent changes in the facts stated or assumed in this opinion letter or of any subsequent changes in applicable law.

Very truly yours,

/s/ Honigman LLP

HONIGMAN LLP

Exhibit 23.1

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, MA
January 23, 2023

Calculation of Filing Fee Table

FORM S-3
(Form Type)

NeuroBo Pharmacetuicals, Inc.
(Exact Name of Registrant as Specified in its Charter)

Table 1: Newly Registered and Carry Forward Securities

	Security Type	Security Class Title	Fee Calculation Rule	Amount to be Registered	Proposed Maximum Offering Price Per Share	Proposed Maximum Aggregate Offering Price	Fee Rate	Amount of Registration Fee (3)
Fees to be paid	Equity	Common stock, $0.0001 par value per share	Other(2)	22,629,907	$0.76	$17,198,729	0.0001102	$1,895.30
	Total Offering Amounts							$1,895.30
	Total Fee Offsets							$-
	Net Fee Due							$1,895.30

(1) Represents shares offered by the selling stockholders consisting of (a) 12,629,907 outstanding shares of the Registrant's common stock and (b) 10,000,000 shares of the Registrant's common stock issuable upon the exercise of outstanding warrants to purchase the Registrant's common stock. Includes an indeterminable number of additional shares of common stock, pursuant to Rule 416 under the Securities Act of 1933, as amended, that may be issued to prevent dilution from stock splits, stock dividends or similar transactions that could affect the shares to be offered by the selling stockholders.

(2) Estimated in accordance with Rules 457(c) and 457(h) solely for the purpose of calculating the registration fee on the basis of $0.76 per share, which represents the average of the high and low prices of the Registrant's common stock as reported on the Nasdaq Capital Market on January 18, 2023.