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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549
Form 10-K

(Mark One)

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2022

OR

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

Commission file number 001-37809

NeuroBo Pharmaceuticals, Inc.

(Exact name of Registrant as specified in its charter)

Delaware	**47-2389984**
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification No.)
200 Berkeley Street, Office 19th Floor **Boston, Massachusetts**	**02116**
(Address of principal executive offices)	(Zip Code)

(857) 702-9600
(Registrant's telephone number, including area code)

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

Title of Each Class	**Trading symbol(s)**	**Name of Exchange on Which Registered**
Common stock, $0.001 par value	NRBO	The Nasdaq Stock Market LLC

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

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

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

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

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

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

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to § 240.10D-1(b). ☐

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

The aggregate market value of the registrant's common stock held by non-affiliates of the registrant was approximately $7.0 million based on the closing price on the Nasdaq Capital Market as of June 30, 2022, the last business day of the registrant's most recently completed second fiscal quarter.

The number of outstanding shares of the registrant's common stock, $0.001 par value per share, as of March 24, 2023 was 27,176,685.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K for the fiscal year ended December 31, 2022 contains "forward-looking statements" within the meaning of the Securities Act of 1933, as amended (the "Securities Act"), and the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Forward-looking statements are neither historical facts nor assurances of future performance. Instead, these forward-looking statements contain information about our expectations, beliefs or intentions regarding our product development and commercialization efforts, business, financial condition, results of operations, strategies or prospects, and other similar matters. These forward-looking statements are based on management's current expectations and assumptions about future events, which are inherently subject to uncertainties, risks and changes in circumstances that are difficult to predict. These statements may be identified by words such as "expects," "plans," "projects," "will," "may," "anticipates," "believes," "should," "intends," "estimates," and other words of similar meaning.

Actual results could differ materially from those contained in forward-looking statements. Many factors could cause actual results to differ materially from those in forward-looking statements, including those matters discussed below, as well as those listed in Item 1A. Risk Factors.

Other unknown or unpredictable factors that could also adversely affect our business, financial condition and results of operations may arise from time to time. Given these risks and uncertainties, the forward-looking statements discussed in this report may not prove to be accurate. Accordingly, you should not place undue reliance on these forward-looking statements, which only reflect the views of NeuroBo Pharmaceuticals, Inc.'s management as of the date of this report. We undertake no obligation to update or revise forward-looking statements to reflect changed assumptions, the occurrence of unanticipated events or changes to future operating results or expectations, except as required by law.

SUMMARY RISK FACTORS

Our business is subject to a number of risks, as fully described in "Item 1A. Risk Factors" in this Annual Report. The principal factors and uncertainties include, among others:

- NeuroBo expects to incur losses for the foreseeable future and may never achieve or maintain profitability;
- NeuroBo will need additional financings to fund operations and such additional financings may cause dilution to existing stockholders, restrict NeuroBo's operations or require NeuroBo to relinquish its technologies;
- The timing and costs related to the clinical development of NeuroBo's products are difficult to predict, and any delays in NeuroBo's clinical trials may lead to a delay in the submission of marketing approval applications;
- NeuroBo may be required to make significant payments under the Dong-A License Agreement;
- The regulatory review and approval processes of the FDA and comparable foreign regulatory authorities are lengthy, time-consuming and inherently unpredictable;
- Undesirable side effects from future product candidates could delay or prevent their marketing approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, and the development of such product candidates exposes NeuroBo to additional risks;
- NeuroBo may engage in future acquisitions, in-licenses of technology, strategic alliances or enter into additional licensing arrangements that could disrupt its business, cause dilution to the organization's stockholders, harm its financial condition and operating results or result in no benefits being realized from such engagement;
- Enrollment and retention of patients in clinical trials is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside of NeuroBo's control;
- NeuroBo faces substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than it does;
- NeuroBo's commercial success depends upon attaining significant market acceptance of its product candidates, if approved, among hospitals, physicians, patients and healthcare payors;
- Product liability lawsuits against NeuroBo could cause it to incur substantial liabilities and could limit commercialization of any product candidate that it may develop;
- NeuroBo relies on third parties to develop NeuroBo's preclinical studies, clinical trials, research programs and product candidates and to manufacture its product candidates and preclinical and clinical drug supplies. If these third parties do not successfully carry out their contractual duties or meet expected deadlines or if they engage in misconduct or other improper activities or if NeuroBo is unable to engage with these third parties, it could have a material adverse effect on NeuroBo's business and NeuroBo's obtaining of regulatory approval and commercialization of its product candidates;
- Any product candidate for which NeuroBo obtains marketing approval could be subject to marketing restrictions or withdrawal from the market, and NeuroBo may be subject to penalties if it fails to comply with regulatory requirements or if it experiences unanticipated problems with our products;
- NeuroBo or any of its potential collaborators may never receive regulatory approval to market NeuroBo's product candidates within or outside of the United States;
- Mechanisms that NeuroBo may utilize to expedite and/or reduce the cost for development or approval of its product candidates may not lead to faster or less expensive development, regulatory review or approval process;
- Legislation may increase the difficulty and cost to obtain marketing approval of and commercialize its product candidates, and governments outside the United States tend to impose strict price controls, which also may adversely affect NeuroBo's revenues;
- NeuroBo's compliance with legal standards related to foreign trade could impair its ability to compete in domestic and international markets, and NeuroBo could face criminal liability and other serious consequences for violations;

- Certain tax matters, including NeuroBo's ability to use its NOLs to offset future taxable income may be subject to certain limitations, could impact its results of operations and financial conditions;
- Inadequate funding for the FDA and other government agencies could prevent those agencies from performing normal business functions on which the operation of NeuroBo's business may rely, which could negatively impact NeuroBo's business;
- If NeuroBo is unable to obtain, maintain and protect sufficient intellectual property rights, its competitive position could be harmed;
- NeuroBo may become involved in lawsuits to protect or enforce its intellectual property, which could be expensive, time consuming, unsuccessful and could distract NeuroBo's personnel from their normal responsibilities;
- NeuroBo has identified material weaknesses in its internal control over financial reporting that could, if not remediated, result in material misstatements in its financial statements or impair its ability to produce accurate and timely consolidated financial statements;
- NeuroBo's obtaining and maintaining patent protection could be reduced or eliminated for non-compliance with certain requirements imposed by governmental patent agencies;
- NeuroBo's business and operations would suffer in the event of system failures or unplanned events;
- Any failure, inadequacy, interruption or security lapse of NeuroBo's information technology could prevent NeuroBo from accessing critical information or expose NeuroBo to liability;
- If securities analysts do not publish research or reports about NeuroBo's business or if they publish negative evaluations of NeuroBo's stock the price of NeuroBo's stock could decline;
- NeuroBo does not anticipate declaring or paying, in the foreseeable future, any cash dividends on its capital stock and, consequently, the ability of its stockholders to achieve a return on their investment will depend on appreciation in the price of NeuroBo's common stock;
- NeuroBo's Bylaws designate the Court of Chancery of the State of Delaware as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by NeuroBo's stockholders, which could limit the ability of NeuroBo's stockholders to obtain a favorable judicial forum for disputes with NeuroBo or its directors, officers or employees;
- Unstable market and economic conditions may have serious adverse consequences on NeuroBo's business, financial condition and stock price;
- The liquidity and trading volume of NeuroBo's common stock could be low, its ownership will be concentrated and the market price of its common stock may be highly volatile;
- NeuroBo's common stock may be delisted from the Nasdaq Capital Market if it fails to comply with the continued listing requirements

PART I

ITEM 1. BUSINESS

Overview

NeuroBo Pharmaceuticals, Inc. (the "Company," "NeuroBo," "we," "us" or "our") is a clinical-stage biotechnology company focused primarily on developing and commercializing novel pharmaceuticals to treat cardiometabolic diseases. NeuroBo has 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. Agonism of GPR119 in the gut promotes the release of key gut peptides GLP-1, GIP, and PYY. These peptides play a further role in glucose metabolism, lipid metabolism and weight loss. DA-1241 has beneficial effects on glucose, lipid profile and liver inflammation, supported by potential efficacy demonstrated during in vivo preclinical studies. The therapeutic potential of DA-1241 has been demonstrated in multiple pre-clinical animal models of NASH and T2D where DA-1241 reduced hepatic steatosis, inflammation, fibrosis, and improved glucose control. Furthermore, in Phase 1a and 1b human trials DA-1241 was well tolerated in both healthy volunteers and those with T2D. We intend to initiate a Phase 2a study with the goal of establishing efficacy of DA-1241 in the treatment of NASH in the third quarter of 2023.

- DA-1726 is a novel oxyntomodulin ("OXM") analogue functioning as a GLP1R/GCGR dual agonist for the treatment of NASH and obesity that is to be administered once weekly subcutaneously. DA-1726 as a dual agonist of GLP-1 receptors ("GLP1R") and glucagon receptors ("GCGR"), leading to weight loss through reduced appetite and increased energy expenditure. DA-1726 has a well understood mechanism and, in preclinical mice models, resulted in improved weight loss, as well as reduced hepatic steatosis, inflammation, and fibrosis compared to semaglutide and cotadutide (another OXM analogue). We intend to file an Investigational New Drug (IND) in the second quarter of 2023.

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

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

While we are primarily focused on development of DA-1241 and DA-1726, we also have four legacy therapeutics programs designed to impact a range of indications in viral, neurodegenerative and cardiometabolic diseases:

- *ANA001* is a proprietary oral niclosamide formulation being developed as a treatment for patients with moderate COVID-19. Niclosamide is a potential oral antiviral and anti-inflammatory agent with a long history of use and well-understood safety in humans.

- *NB-01* was primarily focused on the development of a treatment for painful diabetic neuropathy (PDN) as a first-line pain management therapy for PDN.

- *NB-02* has the potential to treat the symptoms of cognitive impairment and modify the progression of neurodegenerative diseases associated with the misfunction of a protein called tau, and with amyloid beta plaque deposition.

- *Gemcabene* was being developed for the treatment of dyslipidemia, a serious medical condition that increases the risk of life-threatening cardiovascular disease, and was focused on orphan indications such as homozygous familial hypercholesterolemia (HoFH), as well as severe hypertriglyceridemia (SHTG) and we are currently exploring various acute therapeutic indications.

Our Board of Directors has determined to focus our financial resources and management attention on development of DA-1241 for NASH and T2D and DA-1726 for NASH and obesity. We will continue to consider licensing and acquisition opportunities with respect to our legacy programs.

Recent Transactions with Dong-A ST Co., Ltd.

On September 14, 2022, we entered into an exclusive license agreement (the "2022 License Agreement") with Dong-A ST Co., Ltd. ("Dong-A") , a related party, pursuant to which, and subject to the conditions set forth therein, we received an exclusive global license (excluding 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 2022 License Agreement became effective on November 8, 2022.

Under the terms of the 2022 License Agreement, Dong-A (i) received an upfront payment which was settled in 2,200 shares of a new series of preferred stock of the Company designated as "Series A Convertible Preferred Stock", par value $0.001 per share (the "Series A Preferred Stock"), 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 2022 License Agreement and a Qualified Financing (as defined in the Securities Purchase Agreement), which occurred on November 8, 2022 as a result of the Public Offering (as defined below), (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 "Dong-A 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 Dong-A warrants (the "Stockholder Approval") 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 share 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 B 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.

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 Series A Warrants and 2,692,997 Series B Warrants. We received gross proceeds of approximately $17.3 million from the Public Offering. The exercise price for the Series A Warrants and Series B Warrants (the "Public Warrants") was $3.00 per share and the Public Warrants also included a cashless exercise feature pursuant to which the Public Warrants were exercisable for one share each on a cashless basis. 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.

Strategy

Our goal is to discover, develop and commercialize novel therapeutics designed to impact a range of indications primarily in cardiometabolic diseases. The key elements of our business strategy to achieve this goal include:

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

Product Candidates

DA-1241 Treatment of Type 2 Diabetes and NASH

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

DA-1241 is a novel chemical drug candidate selectively activating G protein-coupled receptor 119 (GPR119) which has shown consistent target-related mechanisms and glucose-lowering effects from nonclinical studies to a Phase 1b exploratory clinical trials in patients with T2D in the US. GPR119 is known to be a regulator of both blood glucose and lipid levels. Non-clinical studies suggest DA-1241 selectively activates GPR119, stimulates the secretion of insulin and incretin hormones such as glucagon-like peptide-1 (GLP-1), and thereby reduces plasma glucose levels without hypoglycemia risk and lowers plasma lipids levels of both triglycerides and cholesterol. Preclinical tests have suggested these therapeutic effects are augmented when co-treated with other oral anti-diabetic agents such as metformin, SGLT2 inhibitors, and DPP4 inhibitors which are widely used for treating patients with T2D in the clinic. Moreover, impaired insulin action and lipid metabolism which are frequently observed in T2D patients are highly associated with the pathogenesis of steatosis and inflammation in NASH. Extensive non-clinical studies have shown DA-1241 has therapeutic potential for the reduction in hepatic steatosis, inflammation, fibrosis, and improved glucose control regardless of body weight reduction.

Background

T2D, previously referred to as "noninsulin-dependent diabetes" or "adult-onset diabetes," accounts for 95% of all diabetes worldwide. This form encompasses individuals who have relative insulin deficiency and have peripheral insulin resistance. Based on CDC data, the U.S. population with diabetes is estimated to be 37.3 million in 2022, which accounts for 11.3% of the population. Approximately one-quarter of these people are undiagnosed. Accordingly, GlobalData Plc estimated global anti-diabetic drug sales to be $48.1 billion in nine major markets in 2019 and projected that the global antidiabetic market will continue to grow to $91.9 billion by 2029 at a compound annual growth rate (CAGR) of 6.7%, with the US market accounting for 58% of the global market due to high drug prices.

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

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

DA-1241 Preclinical Development

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

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

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

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

With regard to the NASH indication, DA-1241 has shown to improve fatty liver in various types of mouse models with metabolic diseases. Thereafter, therapeutic potential for treating NASH has been evaluated in several NASH mice models with different pathophysiology. Among them, the STAM-NASH mouse model exhibits mild fatty liver and moderate liver inflammation/fibrosis and is rapidly chemically induced. DA-1241 improved hepatic inflammation and fibrosis, showing a decrease in NAFLD activity score (NAS) and relative fibrotic area of the liver compared to the vehicle-treated control. Diet-induced obesity (DIO)-NASH mice are chronically induced through a Western diet and are characterized by marked fatty liver and mild to moderate hepatic

inflammation/fibrosis. In DIO-NASH mice, DA-1241 improved hepatic steatosis, inflammation, and fibrosis assessed by histological and biochemical methods regardless of body weight reduction. Of note, DA-1241 improved systemic inflammatory status with reduced plasma inflammatory cytokines (TNFα, IL6) and chemokines (CCL2, CXCL1, CXCL2, CXCL10) contributing to tissue damage. Therefore, DA-1241 treatment reduced the levels of plasma liver enzymes (ALT, AST), which were increased due to liver tissue damage in DIO-NASH mice. In mice with metabolic diseases, the effects of DA-1241 on the NASH phenotypes (steatosis, inflammation, and fibrosis in the liver) are enhanced by the co-treatment with a DPP4 inhibitor compared to each treatment alone due to potentiated GLP-1 actions.

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

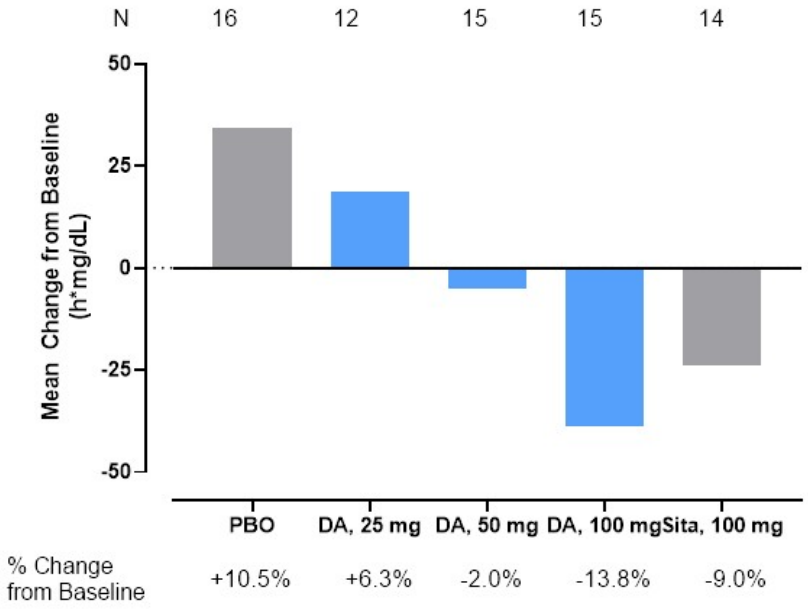
Completed Phase 1a and 1b trials in the US healthy subjects. The first-in-humans Phase 1a study, which was a double-blind, placebo controlled, single ascending dose ("SAD"), single-center study in 60 healthy male volunteers to evaluate the safety, tolerability, pharmacokinetics ("PK"), pharmacodynamics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

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

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

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

Mean Change in Postprandial Glucose Excursion at Week 8

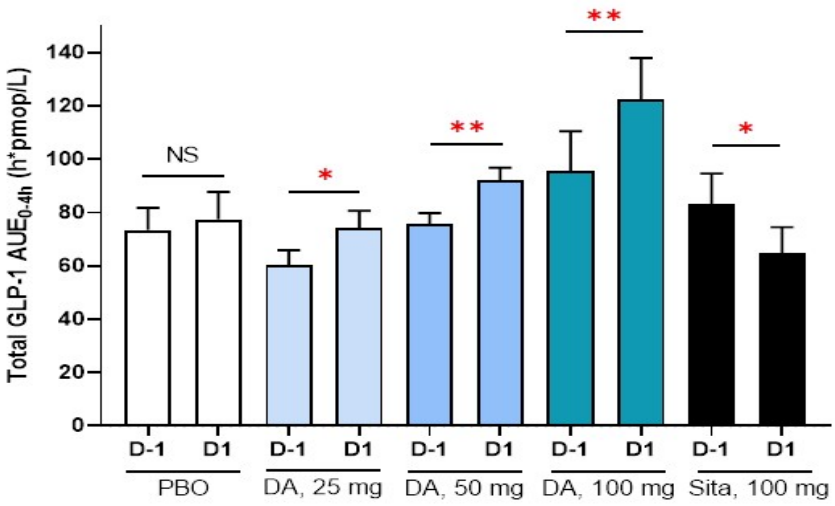


Mean Change in Postprandial Glucose Excursion at Week 8

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

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

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



Total GLP-1 Secretion during Mixed Meal Tolerance Test

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

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

DA-1241 Phase 2 Trial Design. We currently intend to perform two Phase 2 clinical trials in the United States;

NASH Phase 2a: One clinical trial is expected to be a 16-week, multicenter, randomized, double-blind, placebo-controlled, parallel arm clinical trial to establish safety and an early signal of efficacy in NASH as a next-generation competitive oral agent. The trial is expected to enroll a total of 87 subjects, with a planned maximum of 98 subjects to account for early discontinuations, who will be randomized into 4 treatment groups and will be dosed with: DA-1241 50 mg, DA-1241 100 mg, DA-1241 100 mg/Sitagliptin 100 mg, or Placebo in a 1:2:2:2 ratio. Randomization will be stratified by T2DM status at baseline. The primary efficacy endpoint for the planned study will be the change from baseline in the alanine transaminase (ALT) levels at week 16. The secondary efficacy endpoints will evaluate changes in the following at week 16 including: proportion of subjects with normalization of ALT level of < 30 IU/L; relative percent change liver fat fraction from baseline; absolute change in liver fat from baseline; proportion of subjects with a 30% or more reduction in liver fat from baseline; change in aspartate transaminase (AST), gamma glutamyl transpeptidase, and alkaline phosphatase from baseline; change in hemoglobin A1c (HbA1c) (%); change in non-alcoholic fatty liver disease (NAFLD) Fibrosis Score from baseline; liver stiffness measurement assessed by FibroScan® from baseline; and change in FAST (FibroScan - AST) from baseline. Safety will be evaluated by monitoring adverse events (AEs) including determination of serious adverse events (SAEs) and AEs leading to discontinuation and laboratory abnormalities as characterized by type, frequency, timing, severity (mild, moderate, severe), seriousness and relationship to DA-1241, vital signs measurements, clinical laboratory tests and electrocardiogram (ECG) assessments.

NASH Phase 2b: The Phase 2b study is a dose range finding trial to establish clinical efficacy in histological improvement for NASH treatment similar to Phase 3. This planned Phase 2b trial is 52-week, double-blinded, randomized, placebo-controlled clinical study in approximately 400 biopsy confirmed NASH patients with F2-F3 fibrosis. There are four treatment groups and the three dose levels for the planned treatment groups will be determined based on the results of Phase 2a study. This study will be conducted as a multi-center internal study. The primary endpoint is the proportion of patients whose NAFLD activity score (NAS) or fibrosis score (or fibrotic area) are improved by one or more stage from the baseline to Week 24 and Week 52. Various plasma biomarkers

that were improved in the preclinical studies performed in mice will also be evaluated to assess changes in systemic inflammatory (TNFα, CCL2, CXCLs) and fibrotic (TIMP-2, type IV collagen) status.

DA-1726: Treatment of Obesity and NASH

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

DA-1726 is a dual agonist that activates both GLP-1 receptors ("GLP-1R") and glucagon receptors ("GCGR"). Activation of GLP-1R or GCGR contributes to central anorexic effect (appetite suppression) and activation of GCGR peripherally enhances basal metabolic rate. Accordingly, non-clinical studies have shown that DA-1726 not only reduces food intake but also increases energy expenditure even at the basal resting state, leading to persistent weight loss in diet-induced obese mice and rats. DA-1726 directly lowers blood glucose and lipid levels in addition to the accompanying metabolic improvement by weight loss. Weight reduction is closely related to the alleviation of fatty liver. Having stabilized the fragile peptide through several unique modifications, DA-1726 is predicted to be available as a once-weekly regimen to humans.

Background

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

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

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

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

DA-1726 Preclinical Development

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

The mode of action and pharmacological effects of DA-1726 were evaluated in various disease models. In high-fat diet-induced obese mice, DA-1726 showed more body weight loss and increasing energy expenditure than a pair-fed group. In comparison with GLP-1 analogue, DA-1726 represented superior body weight loss compared

to semaglutide in obese mice. At the end of the study, DA-1726 significantly increased the expression of thermogenic genes (*Ucp-1* and *Ppargc1a*) in epididymal fat and increased white adipose tissue browning was histologically confirmed. In addition, DA-1726 inhibited adipocyte differentiation *in vitro*. Taken together, it suggests the GCGR action of DA-1726 contributes to reduced adiposity by enhancing fat burning and inhibiting adipogenesis. DA-1726 effectively reduced postprandial glucose excursion in acute oral glucose tolerance test in normal mice. Notably, DA-1726 showed similar glycemic control and excellent weight loss to semaglutide in obese mice with hyperglycemia. Simultaneously, DA-1726 enhanced insulin sensitivity by significantly reducing fasting plasma insulin and glucose levels. Meanwhile, DA-1726 showed no hypoglycemia risk in overnight fasted normal mice, unlike semaglutide.

In obese NASH mice, DA-1726 significantly reduced plasma clinical chemistry parameters (ALT, AST, ALP, T-BIL, glucose, and cholesterol) and hepatic fat accumulation. In histopathological analysis of steatosis, lobular inflammation, and ballooning in the liver, DA-1726 showed an excellent improvement effect compared to semaglutide. Improvement of liver fibrosis was also observed with DA-1726. In the liver tissue, the expression of inflammation (*Tnfa*, *Il-1β*, and *Ccl2*) and fibrosis (*Acta2*, *Timp1*, *Col1a1*, *Col3a1*, and *Mmp9*) related genes were significantly decreased. Taken together, the findings from the pre-clinical trials suggest DA-1726 has therapeutic potential for NASH in addition to obesity.

DA-1726 Phase 1 Trial Design: The first-in-human Phase 1 studies are being planned to establish safety, tolerability and pharmacokinetics of DA-1726. The Phase 1 program is to consist of a single ascending dose (SAD) study and multiple ascending dose (MAD) study enrolling approximately 100 subjects consisting of healthy and obese volunteers. Doses to be applied in the planned clinical trials will be determined based on the predicted human effective dose assessed by preclinical ADME and repeated toxicity studies. For the MAD trial under the same IND, DA-1726 will be injected subcutaneously once weekly for 12 weeks in obese patients to provide an added clinical signal in obesity.

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

Other Product Candidates

Our Board of Directors has determined to focus our financial resources and management attention on development of DA-1241 for NASH and T2D and DA-1726 for NASH and obesity. We will continue to consider licensing and acquisition opportunities with respect to the following legacy programs.

ANA001: Treatment of COVID-19 Symptoms

ANA001 is a proprietary oral niclosamide formulation and is being developed as a treatment for patients with moderate COVID-19 (patients not requiring ventilators). Niclosamide is a potential oral antiviral and anti-inflammatory agent with a long history of use and documented safety in humans. Enrollment in the Phase 2 clinical trial of ANA001 for treatment of moderate COVID-19 in hospitalized patients was closed in July 2022 and the clinical trial moved to the data analysis phase. Niclosamide has demonstrated both antiviral and immunomodulatory activity with possible downstream effects on coagulation abnormalities observed in COVID-19. In preclinical research by an independent academic group published in Antimicrobial Agents and Chemotherapy, niclosamide inhibited viral replication in vitro and was more potent than remdesivir and chloroquine in the same assay.

Specifically, studies have shown niclosamide prevents replication of SARS-CoV-2 at very low concentrations and that the compound appears to exhibit three distinct mechanisms of action: 1) acting as a potent antiviral to a broad homology of other viruses including influenza; 2) reducing inflammation without suppressing the immune system; and

3) providing bronchodilation, which is a useful pulmonary mechanism for at-risk patients with underlying cardiovascular and/or pulmonary conditions.

As a result, we believes ANA001 has the potential to reduce the viral load and inflammation associated with cytokine dysregulation, acute respiratory distress syndrome (ARDS), and coagulation abnormalities and thus improve time to clinical improvement as defined as hospital discharge recorded using the World Health Organization (“WHO”) Ordinal Scale for Clinical Improvement. We also believe the three key mechanisms of action may also be effective in treating COVID-19 in the outpatient setting or as a prophylaxis.

Following an analysis of the clinical trial data, 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

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

In light of the present business environment and our current focus on DA-1241 and DA-1726, we have ceased development of NB-01 on the prior regulatory pathway and will not advance to Phase 3 clinical trials. We are currently evaluating various alternatives with respect to the future of NB-01,

NB-02

NB-02 is in development for the symptomatic and disease modifying treatment of neurodegenerative diseases, including Alzheimer's disease and tauopathies. In preclinical studies, we have observed the mechanisms of action of NB-02 to include inhibition of tau phosphorylation, acetylcholinesterase (AChE) inhibition, inhibition of Ab toxicity and amyloid plaque formation, and anti-inflammatory effects. Specifically, in both in vitro and in vivo models, NB-02 has demonstrated inhibition of AChE, as is the case with three of the current drugs on the market to treat the symptoms of Alzheimer's disease. It has also demonstrated inhibition of tau phosphorylation and of amyloid plaque formation, both mechanisms believed to contribute to the progression of neurodegenerative diseases.

We are currently exploring out-licensing alternatives for NB-02.

Gemcabene

Gemcabene is a novel, once-daily, oral therapy designed to target known lipid metabolic pathways to lower levels of LDL-C, hsCRP and triglycerides. Gemcabene shares many of the attributes of statin therapy, including broad therapeutic applications, convenient route of administration and cost-effective manufacturing process, but does not appear to increase the reporting of myalgia when added to statin therapy. Gemcabene has also shown additive LDL-C lowering in combination with stable low, moderate or high-intensity statin therapy. As described below, we licensed global rights to Gemcabene from Pfizer in April 2011. Under the terms of the amended and restated license agreement with Pfizer, Pfizer may terminate the license if we have not made a commercial sale by April 2024.

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 acute therapeutic indications and does not intend to direct additional resources towards Gemcabene as a cardiovascular therapy.

Licensing Agreements

License Agreement with Dong-A for DA-1241 and DA-1726

On September 14, 2022, we entered into the 2022 License Agreement with Dong-A pursuant to which, subject to the conditions set forth therein, we received an exclusive license (other than in the Republic of Korea) to two proprietary compounds for specified indications. The 2022 License Agreement covers the rights to DA-1241 for treatment of NASH and DA-1726 for treatment of obesity and NASH. We may also develop DA-1241 for the treatment of T2D. The 2022 License Agreement became effective on November 8, 2022 as a result of the Company closing a Public Offering.

Under the terms of the 2022 License Agreement, Dong-A (i) received an upfront payment of 2,200 shares of Series A Convertible Preferred Stock under the terms of the Securities Purchase Agreement, which was convertible into shares of our common stock upon receipt of the Stockholder Approval; (ii) will be eligible to receive single digit royalties on net sales received by us from the commercial sale of products covering DA-1241 or DA-1726; (iii) will be eligible to receive commercial-based milestone payments, payable in cash or our common stock dependent upon the achievement of specific commercial developments and (iv) will be eligible to receive regulatory milestone payments of up to $178 million for DA-1726 and $138 million for DA-1241, payable in cash or our common stock, dependent upon the achievement of specific regulatory developments.

Our obligation to pay royalties to Dong-A under the 2022 License Agreement continues on a product-by-product and country-by country basis until the later of (i) the fifth anniversary of the first commercial sale of such product in such country, (ii) the expiration or termination of the last valid patent claim that covers a product in such country and (iii) the loss of regulatory exclusivity for such product in such jurisdiction. Either we or Dong-A may terminate the 2022 License Agreement (i) if the other party is in material breach of the agreement and has not cured or started to cure the breach within 60 days of notice of such breach; provided that if the breach cannot be cured within the 60-day period and the breaching party started to remedy the breach, if such breach is not cured within 90 days of receipt of written notice, (ii) if the other party is subject to a bankruptcy or insolvency event (subject to a 30-day cure period in the case of a petition for bankruptcy) or (iii) if we failed to complete the Public Offering by December 31, 2022 (or January 31, 2023 under specified circumstances set forth in the 2022 License Agreement).

License Agreement with Dong-A ST for NB-01

On January 18, 2018, we entered into an exclusive license agreement with Dong-A, (the “2018 License Agreement”) which agreement was amended on April 18, 2018 and July 24, 2019. Under the terms of the 2018 License Agreement, we obtained an exclusive, royalty-bearing, worldwide (except for the Republic of Korea) license to make, use, offer to sell, sell and import products covered by certain Dong-A ST intellectual property rights in its proprietary compound designated as DA-9801 (NB-01). Our license rights cover any and all applications and markets for the therapeutic,

health, nutrition or well-being of humans. We may grant sublicenses to any affiliate or third party. We are responsible for all future patent prosecution costs.

Dong-A retained the exclusive right to conduct clinical studies in the Republic of Korea and sell products to end users in Korea. NeuroBo granted Dong-A an exclusive, royalty free right and license to use, solely for Dong-A's commercialization of products in Korea, any inventions, designs and technology developed by us in its performance of the agreement. If Dong-A terminates the 2018 License Agreement due to a breach by us or a bankruptcy event, then this technology is licensed exclusively to Dong-A at no charge. We may also negotiate in good faith to supply product to Dong-A for clinical studies and sale of products to end-users in Korea under a separate supply agreement.

We are obligated to use commercially reasonable efforts to develop products for use in each of the United States, the European Union, Japan and the People's Republic of China. If we terminate, discontinue or suspend, for longer than 12 months, the development of any product listed as a product under development in any development plan provided to Dong-A (other than for reasons of force majeure or requirements of applicable law), then we are deemed in breach of this development obligation, and Dong-A may terminate the 2018 License Agreement for cause after a 60-day cure period. We are obligated to use commercially reasonable efforts to commercialize products worldwide throughout the term of the 2018 License Agreement.

In connection with obtaining the licenses under the 2018 License Agreement, we paid Dong-A total consideration of $2 million consisting of a one-time upfront license fee and shares of our common stock.

We may be required to pay development milestone payments of up to an aggregate of $98 million related to publication of Phase 3 clinical trial data, the first NDA submission in any country, and NDA approval in the United States, the European Union, Japan and the People's Republic of China. We may also be required to pay sales milestone payments in a specified amount, related to the first time that aggregate net sales of products exceed specified amounts in a calendar year.

We are required to pay Dong-A commercial milestone payments of up to an aggregate of $80 million and a royalty between a single digit and a low double digit percentage of net sales of products. The royalty rate increases as annual net sales increase.

The term of the 2018 License Agreement continues on a country-by country and product-by-product basis until the later of the 12th anniversary of the first commercial sale of such product in such country or expiration or termination of the last valid claim within the patent rights covering the product. The royalty rate is then reduced by 30% in any country that prohibits the payment of royalties on a patent license beyond the expiration or invalidation of the last valid claim covering the product.

Either Dong-A or we may terminate the 2018 License Agreement if the other party is in material breach of the 2018 License Agreement and has not cured or started to cure the breach within 60 days of notice of such breach, or is subject to a bankruptcy or insolvency event. We may terminate the 2018 License Agreement at any time upon 90 days' written notice.

We may assign our rights under the agreement in connection with a merger, consolidation, or sale of substantially all of its assets, with prior written notice to Dong-A, and if the successor entity agrees in writing to be bound by the agreement.

License Agreement with YourChoice

On December 31, 2020, we acquired ANA Therapeutics, Inc. ("ANA"), a privately held biotechnology company developing ANA001. In connection with our acquisition of ANA, we assumed a license agreement (the "YourChoice Agreement") between ANA and YourChoice Therapeutics, Inc. ("YourChoice"). Pursuant to the YourChoice Agreement, YourChoice granted to ANA, during the term of the YourChoice Agreement, an exclusive, worldwide, fee-bearing license derived from the licensed intellectual property throughout the world. The fees due under the YourChoice Agreement include certain single-digit royalty payments and milestone payments in the aggregate of $19.5 million. The

term of the YourChoice Agreement will expire on the expiration or invalidation of the last of the licensed patents under the YourChoice Agreement.

Pfizer License Agreement

In August 2018, an Amended and Restated License Agreement with Pfizer (the "Pfizer Agreement") for the research, development, manufacture and commercialization of Gemcabene went into effect. The Pfizer Agreement amended and restated in full the prior license agreement with Pfizer dated April 16, 2011.

The Pfizer Agreement included milestone payments to Pfizer totaling up to $37 million upon the achievement of certain milestones, including the first NDA (or its foreign equivalent) in any country, regulatory approval in each of the United States, Europe and Japan, the first anniversary of the first regulatory approval in any country, and upon achieving certain aggregate sales levels of Gemcabene. Future milestone payments under the Pfizer Agreement, if any, would not be expected to begin for at least several years and extend over a number of subsequent years.

Pfizer will also receive tiered royalties on a country-by-country basis based upon the annual amount of net sales as specified in the Pfizer Agreement until the later of: (i) five years after the first commercial sale in such country; (ii) the expiration of all regulatory or data exclusivity for Gemcabene in such country; and (iii) the expiration or abandonment of the last valid claim of the licensed patents, including any patent term extensions or supplemental protection certificates in such country. The royalty rates range from the high single digits to the mid-teens depending on the level of net sales. The royalty rates are subject to reduction during certain periods when therapeutically-equivalent generic products represent a certain market share of prescription volume in the country. Under the Pfizer Agreement, commercially reasonable efforts must be used to develop and commercialize Gemcabene.

The Pfizer Agreement will expire upon expiration of the last royalty term. On expiration (but not earlier termination), we will have a perpetual, exclusive, fully paid-up, royalty-free license under the licensed patent rights and related data to make, use, develop, commercialize, import and otherwise exploit the clinical product candidate Gemcabene. Either party may terminate the Pfizer Agreement for the other party's material breach following a cure period or immediately upon certain insolvency events relating to the other party. Pfizer may immediately terminate the Pfizer Agreement in the event that (i) we or any of our affiliates or sublicenses contests or challenges, or supports or assists any third party to contest or challenge, Pfizer's ownership of or rights in, or the validity, enforceability or scope of any of the patents licensed under the Pfizer Agreement or (ii) we or any of our affiliates or sublicensees fails to achieve the first commercial sale in at least one country by April 16, 2024.

License Agreement with Beijing SL

Pursuant to the terms and conditions of a License and Collaboration Agreement dated July 23, 2019 (the "Beijing SL License Agreement"), Beijing SL has an exclusive royalty-bearing license to research, develop, manufacture and commercialize pharmaceutical products comprising, as an active ingredient, Gemcabene in the territory comprised of mainland China, Hong Kong, Macau and Taiwan. We retain all rights to Gemcabene outside of the territory. The parties have agreed to collaborate with respect to development and commercialization activities under the Beijing SL License Agreement through a joint steering committee composed of an equal number of representatives of Beijing SL and us.

Beijing SL is responsible, at its expense, for developing and commercializing products containing Gemcabene in the territory, with certain assistance from us. To the extent mutually agreed to in writing, the parties will collaborate on the Phase 3 clinical trial for HoFH or other clinical trials, with us as the sponsor, and designed to enroll patients both inside and outside the territory, but Beijing SL will be responsible, at its expense, for the conduct of any such study to the extent solely in the territory. Beijing SL will be responsible for development activities, including non-clinical and clinical studies directed at obtaining regulatory approval of the licensed product in the territory. Beijing SL has agreed to use commercially reasonable efforts to commercialize the licensed products for each indication that receives regulatory approval in the territory and shall prepare and present a commercialization plan that shall be subject to approval by the joint steering committee.

Pursuant to the Beijing SL License Agreement, Beijing SL made an upfront gross payment of $2.5 million. Additionally, with respect to each licensed product, Beijing SL will pay (i) payments for specified developmental and regulatory

milestones (including submission of a NDA to China's National Medical Product Administration, dosing of the first patient in a Phase 3 clinical trial in mainland China and regulatory approval for the first and each additional indication of a Licensed Product in the Territory) totaling up to $6 million in the aggregate and (ii) payments for specified global net sales milestones of up to $20 million in the aggregate multiplied by the ratio of the net sales of a licensed product divided by the global net sales of a licensed product, which net sales milestone payments are payable once, upon the first achievement of such milestone.

Beijing SL will also be obligated to pay tiered royalties ranging from the mid-teens to twenty percent on the net sales of all licensed products in the territory until the latest of (a) the date on which any applicable regulatory exclusivity with respect to such Licensed Product expires in such region, (b) the expiration or abandonment of the last valid patent claim or joint patent claim covering such Licensed Product in each region and (c) the fifth anniversary of the first commercial sale of such Licensed Product in such region. Future milestone payments under the Beijing SL License Agreement, if any, are not expected to begin for at least one year and will extend over a number of subsequent years.

Either party may terminate the Beijing SL License Agreement (x) with written notice for the other party's material breach following a cure period or (y) if the other party becomes subject to certain insolvency proceedings. In addition, we may terminate the Beijing SL License Agreement in its entirety if Beijing SL or its affiliates or sublicensees commence a proceeding challenging the validity, enforceability or scope of any of our patents.

The Beijing SL License Agreement contemplates that parties shall, no later than twelve months prior to the anticipated date of the first commercial sale of a licensed product, if any, negotiate in good faith and execute a commercial supply agreement, pursuant to which Beijing SL shall purchase from us, and we shall use commercially reasonable efforts to supply, Gemcabene or licensed product for clinical or commercial purposes, as applicable, until manufacturing and regulatory transfers are complete.

Manufacturing

NeuroBo is required to use Dong-A in South Korea to manufacture clinical quantities of DA-1241 and DA-1726 in accordance with the 2022 License Agreement. As NeuroBo advances the product candidates through clinical development and greater quantities are required, we plan to continue to use third parties including Dong-A ST to manufacture our product candidates.

Among the conditions for FDA approval of a pharmaceutical product is the requirement that the manufacturer’s quality control and manufacturing procedures conform to cGMP, which must be followed at all times. The FDA typically inspects manufacturing facilities every two years. In complying with cGMP regulations, pharmaceutical manufacturers must expend resources and time to ensure compliance with product specifications as well as production, record keeping, quality control, reporting and other requirements.

Competition

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

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

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

DA-1241 and DA-1726-NASH

There are currently no medications approved for the treatment of NASH. However, various therapeutics are used off-label for the treatment of NASH, including vitamin E (an antioxidant), insulin sensitizers (e.g., metformin, pioglitazone), antihyperlipidemic agents (e.g., gemfibrozil), pentoxifylline and ursodeoxycholic acid (UDCA). There are several product candidates in Phase 3 or earlier clinical or preclinical development for the treatment of NASH, including Madrigal Pharmaceuticals, Inc.'s THR beta agonist (resmetirom), Novo Nordisk's GLP1 agonist (semaglutide), Akero Therapeutics's FGF21 analog (efruxifermin), 89 Bio's FGF21 analog (pegaozafermin) and Inventiva's pan-PPAR agonist (lanifibranor), as well as FXR agonists from Intercept Pharmaceuticals Inc. (obeticholic acid), Novartis AG (tropifexor, nidufexor), Metacrine (MET409, MET642), Terns Pharmaceuticals (TERN-101), Gilead Sciences, Inc. (cilofexor) and Enanta Pharmaceuticals, Inc. (EDP-305).

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

DA-1726-Obesity

Due to the growing overweight and obesity epidemic and consumer demand, there are many competitors in the field of obesity treatment. Obesity treatments range from behavioral modification, to drugs and medical devices, and surgery, generally as a last resort. If DA-1726 were approved for obesity, our primary competition in the obesity treatment market would currently be from approved and marketed products, including 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 (tirzepatide), Novo Nordisk's CagriSema (a combination drug of semaglutide and a novel amylin analogue), Zafgen's ZGN-1061 or ZGN-1258 (MetAP2) product candidates and various FGF21 ligands in development. To the extent any of our product candidates are approved for cardio-metabolic indications, particularly obesity, the commercial success of our products will also depend on our ability to demonstrate benefits over the then-prevailing standard of care, including diet and exercise. Finally, morbidly obese patients sometimes undergo the gastric bypass procedure, with salutary effects on the many co-morbid conditions of obesity. Some of these programs have been advanced further in clinical development then our clinical programs or have already received regulatory approval.

DA-1241-T2D

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

Intellectual Property

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

As with other biotechnology and pharmaceutical companies, our ability to maintain and solidify our proprietary and intellectual property position for our product candidates, preclinical compounds, and its core technologies will depend on our success in obtaining effective patent claims and enforcing those claims if granted. However, patent applications that we may file or license from third parties may not result in the issuance of patents. We also cannot predict the breadth of claims that may be allowed or enforced in our patents. Any issued patents that we may receive in the future may be challenged, invalidated or circumvented. For example, prior to March 16, 2013, in the United States, patent applications were subject to a “first to invent” rule of law. Applications effectively filed on or after March 16, 2013, are subject to a “first to file” rule of law.

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

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

Our ability to commercialize product candidates depends in large part on our ability to obtain and maintain intellectual property protection for our product candidates. Our policy is to seek to protect our intellectual property position by, among other methods, filing U.S. and foreign patent applications related to the technology, inventions and improvements that are important to the development and implementation of our business strategy. We also rely on trade secrets, know-how and continuing technological innovation to develop and maintain our proprietary position.

DA-1241

As of December 31, 2022, our exclusively licensed intellectual property portfolio for DA-1241 includes one U.S. patent directed to both composition of matter and a process of making the composition and one U.S. non-provisional patent application directed to both composition of matter and use of the composition. The issued U.S. patent is expected to expire in July 2035, excluding any additional term for patent term adjustments or patent term extensions. NeuroBo's intellectual property portfolio for DA-1241 also includes approximately 17 non-U.S. patents and 14 non-U.S. patent applications directed to composition of matter and/or use of the composition. The issued non-U.S. patents is expected to expire between 2035 and 2039, excluding any additional term for patent term adjustments or patent term extensions. The jurisdictions for the non-U.S. patents and applications include: Australia, Brazil, Canada, China, the European Patent Convention, Hong Kong, India, Israel, Japan, Mexico, New Zealand, Philippines, Republic of Korea, Russia, Saudi Arabia, and Singapore.

DA-1726

As of December 31, 2022, our exclusively licensed intellectual property portfolio for DA-1726 includes one U.S. patent directed to both composition of matter and use of the composition and one U.S. non-provisional patent application directed to both composition of matter and use of the composition. The issued U.S. patent is expected to expire in 2038, excluding any additional term for patent term adjustments or patent term extensions. Our intellectual property portfolio for DA-1726 would also include (i) a PCT application that would enter national phases in October 2022 and (ii) approximately five non-U.S. patents directed to composition of matter and eight non-U.S. patent applications directed to composition of matter and/or use. The issued non-U.S. patents is expected to expire between 2038 and 2040, excluding any additional term for patent term adjustments or patent term extensions. The jurisdictions for the non-U.S. patents and applications include: Australia, Brazil, Canada, China, the European Patent Convention, Japan, Philippines, Republic of Korea, Russia, and Singapore.

ANA001

As of December 31, 2022, our intellectual property portfolio for ANA001 included one US non-provisional application and two non-US applications (Argentina and Europe) directed to niclosamide formulation and one PCT application directed to combined use of niclosamide and gemcabene. Patent applications may be issued in the U.S. and any countries in which the Company files national phase applications of the PCT application. The patents issued from the national phase applications are estimated to expire 2041 to 2042.

As described in more detail above under "Licensing Agreements – License Agreement with YourChoice," pursuant to the YourChoice Agreement, the Company has licensed several patent applications relating to ANA from YourChoice. A PCT application to which claims priority to the U.S. provisional applications was filed in 2021. Patent applications may be issued in any countries in which the Company files national phase applications of the PCT application. The patents issued from the national phase applications are estimated to expire 2041.

NB-01 and NB-02

As of December 31, 2022, our intellectual property portfolio for NB-01 included four issued U.S. patents, comprised of one patent directed to composition of matter and three patents directed to use, and two pending U.S. non-provisional patent applications, comprised of one directed to composition of matter and another directed to use, and 62 granted foreign patents, all related to its NB-01 programs in peripheral neuropathy and neurological conditions. The issued patents have expiration dates ranging from October 27, 2026 to June 22, 2033. The patent issuing from the application, if any, is expected to expire December 2031. The jurisdictions for the foreign patents and application include: Brazil, Canada, China, the European Patent Convention (including Austria, Belgium, Finland, France, Germany, Greece, Hungary, Italy, Netherlands, Poland, Portugal, Romania, Spain, Switzerland, Turkey, and the United Kingdom), India, Japan, Mexico, the Republic of Korea, and Russia. One patent family including some of the above patents for NB-01 is assigned to University-Industry Cooperation Group of Kyung Hee University, and is exclusively licensed from Kyung Hee University to Dong-A ST and then from Dong-A ST to us pursuant to the terms of the corresponding agreements. The other two patent families including the other above patents and patent applications for NB-01 are assigned to Dong-A ST and exclusively licensed to us.

As of December 31, 2022, our intellectual property portfolio for NB-02 included three issued U.S. patents, one pending U.S. non-provisional patent application, 74 foreign granted patents, and 1 foreign patent application. Patents issuing from these applications, if any, are expected to expire around 2035. The issued patents have an expiration date of December 3, 2035 and December 19, 2035. The jurisdictions for the foreign patents and applications include: Brazil, Canada, China, the European Patent Convention (including Austria, Belgium, Finland, France, Germany, Greece, Hungary, Italy, Netherlands, Poland, Portugal, Romania, Spain, Switzerland, Turkey, and the United Kingdom), India, Japan, Mexico, the Republic of Korea, and Russia. All of the above patents and patent applications for NB-02 were assigned to us.

Gemcabene

As of December 31, 2022, our intellectual property portfolio relating to Gemcabene included six issued U.S. patents, three pending U.S. patent applications, 43 foreign-granted patents and 21 foreign patent applications directed to formulations, compositions, methods of use and methods of manufacturing. The Gemcabene intellectual property includes both owned and Pfizer-licensed issued and pending patents in the United States and foreign jurisdictions. The issued patents in the United States and foreign countries have expiration dates between December 2031 and November 2036. The patents in the United States and foreign countries that may be issued from pending applications, if any, are expected to expire between December 2031 and October 2039. The jurisdictions for the foreign countries include Argentina, Australia, Brazil, Canada, China, Europe, Hong Kong, India, Israel, Japan, Mexico, New Zealand, Philippines, Korea, Russia, Singapore, South Africa, Taiwan and Thailand.

Government Regulation

Government authorities at the federal, state and local level in the United States and in other countries extensively regulate, among other things, the research, development, testing, manufacture (including any manufacturing changes), packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, post-approval monitoring and reporting, import and export of pharmaceutical products, such as those we are developing.

United States — FDA Regulation

In the United States, pharmaceutical products are subject to extensive regulation by the FDA. The Federal Food, Drug, and Cosmetic Act, or the FDCA, and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling, and import and export of pharmaceutical products. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as imposition of clinical holds, refusal by the FDA to approve pending NDAs, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement, civil penalties and criminal prosecution.

Pharmaceutical product development in the United States typically involves preclinical or other nonclinical laboratory and animal tests and the submission to the FDA of an Investigational New Drug (IND) application, which must become effective before clinical testing may commence. For commercial approval, the sponsor must submit adequate tests by all methods reasonably applicable to show that the drug is safe for use under the conditions prescribed, recommended or suggested in the proposed labeling. The sponsor must also submit substantial evidence, generally consisting of adequate, well-controlled clinical trials to establish that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended or suggested in the proposed labeling. In certain cases, the FDA may determine that a drug is effective based on one clinical study plus confirmatory evidence. Satisfaction of the FDA pre-market approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity and novelty of the product or disease. For botanical drug products in particular, which may be heterogeneous in nature and may carry additional uncertainty about their active constituents in comparison to synthetic small-molecule drug products, one of the critical issues during drug development is ensuring that the therapeutic effect for marketed drug product batches is consistent.

Nonclinical tests include laboratory evaluation of product chemistry, formulation and toxicity, as well as animal studies to assess the characteristics and potential safety and efficacy of the product. The conduct of the nonclinical tests must comply with federal requirements, including the FDA's good laboratory practice regulations and the U.S. Department of Agriculture's, or USDA's, regulations implementing the Animal Welfare Act. The results of nonclinical testing are

submitted to the FDA as part of an IND along with other information, including information about product chemistry, manufacturing and controls, and a proposed clinical trial protocol. Long-term nonclinical tests, such as animal studies of reproductive toxicity and carcinogenicity, may continue after the IND is submitted.

A 30-day waiting period after the submission of each IND is required prior to the commencement of clinical testing in humans. If the FDA has not imposed a clinical hold on the IND or otherwise commented or questioned the IND within this 30-day period, the clinical trial proposed in the IND may begin.

Clinical trials involve the administration of the investigational new drug to healthy volunteers or patients under the supervision of a qualified investigator. Clinical trials must be conducted: (i) in compliance with federal regulations, (ii) in compliance with good clinical practice (“GCP”), an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators and monitors (some of which have been codified into U.S. federal regulations), and (iii) under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to the FDA as part of the IND.

The FDA may order the temporary, or permanent, discontinuation of a clinical trial at any time or impose other sanctions if it believes that the clinical trial either is not being conducted in accordance with the FDA requirements or presents an unacceptable risk to the clinical trial patients. The trial protocol and informed consent information for patients in clinical trials must also be submitted to an institutional review board, or IRB, at each site where a trial will be conducted for approval. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements or may impose other conditions. Clinical trials to support NDAs for marketing approval are typically conducted in three sequential phases, but the phases may overlap. In general, in Phase 1, the initial introduction of the drug into healthy human volunteers or, in some cases, patients, the drug is tested to assess metabolism, pharmacokinetics, pharmacological actions, side effects associated with increasing doses and, if possible, early evidence of effectiveness. Phase 2 usually involves trials in a limited patient population to determine the effectiveness of the drug for a particular indication, dosage tolerance and optimum dosage, and to identify common adverse effects and safety risks. If a compound demonstrates evidence of effectiveness and an acceptable safety profile in Phase 2 evaluations, Phase 3 trials are undertaken to obtain the additional information about clinical efficacy and safety in a larger number of patients, typically at geographically dispersed clinical trial sites, to permit the FDA to evaluate the overall benefit-risk relationship of the drug and to provide adequate information for the labeling of the drug. In most cases, the FDA requires two adequate and well-controlled Phase 3 clinical trials to demonstrate the efficacy of the drug. The FDA may, however, determine that a drug is effective based on one clinical trial plus confirmatory evidence. Only a small percentage of investigational drugs complete all three phases and obtain marketing approval. In some cases, the FDA may require post-market studies, known as Phase 4 studies, to be conducted as a condition of approval to gather additional information on the drug's effect in various populations and any side effects associated with long-term use. Depending on the risks posed by the drugs, other post-market requirements may be imposed.

After completion of the required clinical testing, an NDA is prepared and submitted to the FDA. FDA approval of the NDA is required before marketing of the product may begin in the United States. The NDA must include the results of all preclinical, clinical, and other testing and a compilation of data relating to the product's pharmacology, chemistry, manufacture, and controls. The cost of preparing and submitting an NDA is substantial. Under federal law, the submission of most NDAs is additionally subject to a substantial application user fee.

The FDA has 60 days from its receipt of an NDA to determine whether the application will be accepted for filing based on the agency's threshold determination that it is sufficiently complete to permit substantive review. Once the submission is accepted for filing, the FDA begins an in-depth review. Under the statute and implementing regulations, the FDA has 180 days (the initial review cycle) from the date of filing to issue either an approval letter or a complete response letter, unless the review period is adjusted by mutual agreement between the FDA and the applicant or as a result of the applicant submitting a major amendment. In practice, the performance goals established pursuant to the Prescription Drug User Fee Act have effectively extended the initial review cycle beyond 180 days. The FDA's current performance goals call for the FDA to complete review of 90% of standard (non-priority) NDAs within 10 months of receipt and within six months for priority NDAs, but two additional months are added to standard and priority NDAs for a new molecular entity, or NME, such that the 10-month and 6-month action goals for NME applications begin to run from the 60-day filing date rather than from receipt of the original NDA submission.

The FDA may also refer applications for novel drug products, or drug products that present difficult questions of safety or efficacy, to an advisory committee, which is typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. Before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. Additionally, the FDA will inspect the facility or the facilities at which the drug is manufactured. The FDA will not approve the product unless compliance with current good manufacturing practice (GMP) regulations is satisfactory and the NDA contains data that provide substantial evidence that the drug is safe and effective in the indication studied.

After the FDA evaluates the NDA and the manufacturing facilities, it issues either an approval letter or a complete response letter. A complete response letter (CRL) generally outlines the deficiencies in the submission and may require substantial additional testing, or information, in order for the FDA to reconsider the application. If, or when, those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. The FDA has committed to reviewing 90% of NDA resubmissions within two to six months depending on the type of information included in response to the deficiencies identified in the CRL.

An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. As a condition of NDA approval, the FDA may require a risk evaluation and mitigation strategy, or REMS, to help ensure that the benefits of the drug outweigh the potential risks. REMS can include medication guides, communication plans for health care professionals, and/or elements to assure safe use, or ETASU. ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patient registries. The requirement for a REMS can materially affect the potential market and profitability of the drug. Moreover, product approval may require substantial post-approval testing and surveillance to monitor the drug's safety or efficacy. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

Fast Track Designation and Accelerated Approval

The FDA is authorized to facilitate the development, and expedite the review, of drugs that are intended for the treatment of a serious or life-threatening disease or condition for which there is no effective treatment and which demonstrate the potential to address unmet medical needs for the condition. These programs include fast track designation, breakthrough therapy designation, priority review designation and other accelerated approvals.

Under the Fast Track Program, the sponsor of a new drug candidate that is intended to treat a serious condition may request that the FDA designate the drug candidate for a specific indication as a Fast Track drug concurrent with, or after, the filing of the IND for the drug candidate. The FDA must determine if the drug candidate qualifies for Fast Track designation within 60 days of receipt of the sponsor's request. In addition to other benefits such as the ability to engage in more frequent interactions with the FDA, the FDA may initiate review of sections of a Fast Track drug's NDA before the application is complete. This rolling review is available if the applicant provides, and the FDA approves, a schedule for the submission of the remaining information and the applicant pays applicable user fees. However, the FDA's time period goal for reviewing an application does not begin until the last section of the NDA is submitted. Additionally, the Fast Track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

In 2012, Congress enacted the Food and Drug Administration Safety and Innovation Act, or FDASIA. This law established a new regulatory program for products designated as “breakthrough therapies.” A product may be designated as a breakthrough therapy if it is intended, either alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The FDA may take certain actions with respect to designated breakthrough therapies, including: holding meetings with the sponsor throughout the development process; providing timely advice to the product sponsor regarding development and approval; involving more senior staff in the review process; assigning a cross-disciplinary project lead for the review team; and taking other steps to design the clinical trials in an efficient manner.

The FDA may also designate a product for priority review if it is a drug that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. The FDA determines at the time that the marketing application is submitted, on a case- by-case basis, whether the proposed drug represents a significant improvement when

compared with other available therapies. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting drug reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes, or evidence of safety and effectiveness in a new subpopulation. A priority review designation is intended to direct overall attention and resources to the evaluation of such applications, and to shorten the FDA's goal for taking action on a marketing application from ten months to six months.

Under the FDA's accelerated approval regulations, the FDA may approve a drug for a serious or life-threatening illness that provides meaningful therapeutic benefit to patients over existing treatments based upon a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. The accelerated approval regulations are codified within Title 21 of the Code of Federal Regulations, as Subpart H under Part 314, the part of the FDA regulations covering applications for FDA approval to market a new drug, and as such the accelerated approval pathway is sometimes referred to as approval under "Subpart H."

In clinical trials, a surrogate endpoint is a measurement of laboratory or clinical signs of a disease or condition that substitutes for a direct measurement of how a patient feels, functions or survives. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. A drug candidate approved under Subpart H is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or confirm a clinical benefit during post-marketing studies, will allow the FDA to withdraw the drug from the market on an expedited basis. Unless otherwise informed by the FDA, for an accelerated approval product an applicant must submit to the FDA for consideration during the preapproval review period copies of all promotional materials, including promotional labeling as well as advertisements, intended for dissemination or publication within 120 days following marketing approval. After 120 days following marketing approval, unless otherwise informed by the FDA, the applicant must submit promotional materials at least 30 days prior to the intended time of initial dissemination of the labeling or initial publication of the advertisement. The accelerated approval pathway is most often used in settings in which the course of a disease is long and an extended period of time is required to measure the intended clinical benefit of a drug, even if the effect on the surrogate or intermediate clinical endpoint occurs rapidly. For example, accelerated approval has been used extensively in the development and approval of drugs for treatment of a variety of cancers in which the goal of therapy is generally to improve survival or decrease morbidity and the duration of the typical disease course requires lengthy and sometimes large clinical trials to demonstrate a clinical or survival benefit.

Orphan Drugs

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition—generally a disease or condition that affects fewer than 200,000 individuals. The U.S. Orphan Drug Designation must be requested before submitting an NDA. After the FDA grants orphan drug designation, the generic identity and trade name, if any, of the drug and its designated use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. The first NDA applicant to receive FDA approval for a particular active ingredient to treat a particular disease with FDA orphan drug designation is entitled to a seven-year exclusive marketing period in the United States for that product, for that indication. During the seven-year exclusivity period, the FDA may not approve any other applications to market the same drug for the same disease, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity. Orphan drug exclusivity does not prevent the FDA from approving a different drug for the same disease or condition, or the same drug for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the NDA application user fee.

Pediatric Information

Under the Pediatric Research Equity Act (PREA), NDAs or supplements to NDAs must contain data to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the drug is safe and effective. The FDA may grant full or partial waivers for submission of data, as well as deferrals for several reasons, including a finding that the drug is ready for approval for use in adults before pediatric studies are complete or that additional safety or effectiveness data needs to

be collected before the pediatric studies begin. Unless otherwise required by regulation, PREA does not apply to any drug for an indication for which orphan designation has been granted.

The Best Pharmaceuticals for Children Act (BPCA) provides NDA holders a six-month extension of any exclusivity—patent or non-patent—for a drug if certain conditions are met. Conditions for exclusivity include the FDA's determination that information relating to the use of a new drug in the pediatric population may produce health benefits in that population, the FDA making a written request for pediatric studies, and the applicant agreeing to perform, and reporting on, the requested studies within the statutory timeframe. Applications under the BPCA are treated as priority applications, with all of the benefits that designation confers.

Special Protocol Assessment

A company may reach an agreement with the FDA under the Special Protocol Assessment, or SPA, process as to the required design and size of clinical trials intended to form the primary basis of an efficacy claim for a new drug product. According to its performance goals, the FDA seeks to evaluate the protocol within 45 days of the request to assess whether the proposed trial is adequate, and that evaluation may result in discussions and a request for additional information. An SPA request must be made before the proposed trial begins, and all open issues must be resolved before the trial begins. If a written agreement is reached, it will be documented and made part of the administrative record. Under the FDCA and FDA guidance implementing the statutory requirement, an SPA is generally binding on the FDA except in limited circumstances, such as if the FDA identifies a substantial scientific issue essential to determining safety or efficacy after the study begins, public health concerns emerge that were unrecognized at the time of the protocol assessment, the sponsor and the FDA agree to the change in writing, or if the study sponsor fails to follow the protocol that was agreed upon with the FDA.

Disclosure of Clinical Trial Information

Sponsors of clinical trials of certain FDA-regulated products, including prescription drugs, are required to register and disclose certain clinical trial information on a public website maintained by the U.S. National Institutes of Health (NIH). Information related to the product, patient population, phase of investigation, study sites and investigator, and other aspects of the clinical trial is made public as part of the registration. Sponsors are also obligated to disclose the results of these trials after completion. Disclosure of the results of these trials can be delayed for up to two years if the sponsor certifies that it is seeking approval of an unapproved product or that it will file an application for approval of a new indication for an approved product within one year. Competitors may use this publicly available information to gain knowledge regarding the design and progress of the development programs. Failure to timely register a covered clinical study or to submit study results as provided for in the law can give rise to civil monetary penalties and also prevent the non-compliant party from receiving future grant funds from the federal government. Since the NIH's Final Rule on ClinicalTrials.gov registration and reporting requirements became effective in 2017, both NIH and FDA have signaled the government's willingness to begin enforcing those requirements against clinical trial sponsors who fail to meet those legal obligations, with FDA releasing a guidance document in August 2020 for certain procedural steps it intends to take when determining whether and how to assess civil monetary penalties against a non-compliant party.

Post-Approval Requirements

Drugs manufactured, marketed or distributed pursuant to FDA approval decisions are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion, and reporting of adverse experiences with the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to FDA review and approval before they can be implemented. There also are continuing, annual user fee requirements for any marketed products and related manufacturing facilities, as well as new application fees for supplemental applications.

In addition, drug manufacturers and other entities involved in the manufacture of approved drugs are required to register their facilities with the FDA and state agencies, and are subject to periodic unannounced inspections by the FDA for compliance with GMP requirements. Prescription drug distribution facilities are also subject to state licensure, including inspections, by the relevant local regulatory authority. Changes to the manufacturing process, specifications or container closure system for an approved drug are strictly regulated and often require prior FDA approval before being

implemented. FDA regulations also require investigation and correction of any deviations from GMP and impose reporting and documentation requirements upon the sponsor and others involved in the drug manufacturing process. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain GMP compliance and ensure ongoing compliance with other statutory requirements the FDCA, such as the requirements for making manufacturing changes to an approved NDA.

Thus, even after new drug approval is granted, Regulatory authorities may withdraw that approval or request product recalls if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences of regulatory non-compliance include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending NDAs or supplements to approved NDAs, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

As described further below, the FDA strictly regulates marketing, labeling, advertising and promotion of prescription drug products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant penalties.

The Hatch-Waxman Amendments

Orange Book Listing

In 1984, with passage of the Hatch-Waxman Amendments to the FDCA, Congress authorized the FDA to approve generic drugs that are the same as drugs previously approved by the FDA under the NDA provisions of the statute. As part of the marketing application process when seeking approval for a new drug through an NDA, applicants are required to list with the FDA every patent of which claims cover the applicant's product or an approved method of using the product. Upon approval of a drug, approval information about the drug along with each of the applicant's listed patents is then published in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly known as the "Orange Book." Pursuant to the Hatch-Waxman Amendments, drugs listed in the Orange Book can, in turn, be cited by potential generic competitors in support of approval of an abbreviated new drug application, or ANDA. An ANDA provides for marketing of a drug product that has the same active ingredients in the same strengths and dosage form as the reference license drug (“RLD”) and has been shown through bioequivalence testing to be bioequivalent to the RLD. The FDA is responsible for determining that the generic drug is "bioequivalent" to the innovator drug, although under the statute, a generic drug is bioequivalent to a RLD if "the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug."

Other than the requirement for bioequivalence testing, ANDA applicants are not required to conduct, or submit results of, preclinical or clinical tests to prove the safety or effectiveness of their drug product. Drugs approved in this way are most often considered to be therapeutically equivalent to the RLD, are commonly referred to as "generic equivalents" to the RLD, and can often be substituted by pharmacists under prescriptions written for the original RLD in accordance with state law. Specifically, upon approval of an ANDA, the FDA indicates whether the generic product is "therapeutically equivalent" to the RLD in the Orange Book. By operation of certain state laws and numerous health insurance programs, the FDA's designation of therapeutic equivalence in the Orange Book often results in substitution of the generic drug without the knowledge or consent of either the prescribing physician or the patient.

The Hatch-Waxman Amendments also amended the FDCA to enact Section 505(b)(2) of the FDCA, which permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. A Section 505(b)(2) applicant may eliminate the need to conduct certain preclinical or clinical studies, if it can establish that reliance on studies conducted for a previously-approved product is scientifically appropriate. The FDA may also require companies to perform additional trials or measurements to support the change from the approved product. The FDA may then approve the new product for all or some of the label indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant. With respect to listed patents, patent certification requirements, and the blocking of follow-on marketing applications for the drug product previously approved under an NDA and listed in the Orange Book—known as the reference listed drug, or RLD—505(b)(2) NDA applications and ANDAs are required under the statute and FDA's implementing regulations to follow similar procedures and are subject to similar conditions. However, only in some cases is a 505(b)(2) NDA-approved drug product determined by FDA to be therapeutically equivalent to the original innovator RLD.

As part of its own marketing application process, the ANDA/505(b)(2) applicant is required to certify to the FDA concerning any patents listed for the relevant RLD in the FDA's Orange Book. Specifically, the applicant must certify either that: (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid or will not be infringed by the generic product. The ANDA applicant may also elect to submit a section viii statement, certifying that its proposed ANDA or 505(b)(2) labeling does not contain (or carves out) any language regarding the patented method-of-use, rather than certify to a listed method-of-use patent.

If the ANDA/505(b)(2) applicant does not challenge the innovator's listed patents, or indicates that it is not seeking approval of a patented method of use, the ANDA/505(b)(2) application will not be approved by the FDA until all the listed patents claiming the referenced product have expired.

A certification that the new product will not infringe the already approved product's listed patents, or that such patents are invalid, is called a Paragraph IV certification. If the ANDA/505(b)(2) applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of that Paragraph IV certification to the NDA sponsor and patent holders once FDA accepts the ANDA/505(b)(2) application for filing. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification, as provided for in the statute. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA/505(b)(2) NDA until the earlier of 30 months, expiration of the patent, settlement of the lawsuit, or a decision in the infringement case that is favorable to the ANDA/505(b)(2) applicant.

Non-Patent Exclusivity

Under the Hatch-Waxman Amendments, the FDA also may not approve an ANDA or 505(b)(2) NDA until any applicable period of non-patent exclusivity for the RLD has expired. The FDCA provides a period of five years of non-patent exclusivity for a new drug containing a new chemical entity, or NCE, which is a drug that contains no active moiety that has been approved by the FDA in any other NDA. During this five years of marketing exclusivity, the FDA cannot receive any ANDA or 505(b)(2) application seeking approval of a drug that references a version of the NCE drug.

The FDCA also provides for a period of three years of exclusivity if the NDA includes reports of one or more new clinical investigations, other than bioavailability or bioequivalence studies, that were conducted by or for the applicant and are essential to the approval of the application. This three-year exclusivity period often protects changes to a previously approved drug product, such as a new dosage form, route of administration, combination or the addition of a new indication. During this three-year period of exclusivity, the FDA cannot approve an ANDA or 505(b)(2) application that includes the change.

An ANDA or 505(b)(2) application may be submitted one year before NCE exclusivity expires if a Paragraph IV certification is filed. If there is no listed patent in the Orange Book, there may not be a Paragraph IV certification

requirement, and in such situations, no ANDA or 505(b)(2) application may be filed before the expiration of the exclusivity period.

For a botanical drug, the FDA may determine that the active moiety is one or more of the principal components, or the complex mixture as a whole. This determination would affect the possibility of any five-year exclusivity as well as the ability of any potential generic competitor to demonstrate that it is the same drug as the original botanical drug. Because the agency has not promulgated specific regulations for botanical drug products and is approaching the development of such products, especially those that are composed of more complex mixtures, on a case-by-case basis, the 2016 Botanical Drug Development guidance for industry represents the best source for the FDA's current thinking on these drug products.

Patent Term Extension

After NDA approval, owners of relevant drug patents may apply for up to a five-year patent extension. The allowable patent term extension is calculated as half of the drug's testing phase—the time between IND submission and NDA submission—and all of the review phase—the time between NDA submission and approval up to a maximum of five years. The time can be shortened if the FDA determines that the applicant did not pursue approval with due diligence. The total patent term after the extension may not exceed 14 years from market approval.

For patents that might expire during the application phase, the patent owner may request an interim patent extension. An interim patent extension increases the patent term by one year and may be renewed up to four times. For each interim patent extension granted, the post-approval patent extension is reduced by one year. The director of the U.S. Patent and Trademark Office must determine that approval of the drug covered by the patent for which a patent extension is being sought is likely. Interim patent extensions are not available for a drug for which an NDA has not been submitted.

Prescription Drug Marketing Act

As part of the sales and marketing process, pharmaceutical companies frequently provide samples of approved drugs to physicians. The Prescription Drug Marketing Act (PDMA) imposes requirements and limitations upon the provision of drug samples to physicians, as well as prohibits states from licensing distributors of prescription drugs unless the state licensing program meets certain federal guidelines that include minimum standards for storage, handling and record keeping. In addition, the PDMA sets forth civil and criminal penalties for violations.

New Legislation and Regulations

From time to time, legislation is drafted, introduced and passed in Congress that could significantly change the statutory provisions governing the testing, approval, manufacturing and marketing of products regulated by the FDA and relevant regulatory authorities outside the United States. In addition to new legislation, regulations and policies are often revised or interpreted by regulatory authorities in ways that may significantly affect our business and our product candidates. It is impossible to predict whether further legislative changes will be enacted or whether regulations, guidance, policies or interpretations will be changed or what the effect of such changes, if any, may be.

Other U.S. Healthcare Laws and Compliance Requirements

If we obtain regulatory approval of our product candidates and launch them commercially in the United States, we may be subject to various federal and state laws targeting fraud and abuse in the healthcare industry. These laws may impact, among other things, our proposed sales, marketing and education programs. In addition, we may be subject to patient privacy regulation by both the federal government and the states in which we conduct our business. Some of the laws that may affect our future ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs;

- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payers that are false or fraudulent;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology and Clinical Health Act, or HITECH, and its implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information;
- the federal transparency requirements under the Physician Payments Sunshine Act require manufacturers of FDA-approved drugs, devices, biologics and medical supplies covered by Medicare or Medicaid to report, on an annual basis, to the Department of Health and Human Services information related to payments and other transfers of value to physicians, teaching hospitals, and certain advanced non-physician health care practitioners and physician ownership and investment interests; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws, which may apply to items or services reimbursed by any third-party payer, including commercial insurers, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Moreover, some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines, or the relevant compliance guidance promulgated by the federal government, in addition to requiring drug manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures to the extent that those laws impose requirements that are more stringent than the Physician Payments Sunshine Act.

Europe/Rest of World Government Regulation

In addition to regulations in the United States, we are and will be subject, either directly or through our distribution partners, to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of its products, if approved.

Whether or not we obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in non-U.S. countries prior to the commencement of clinical trials or marketing of the product in those countries.

The approval process varies from country to country and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others.

In the European Union, medicinal products are subject to extensive pre- and post-marketing regulation by regulatory authorities at both the European Union and national levels. Additional rules also apply at the national level to the manufacture, import, export, storage, distribution and sale of controlled substances. In many European Union. member states the regulatory authority responsible for medicinal products is also responsible for controlled substances. Responsibility is, however, split in some member states. Generally, any company manufacturing or distributing a medicinal product containing a controlled substance in the European Union will need to hold a controlled substances license from the competent national authority and will be subject to specific record-keeping and security obligations. Separate import or export certificates are required for each shipment into or out of the member state.

Clinical Trials and Marketing Approval

Certain countries outside of the United States have a process that requires the submission of a clinical trial application much like an IND prior to the commencement of human clinical trials. In Europe, for example, a clinical trial application, or CTA, must be submitted to the competent national health authority and to independent ethics committees in each country in which a company intends to conduct clinical trials. Once the CTA is approved in accordance with a

country's requirements and a company has received favorable ethics committee approval, clinical trial development may proceed in that country.

The requirements and process governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country, even though there is already some degree of legal harmonization in the European Union member states resulting from the national implementation of underlying European Union. legislation. In all cases, the clinical trials must be conducted in accordance with the International Conference on Harmonization, or ICH, guidelines on GCP and other applicable regulatory requirements.

To obtain regulatory approval to place a drug on the market in the European Union, we must submit a marketing authorization application. This application is similar to the NDA in the United States, with the exception of, among other things, country-specific document requirements. All application procedures require an application in the common technical document, or CTD, format, which includes the submission of detailed information about the manufacturing and quality of the product, and non-clinical and clinical trial information. Drugs can be authorized in the European Union by using (i) the centralized authorization procedure, (ii) the mutual recognition procedure, (iii) the decentralized procedure or (iv) national authorization procedures.

The European Commission created the centralized procedure for the approval of human drugs to facilitate marketing authorizations that are valid throughout the European Union and, by extension (after national implementing decisions) in Iceland, Liechtenstein and Norway, which, together with European Union member states, comprise the European Economic Area, or EEA. Applicants file marketing authorization applications with the EMA, where they are reviewed by a relevant scientific committee, in most cases the Committee for Medicinal Products for Human Use, or CHMP. The EMA forwards CHMP opinions to the European Commission, which uses them as the basis for deciding whether to grant a marketing authorization. This procedure results in a single marketing authorization granted by the European Commission that is valid across the European Union, as well as in Iceland, Liechtenstein and Norway. The centralized procedure is compulsory for human drugs that are: (i) derived from biotechnology processes, such as genetic engineering, (ii) contain a new active substance indicated for the treatment of certain diseases, such as HIV/AIDS, cancer, diabetes, neurodegenerative diseases, autoimmune and other immune dysfunctions and viral diseases, (iii) officially designated "orphan drugs" (drugs used for rare human diseases) and (iv) advanced-therapy medicines, such as gene-therapy, somatic cell-therapy or tissue-engineered medicines. The centralized procedure may, at the voluntary request of the applicant, also be used for human drugs which do not fall within the above-mentioned categories if the CHMP agrees that (a) the human drug contains a new active substance not yet approved on November 20, 2005; (b) it constitutes a significant therapeutic, scientific or technical innovation or (c) authorization under the centralized procedure is in the interests of patients at the European Union. level.

Under the centralized procedure in the European Union, the maximum timeframe for the evaluation of a marketing authorization application by the EMA is 210 days (excluding clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the CHMP), with adoption of the actual marketing authorization by the European Commission thereafter. Accelerated evaluation might be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of a major public health interest from the point of view of therapeutic innovation, defined by three cumulative criteria: the seriousness of the disease to be treated, the absence of an appropriate alternative therapeutic approach, and anticipation of exceptional high therapeutic benefit. In this circumstance, the EMA ensures that the evaluation for the opinion of the CHMP is completed within 150 days and the opinion issued thereafter.

For those medicinal products for which the centralized procedure is not available, the applicant must submit marketing authorization applications to the national medicines regulators through one of three procedures: (i) the mutual recognition procedure (which must be used if the product has already been authorized in at least one other European Union member state, and in which the European Union member states are required to grant an authorization recognizing the existing authorization in the other European Union member state, unless they identify a serious risk to public health), (ii) the decentralized procedure (in which applications are submitted simultaneously in two or more European Union member states) or (iii) national authorization procedures (which results in a marketing authorization in a single European Union member state).

Mutual Recognition Procedure

The mutual recognition procedure, or MRP, for the approval of human drugs is an alternative approach to facilitate individual national marketing authorizations within the European Union. Basically, the MRP may be applied for all human drugs for which the centralized procedure is not obligatory. The MRP is applicable to the majority of conventional medicinal products and must be used if the product has already been authorized in one or more member states.

The characteristic of the MRP is that the procedure builds on an already—existing marketing authorization in a member state of the European Union that is used as a reference in order to obtain marketing authorizations in other European Union member states. In the MRP, a marketing authorization for a drug already exists in one or more member states of the European Union and subsequently marketing authorization applications are made in other European Union member states by referring to the initial marketing authorization. The member state in which the marketing authorization was first granted will then act as the reference member state. The member states where the marketing authorization is subsequently applied for act as concerned member states. The concerned member states are required to grant an authorization recognizing the existing authorization in the reference member state, unless they identify a serious risk to public health.

The MRP is based on the principle of the mutual recognition by European Union. member states of their respective national marketing authorizations. Based on a marketing authorization in the reference member state, the applicant may apply for marketing authorizations in other member states. In such case, the reference member state shall update its existing assessment report about the drug in 90 days. After the assessment is completed, copies of the report are sent to all member states, together with the approved summary of product characteristics, labeling and package leaflet. The concerned member states then have 90 days to recognize the decision of the reference member state and the summary of product characteristics, labeling and package leaflet. National marketing authorizations shall be granted within 30 days after acknowledgement of the agreement.

If any European Union member state refuses to recognize the marketing authorization by the reference member state, on the grounds of potential serious risk to public health, the issue will be referred to a coordination group. Within a timeframe of 60 days, member states shall, within the coordination group, make all efforts to reach a consensus. If this fails, the procedure is submitted to an EMA scientific committee for arbitration. The opinion of this EMA Committee is then forwarded to the European Commission for the start of the decision making process. As in the centralized procedure, this process entails consulting various European Commission Directorates General and the Standing Committee on Human Medicinal Products.

Data and Market Exclusivity in the European Union

In the European Union, NCEs qualify for eight years of data exclusivity upon marketing authorization and an additional two years of market exclusivity. This data exclusivity, if granted, prevents regulatory authorities in the European Union from referencing the innovator's data to assess a generic (abbreviated) application for eight years, after which generic marketing authorization can be submitted, and the innovator's data may be referenced, but not approved for two years. The overall ten-year period will be extended to a maximum of eleven years if, during the first eight years of those ten years, the marketing authorization (MA) holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. Even if a compound is considered to be a NCE and the sponsor is able to gain the prescribed period of data exclusivity, another company nevertheless could also market another version of the drug if such company can complete a full MAA with a complete database of pharmaceutical test, preclinical studies and clinical trials and obtain marketing approval of its product.

Pharmaceutical Coverage, Pricing and Reimbursement

Sales of pharmaceutical products approved for marketing in the United States by the FDA will depend, in part, on the extent to which the costs of the products will be covered by third-party payers, such as government health programs, and commercial insurance and managed health care organizations. These third-party payers are increasingly challenging the prices charged for medical products and services. Additionally, the containment of health care costs has become a

priority of federal and state governments, and the prices of drugs have been a focus in this effort. The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost-containment programs, including price controls, utilization management and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our operating results. If these third-party payers do not consider our products to be cost-effective compared to other available therapies, they may not cover our products after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell its products on a profitable basis.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or the MMA, imposed requirements for the distribution and pricing of prescription drugs for Medicare beneficiaries and included a major expansion of the prescription drug benefit under Medicare Part D. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities that provide coverage of outpatient prescription drugs. Part D is available through both stand-alone prescription drug benefit plans and prescription drug coverage as a supplement to Medicare Advantage plans. Unlike Medicare Parts A and B, Part D coverage is not standardized. Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. However, Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, though not necessarily all the drugs in each category or class. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee.

Government payment for some of the costs of prescription drugs may increase demand for products for which we receive marketing approval in the U.S. However, any negotiated prices for our products covered by a Part D prescription drug plan will likely be lower than the prices we might otherwise obtain. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private payers often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment that results from the MMA may result in a similar reduction in payments from non-governmental payers.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act of 2010 (collectively, the “ACA”), was enacted with the goal of expanding coverage for the uninsured while at the same time containing overall health care costs. With regard to pharmaceutical products, among other things, the ACA expanded and increased industry rebates for drugs covered under Medicaid programs and made changes to the coverage requirements under the Medicare Part D program.

Individual states in the United States have also become increasingly active in implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine which drugs and suppliers will be included in their healthcare programs Furthermore, there has been increased interest by third party payors and governmental authorities in reference pricing systems and publication of discounts and list prices.

In the United States, Medicare covers certain drug purchases by the elderly and eligible disabled people and introduced a reimbursement methodology based on average sales prices for physician-administered drugs. In addition, Medicare may limit the number of drugs that will be covered in any therapeutic class. Ongoing cost reduction initiatives and future laws could decrease the coverage and price that we will receive for any approved products. While Medicare beneficiaries are limited to most elderly and certain disabled individuals, private payors often follow Medicare coverage policy and payment limitations in setting their own payment rates.

Among the provisions of the ACA of importance to our product candidates are the following:

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic products;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- expansion of healthcare fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices;
- extension of manufacturers' Medicaid rebate liability;
- expansion of eligibility criteria for Medicaid programs;
- expansion of the entities eligible for discounts under the Public Health Service Act's pharmaceutical pricing program;
- new requirements to report financial arrangements with physicians and teaching hospitals (i.e., the Federal Physician Payment Sunshine Act, which has since been expanded to cover additional specified healthcare providers);
- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

We expect that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we will receive for any approved product. Any reduction in payments from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products.

There remain judicial and political challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court’s decision, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to health care, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. These changes included aggregate reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, including the Bipartisan Budget Act of 2018, will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022, unless additional Congressional action is taken. In addition, on January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Moreover, there has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for pharmaceutical products. The likelihood of success of these and other measures initiated by the former Trump administration is uncertain.

In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, some European

Union jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost-effectiveness of a particular product candidate to currently available therapies. Other member states allow companies to fix their own prices for medicines but monitor and control company profits. Such differences in national pricing regimes may create price differentials between European Union member states. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the European Union do not follow price structures of the United States. In the European Union, the downward pressure on healthcare costs in general, particularly prescription medicines, has become intense. As a result, barriers to entry of new products are becoming increasingly high and patients are unlikely to use a drug product that is not reimbursed by their government.

Human Capital

As of December 31, 2022, we had 2 full-time employees, 2 full-time consultants and 2 part-time consultants, all located in the United States. Of these employees and consultants, two were engaged in research and development and four were engaged in general and administrative functions. We have no collective bargaining agreements with our employees and have not experienced any work stoppages. We consider our relationships with our employees to be good.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and new employees and consultants. The principal purposes of our equity and cash incentive plans are to attract, retain and reward personnel through the granting of stock-based and cash-based compensation awards, in order to increase stockholder value and the success of our company by motivating such individuals to perform to the best of their abilities and achieve our objectives.

Corporate Information

NeuroBo was incorporated under the laws of the State of Delaware in July 2017. Our principal executive offices are located at 200 Berkeley Street, 19th Floor, Boston, Massachusetts, 02116. Our website address is www.neurobopharma.com. The information contained on, or that can be accessed through, our website is not a part of this report.

ITEM 1A. RISK FACTORS

Our business, prospects, financial condition or results of operations could be materially adversely affected by any of the risks and uncertainties set forth below, as well as in any amendments or updates reflected in subsequent filings with the Securities and Exchange Commission (the “SEC”). In assessing these risks, you should also refer to other information contained in this report, including our financial statements and related notes.

Risks Related to our Operations and to Development, Marketing, Commercialization and Regulation of Our Product Candidates

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 $95.8 million as of December 31, 2022. It is possible we will never generate revenue or profit.

Although we are exploring financing opportunities and carefully monitoring the capital markets, we do not yet have any commitments for additional financing and may not be successful in our efforts to raise additional funds. There can be no assurances that additional financing will be available to us on satisfactory terms, or at all. If we are unable to raise sufficient additional capital (which is not assured at this time, particularly as a result of recent depressed capital market conditions), our long-term business plan may not be accomplished, and we may be forced to cease, reduce, or delay operations. For more information about our liquidity and capital resources, see Part II, Item 7 “Management’s Discussion and Analysis of Financial Condition and Results of Operations — Liquidity and Capital Resources.”

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.

Worldwide economic and social instability could adversely affect our revenue, financial condition, or results of operations.

The health of the global economy, and the credit markets and the financial services industry in particular, as well as the stability of the social fabric of our society, affects our business and operating results. For example, the credit and financial markets may be adversely affected by the turmoil in the banking section in the wake of the failure of Silicon Valley Bank and measures taken in response thereto. If the credit markets are not favorable, we may be unable to raise additional financing when needed or on favorable terms. Our customers may experience financial difficulties or be unable to borrow money to fund their operations, which may adversely impact their ability to purchase our products or to pay for our products on a timely basis, if at all. In addition, adverse economic conditions, such as recent supply chain disruptions and labor shortages and persistent inflation, have impacted, and may continue to adversely impact our suppliers' ability to provide our manufacturer with materials and components, which may negatively impact our business. These economic conditions make it more difficult for us to accurately forecast and plan our future business activities.

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

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

We will have acquired exclusive rights (other than in the Republic of Korea) to DA-1241 and DA-1726 for the specific indications provided in the 2022 License Agreement. Under the 2022 License Agreement, in consideration for the license, we made an upfront payment of 2,200 shares of our 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 DA-1241 and DA-1726

We are not permitted to market DA-1241 or DA-1726 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 DA-1241 or DA-1726, we must successfully complete several clinical trials demonstrating efficacy and safety. DA-1241 and DA-1726 may not be successful in clinical trials or receive regulatory approval. Further, DA-1241 and DA-1726 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 DA-1241 and DA-1726 will never obtain regulatory approval. The FDA may delay, limit or deny approval of DA-1241 or DA-1726 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 DA-1241 or DA-1726;
- 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 DA-1241 or DA-1726 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 DA-1241 and DA-1726.

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.

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, 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, 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.

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.

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), Akero Therapeutics's FGF21 analog (efruxifermin), 89 Bio's FGF21 analog (pegaozafermin 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),

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.

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. In particular, we rely on Dong-A to provide services with respect to our development of DA-1241 and DA-1726. In addition, we had, have and will continue to have discussions on potential partnering opportunities with various pharmaceutical and medical device companies. If we fail to enter into or maintain collaborative agreements on reasonable terms or at all, our ability to develop our existing or future research programs and product candidates could be delayed, the commercial potential of our products could change, and our costs of development and commercialization could increase.

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

- We may not be able to control the amount or timing of resources that collaborative partners devote to our research programs and product candidates;
- We may be required to relinquish significant rights, including intellectual property, marketing and distribution rights;
- We rely on the information and data received from third parties regarding our research programs and product candidates and will not have control of the process conducted by the third party in gathering and composing such data and information. We may not have formal or appropriate guarantees from our contract parties with respect to the quality and the completeness of such data;
- A collaborative partner may develop a competing product either by itself or in collaboration with others, including one or more of our competitors;
- Our collaborative partners’ willingness or ability to complete their obligations under our collaboration arrangements may be adversely affected by business combinations or significant changes in a collaborative partner’s business strategy; and/or
- We may experience delays in, or increases in the costs of, the development of our research programs and product candidates due to the termination or expiration of collaborative research and development arrangements.

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

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

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

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

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

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

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

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

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

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

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

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

- restrictions on such products, manufacturers or manufacturing processes;
- restrictions on the labeling, marketing, distribution or use of a product;
- requirements to conduct post-approval clinical trials;
- warning or untitled letters;

- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- fines, restitution or disgorgement of profits or revenue;
- suspension or withdrawal of marketing approvals for the drug products;
- refusal to permit the import or export of our products;
- product seizure; and
- injunctions or the imposition of civil or criminal penalties.

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

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

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

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

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

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

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

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

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

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

Healthcare providers and third-party payors will play a primary role in the recommendation and prescription of any product candidate for which we obtain marketing approval. Our arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute any product candidate for which we obtain marketing approval. Restrictions and obligations under applicable federal and state healthcare laws and regulations are noted in the section “Item 1—Business—Government Regulation” above.
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, were subject to limitation arising from an ownership change related to the Dong-A Financing and the Public Offering. 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.

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 currently have no plans to build our own clinical or commercial scale manufacturing capabilities. We currently work exclusively with Dong-A ST as the sole manufacturer for the production of DA-1241 and DA-1726. To meet our projected needs for clinical supplies to support our activities for DA-1241 and DA-1726 through regulatory approval and commercial manufacturing, Dong-A 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.

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

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

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

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

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

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

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

- problems integrating the purchased or licensed business, products or technologies;
- increases to our expenses;
- the failure to have discovered undisclosed liabilities of the acquired or licensed asset or company;
- diversion of management's attention from their day-to-day responsibilities;
- harm to our operating results or financial condition;
- entrance into markets in which we have limited or no prior experience; and

- potential loss of key employees, particularly those of the acquired entity.

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

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

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

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

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;
- collaborators may not pursue development and commercialization or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborator's strategic focus or available funding or external factors such as an acquisition that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive;
- a collaborator with marketing and distribution rights to one or more product candidates may not commit sufficient resources to the marketing and distribution of any such product candidate;
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information or expose us to potential litigation;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- disputes may arise between the collaborators and us that result in the delay or termination of the research, development or commercialization of our product candidate or that result in costly litigation or arbitration that diverts management’s attention and resources;
- we may lose certain valuable rights under circumstances identified in its collaborations, including if it undergoes a change of control;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates;
- collaborators may learn about our discoveries and use this knowledge to compete with us in the future;
- the results of collaborators' preclinical or clinical studies could harm or impair other development programs;
- there may be conflicts between different collaborators that could negatively affect those collaborations and potentially others;

- the number and type of our collaborations could adversely affect our attractiveness to future collaborators or acquirers;
- collaboration agreements may not lead to development or commercialization of our product candidate in the most efficient manner or at all. If our present or future collaborator were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program under such collaboration could be delayed, diminished or terminated; and
- collaborators may be unable to obtain the necessary marketing approvals.

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

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

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

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

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

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

We are exposed to the risk that our employees, principal investigators, CROs and consultants may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include failures to comply with FDA regulations or similar regulations of comparable foreign regulatory authorities, to provide accurate information to the FDA or comparable foreign regulatory authorities, to comply with manufacturing standards we have established, to comply with federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable foreign regulatory authorities, to report financial information or data accurately or to disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee or third-party misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity, such as employee training, may not be effective in controlling

unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending such action or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant fines or other sanctions.

Risks Related to Intellectual Property

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

We depend on our ability to protect our proprietary technology. 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. Our success depends 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 have the right to do so under our license agreements, we seek to protect our proprietary position by filing patent applications in the United States and abroad 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 police and protect our proprietary rights may not be adequate to preclude misappropriation of our proprietary information or infringement of our intellectual property rights, both inside and outside the United States. The rights already granted under any of our currently issued patents and those that may be granted under future issued patents may not provide us with the proprietary protection or competitive advantages that we are seeking. If we are unable to obtain and maintain 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, and our ability to successfully commercialize our technology and products may be adversely affected.

With respect to patent rights, we do not know whether any of our 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 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 our license agreement with Dong-A ST 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, 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 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 have not obtained patent protection, competitors may use our intellectual property to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but where it is more difficult to enforce a patent as compared to the U.S. competitor products may compete with our product candidates, if approved, or any future product candidate in jurisdictions where we do not have issued or granted patents or where we 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 relating to pharmaceuticals. This could make it difficult for us to prevent the infringement of its patents or marketing of competing products in violation of our proprietary rights generally in certain jurisdictions. Proceedings to enforce our 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 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 intellectual property does not cover its technology. An adverse determination in any litigation or defense proceedings could put our intellectual property at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing.

If the breadth or strength of our patent or other intellectual property rights 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 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 the combined organization's 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, 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.

We may be subject to damages resulting from claims that our employees or we have wrongfully used or disclosed alleged trade secrets of their former employers.

Our employees and consultants have been previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we are not aware of any claims currently pending against us, we may be subject to claims that these employees, or we have, inadvertently or otherwise used or disclosed trade secrets or other proprietary information or intellectual property of the former employers of our employees. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management. If we fail in defending such claims, in addition to paying money claims, we may lose valuable intellectual property rights or personnel. A loss of key personnel or their work product could hamper or prevent our ability to commercialize product candidates, which would adversely affect our commercial development efforts.

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 product 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 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 Related Operations, Employee Matters and Managing Growth

We currently have no employees and a limited number of consultants and our future success depends on our ability to retain our executive officers and to attract, retain and motivate qualified personnel.

Because of the specialized scientific nature of our business, we rely heavily on our ability to attract and retain qualified scientific, technical and managerial personnel. We are highly dependent upon current members of our management and scientific team, each of whom serves as a consultant. We intend to increase our technical and management staff as needs arise and supporting resources become available, but the loss of one or more of our senior executive officers could be detrimental to us if we cannot recruit suitable replacements in a timely manner. The competition for qualified personnel in the pharmaceutical field is intense and as a result, we may be unable to continue to attract and retain qualified personnel necessary for the development of our business or to recruit suitable replacement personnel.

We will need to grow the size of our organization, and we may experience difficulties in managing this growth.

As of December 31, 2022, we had 2 full-time employees, 2 full-time consultants and 2 part-time consultants, all located in the United States. As of March 24, 2023, we had no full-time employees, 3 full-time consultants and 2 part-time consultants. As our development and commercialization plans and strategies develop, or as a result of any future acquisitions, we will need additional managerial, operational, development, sales, marketing, financial and other resources. Our management, personnel and systems currently in place will not be adequate to support our future growth. Future growth would impose significant added responsibilities on our employees, including:

- managing our clinical trials effectively;
- identifying, recruiting, maintaining, motivating and integrating additional employees;
- managing our internal development efforts effectively while complying with our contractual obligations to licensors, contractors and other third parties; and
- improving our managerial, development, operational and finance systems

As our operations expand, we will need to manage additional relationships with various CROs, strategic partners, and other third parties. Our future financial performance and our ability to commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to manage our development efforts and clinical trials effectively and hire, train and integrate additional management, administrative, research and development, and sales and marketing personnel. We may not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from successfully growing the Company.

We intend to market our product candidates outside of the United States, and if we do, we will be subject to the risks of doing business outside of the United States.

Because we intend to market our product candidates, if approved, outside of the United States, our business is subject to risks associated with doing business outside of the United States. Accordingly, our business and financial results in the future could be adversely affected due to a variety of factors, including:

- failure to develop an international sales, marketing and distribution system for our products;

- changes in a specific country's or region's political and cultural climate or economic condition;
- unexpected changes in foreign laws and regulatory requirements;
- difficulty of effective enforcement of contractual provisions in local jurisdictions;
- inadequate intellectual property protection in foreign countries;
- inadequate data protection against unfair commercial use;
- trade-protection measures, import or export licensing requirements such as Export Administration Regulations promulgated by the United States Department of Commerce and fines, penalties or suspension or revocation of export privileges;
- the effects of applicable foreign tax structures and potentially adverse tax consequences; and
- significant adverse changes in foreign currency exchange rates.

The pharmaceutical industry is highly competitive and is subject to rapid and significant technological change, which could render our technologies and products obsolete or uncompetitive.

The pharmaceutical industry is highly competitive and is subject to rapid and significant technological change, which could render certain of our products obsolete or uncompetitive. This is particularly true in the development of therapeutics for indications where new products and combinations of products are rapidly being developed that change the treatment paradigm for patients. There is no assurance that our product candidates will be the most effective, have the best safety profile, be the first to market, or be the most economical to make or use. The introduction of competitive therapies as alternatives to our product candidates could dramatically reduce the value of those development projects or chances of successfully commercializing those product candidates, which could have a material adverse effect on our long-term financial success.

We will compete with companies in the United States and internationally, including major pharmaceutical and chemical companies, specialized CROs, research and development firms, universities and other research institutions. Many of our competitors have greater financial resources and selling and marketing capabilities, greater experience in clinical testing and human clinical trials of pharmaceutical products and greater experience in obtaining FDA and other regulatory approvals than we do. In addition, some of our competitors may have lower development and manufacturing costs.

Risks Related to Common Stock

The price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses of our common stock.

The trading price of our common stock is likely to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. In addition to the factors discussed in this "Risk Factors" section, these factors include:

- adverse results or delays in preclinical studies, clinical trials, regulatory decisions or the development status of our product candidates or any product candidates we may pursue in the future;
- our ability to raise sufficient additional funds necessary for the continued development of our product candidates whether through potential collaborative, partnering or other strategic arrangements or otherwise;
- the terms and timing of any future collaborative, licensing or other strategic arrangements that we may establish;
- uncertainties created by our future management turnover;
- our inability to comply with the minimum listing requirements of the Nasdaq Stock Market LLC;
- the timing of achievement of, or failure to achieve, our, or any potential collaborator’s clinical, regulatory and other milestones, such as the commencement of clinical development, the completion of a clinical trial or the receipt of regulatory approval;
- decisions to initiate a clinical trial, not initiate a clinical trial, or terminate an existing clinical trial;
- adverse regulatory decisions, including failure to receive regulatory approval for our product candidates or regulatory actions requiring or leading to a delay or stoppage of any clinical trials;
- the commercial success of any product approved by the FDA or its foreign counterparts;
- changes in applicable laws, rules or regulations;
- adverse developments concerning our manufacturers, suppliers, collaborators and other third parties;

- occurrence of health epidemics or contagious diseases, and potential effects on our business, clinical trial sites, supply chain and manufacturing facilities;
- our failure to commercialize our product candidates;
- the success of competitive drugs;
- if our patents covering our product candidates expire or are invalidated or are found to be unenforceable, or if some or all of our patent applications do not result in issued patents or result in patents with narrow, overbroad, or unenforceable claims;
- additions or departures of key scientific or management personnel;
- unanticipated safety concerns related to the use of any product candidates;
- our announcements or our competitor's announcements regarding new products, enhancements, significant contracts, acquisitions or strategic partnerships and investments;
- the size and growth of our target markets;
- our, or companies perceived to be similar to us, failure to meet external expectations or management guidance;
- fluctuations in our quarterly financial results or the quarterly financial results of companies perceived to be similar to us;
- publication of research reports about us or our industry, recommendations, earning results or estimates or withdrawal of research coverage by securities analysts;
- changes in the market valuations of similar companies;
- changes in general economic, political and market conditions in any of the regions in which we conduct our business;
- changes in our capital structure or dividend policy, future issuances of securities, sales of common stock by officers, directors and significant stockholders or our incurrence of additional debt;
- trading volume of our common stock;
- changes in accounting practices and ineffectiveness of our internal controls;
- disputes, litigation or developments relating to proprietary rights;
- timing of milestones and royalty payments; and
- other events or factors, many of which are beyond our control.

In addition, the stock market in general, Nasdaq, and the stock of biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company's securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management's attention and resources, which would harm our business, operating results or financial condition.

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

On February 8, 2023, 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 August 7, 2023.

We continue to monitor the closing bid price of our common stock and consider our available options to resolve our noncompliance with the minimum bid price requirement. There can be no assurance that we will be able to regain compliance with the minimum bid price requirement or we will otherwise be in compliance with other Nasdaq listing

criteria. If we fail to regain compliance with the minimum bid requirement or to meet the other applicable continued listing requirements for the Nasdaq Capital Market in the future and Nasdaq may delist our common stock.

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

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

If we seek to implement a reverse stock split to remain listed on the NASDAQ Capital Market, the announcement or implementation of a reverse stock split could significantly negatively affect the price of our common stock. Additionally, in 2020, the SEC approved a previously proposed NASDAQ rule change to expedite delisting of securities with a closing bid price at or below $0.10 for 10 consecutive trading days during any bid price compliance period and that have had one or more reverse stock splits with a cumulative ratio of 1 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 of 1 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)).

We continue to actively monitor our performance with respect to the listing standards and are considering available options to resolve the deficiency and regain compliance with the NASDAQ rules. There can be no assurance that we will be able to regain compliance with any deficiency, or maintain compliance even if we implement an option that regains our compliance.

We may enter into financing transactions that are dilutive to our stockholders, impose material restrictions on our business and/or require us to relinquish valuable rights.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances, and marketing, distribution or licensing arrangements with third parties. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of current stockholders may be materially diluted, and the terms of such securities could include liquidation or other preferences that adversely affect the rights of our current stockholders. Debt financing and preferred equity financing, if available, may involve agreements that include restrictive covenants that limit our ability to take specified actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed, we may be required to delay, scale back or discontinue the development and commercialization of one or more of our product candidates or delay our pursuit of potential in-licenses or acquisitions.

Our largest shareholder may use its significant interest to take actions not supported by our other shareholders.

As of March 24, 2023, our largest shareholder, Dong-A beneficially owned 45.7% of our voting rights, and if the warrants held by Dong-A were exercised, Dong-A would hold 60.3% of our voting rights. As a result, Dong-A may be able to exert a significant influence on the outcome of corporate actions requiring shareholder approval, including mergers, share capital increases and other extraordinary items.

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, which may result in Dong-A controlling both the determinations of the Board of Directors and the vote of all matters submitted to a vote of our shareholders, which enables them to control all corporate decisions. This concentration of ownership may delay, deter or prevent acts that would be favored by our other shareholders. The interests of Dong-A may not always coincide with our interests or the interests of our other shareholders. For as long as Dong-A owns shares of our common stock and the Investor Rights Agreement is effective, Dong-A will have significant influence on our management, business plans and policies, including the appointment and removal of our officers, decisions on whether to raise future capital and amending our charter and bylaws, which govern the rights attached to our common stock. In particular, if Dong-A owns a significant percentage of our stock, Dong-A will be able to cause or prevent a change of control of us or a change in the composition of our Board and could preclude any unsolicited acquisition of us. The concentration of ownership could deprive you of an opportunity to receive a premium for your shares of common stock as part of a sale of us and ultimately might affect the market price of our common stock. In addition, this concentration of ownership may adversely affect the trading price of our common stock because investors may perceive disadvantages in owning shares in a company with significant stockholders.

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

We may be a "controlled company" within the meaning of the Nasdaq listing rules and may follow certain exemptions from certain corporate governance requirements that could adversely affect our public shareholders.

As of March 24, 2023, our largest shareholder, Dong-A beneficially owned 45.7% of our voting rights. To the extent that Dong-A acquires additional shares of common stock, including through the exercise of the warrants that it currently holds or otherwise, such that Dong-A would own more than 50% of our outstanding common stock, we would meet the definition of a "controlled company" under the corporate governance standards for Nasdaq listed companies. For so long as we would be a "controlled company" under this definition, we would be eligible to utilize certain exemptions from the corporate governance requirements of Nasdaq, including the requirements (i) that a majority of the Board consist of independent directors, (ii) to have a governance committee that is composed entirely of independent directors with a written charter addressing the committee's purpose and responsibilities, (iii) to have a compensation committee that is composed entirely of independent directors with a written charter addressing the committee's purpose and responsibilities, (iv) that the compensation committee consider certain independence factors when engaging legal counsel and other committee advisors and (v) for an annual performance evaluation of the governance and compensation committees. Although we do not currently intend to rely on the "*controlled company*" exemptions under the Nasdaq listing rules even if we would be deemed to 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, stockholders would not have the same protections afforded to shareholders of companies that are subject to all of the corporate governance requirements of Nasdaq.

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

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

- establish a classified board of directors such that not all members of the board are elected at one time;
- allow the authorized number of our directors to be changed only by resolution of our board of directors;
- limit the manner in which our stockholders can remove directors from the board;
- establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our board of directors;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- prohibit our stockholders from calling special meetings;
- authorize our board to issue preferred stock without stockholder approval, which preferred stock may include rights superior to the rights of the holders of common stock, and which could be used to institute a shareholder rights plan, or so-called "poison pill," that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board; and
- require the approval of the holders of at least two-thirds of the votes that all our stockholders would be entitled to cast to amend or repeal certain provisions of our charter or bylaws.

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

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

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

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

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

We concluded that there were material weaknesses relating to our internal control over financial reporting relating to a lack of segregation of duties over certain financial processes, management review over financial reporting and logical access to financial reporting systems. For more information about these material weaknesses, see Part II, Item 9A (Controls and Procedures) of this report. 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 Risk Factors

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 a "smaller reporting company", as defined in the Exchange Act. For as long as we continue to be an smaller reporting company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies", including exemption from compliance with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002 (Sarbanes-Oxley Act), only being required to provide two years of audited financial statements in annual reports and reduced disclosure obligations regarding executive compensation in its periodic reports and proxy statements If our public float is above $75 million as of the last business day of our most recently completed second fiscal quarter or, if before such date, we opt to no longer take advantage of the applicable exemption, we will be required to include an opinion from our independent registered public accounting firm on the effectiveness of our internal control over financial reporting.

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

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

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

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

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

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

Our Bylaws provide that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will generally be the sole and exclusive forum for any derivative action or proceeding brought on its behalf, any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders, any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, as amended, the certificate of incorporation or the bylaws or any other action asserting a

claim governed by the internal affairs doctrine. This provision does not apply to claims arising under the Securities Act and the Exchange Act or any claim for which the federal courts have exclusive jurisdiction. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and to have consented to the provisions of the bylaws described above. This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and employees. Alternatively, if a court were to find this provision inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our business and financial condition.

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

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

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable

ITEM 2. PROPERTIES

We currently lease space in Boston, Massachusetts. Effective January 2022, we entered into an amendment to our lease agreement for approximately 40 square feet of office space, which, including subsequent amendments, is due to expire in March 2023. We previously leased approximately 574 square feet of lab and office space in Seoul, South Korea until April 30, 2022. We believe that our leased properties are adequate for our purposes and to pursue our strategy.

ITEM 3. LEGAL PROCEEDINGS

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

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Common Stock

Our common stock is listed on Nasdaq under the symbol "NRBO."

Stockholders

On March 24, 2023, we had 27,176,685 shares of common stock outstanding and 73 holders of record of our common stock. The transfer agent and registrar for our common stock is American Stock Transfer & Trust Company, LLC.

Dividend Policy

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

ITEM 6. [Reserved]

ITEM 7 MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion of our financial condition and results of operations should be read in conjunction with the financial statements and notes included in Part II, Item 8 "Consolidated Financial Statements and Supplementary Data" of this report.

Overview

We are a clinical-stage biotechnology company focused on developing and commercializing novel pharmaceuticals to treat cardiometabolic disorders. For more information on our business and product candidates, see "Business-Overview" in Part I, Item 1 of this report.

Recent Developments

Dong-A ST License Agreement

On September 14, 2022, we entered into the 2022 License Agreement with Dong-A, pursuant to which, we ultimately received an exclusive global license (other than in the Republic of Korea) to two proprietary compounds for specified indications upon meeting certain financing milestones. The 2022 License Agreement covers the rights to DA-1241 for treatment of NASH and DA-1726 for treatment of obesity and NASH. We may also develop DA-1241 for the treatment of T2D. Under the terms of the 2022 License Agreement, we agreed to pay Dong-A an upfront payment to be settled with 2,200 shares of Series A Preferred Stock upon completion of a private placement.

In addition, Dong-A will be eligible to receive (i) 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; (ii) commercial-based milestone payments, dependent upon the achievement of specific commercial developments; and (iii) single digit royalties on net sales received by us from the commercial sale of products covering DA-1241 or DA-1726.

The term of the 2022 License Agreement continues on a product-by-product and country-by country basis until the later of (i) the fifth anniversary of the first commercial sale of such product in such country, (ii) the expiration or termination of the last valid patent claim that covers a product in such country and (iii) the loss of regulatory exclusivity for such product in such jurisdiction. Either Dong-A or the Company may terminate the 2022 License Agreement (i) if the other party is in material breach of the agreement and has not cured or started to cure the breach within 60 days of notice of such breach; provided that if the breach cannot be cured within the 60-day period and the breaching party started to remedy the breach, if such breach is not cured within 90 days of receipt of written notice, (ii) if the other party is subject to a bankruptcy or insolvency event (subject to a 30-day cure period in the case of a petition for bankruptcy), or (iii) in the event we had failed to complete the Public Offering as further described below by December 31, 2022 (or January 31, 2023 under specified circumstances set forth in the License Agreement).

None of the milestone or royalty payments under the 2022 License Agreement were triggered as of the issuance of this report.

Shared Services Agreement

On September 14, 2022, in conjunction with the 2022 License Agreement, we entered into a shared services agreement with Dong-A (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 on a cost plus margin basis. In addition, the Shared Services Agreement provides that Dong-A will manufacture all of the Company's clinical requirements of DA-1241 and DA-1726 on a cost plus margin basis.

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.

The Company did not incur any research and development expenses under the Shared Services Agreement as of the issuance of this report.

Current Scientific Activity

Following consummation of the 2022 License Agreement, we have two primary programs focused on treatment of NASH, obesity and T2D:

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

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

Our Board of Directors has determined to focus our financial resources and management attention on development of DA-1241 for NASH and T2D and DA-1726 for NASH and obesity. We will continue to consider licensing and acquisition opportunities with respect to our legacy programs designed to impact a range of indications in viral, neurodegenerative and cardiometabolic diseases:

- *ANA001* is a proprietary oral niclosamide formulation being developed as a treatment for patients with moderate COVID-19. Niclosamide is a potential oral antiviral and anti-inflammatory agent with a long history of use and well-understood safety in humans..

- *NB-01* was being developed as a treatment for painful diabetic neuropathy (PDN) as a first-line pain management therapy for PDN.

- *NB-02* was being developed to treat the symptoms of cognitive impairment and modify the progression of neurodegenerative diseases associated with the misfunction of a protein called tau, and with amyloid beta plaque deposition.

- *Gemcabene* was being developed for the treatment of dyslipidemia, a serious medical condition that increases the risk of life-threatening cardiovascular disease, and was focused on orphan indications such as homozygous familial hypercholesterolemia (HoFH), as well as severe hypertriglyceridemia (SHTG) and we are currently exploring various acute therapeutic indications.

Key operating data

We have incurred significant operating losses since inception. Our ability to generate product revenue sufficient to achieve profitability will depend on the successful development and eventual commercialization of one or more of our current or future product candidates. Our net losses were $14.0 million and $15.3 million for the years ended December 31, 2022 and 2021, respectively. To date, we have not generated any revenue from product sales, collaborations with other companies, government grants or any other source, and do not expect to generate any revenue in the foreseeable future.

As of December 31, 2022, we had an accumulated deficit of $95.8 million. We expect to continue to incur significant expenses and increasing operating losses for at least the next several years. We expect that our expenses and capital requirements will increase substantially in connection with our ongoing activities, particularly if and as we:

- pursue clinical development for our current product candidates;
- initiate preclinical studies and clinical trials with respect to our current product candidates and indications and any future product candidates or indications that we may pursue;
- acquire or in-license other product candidates and/or technologies;
- develop, maintain, expand and protect our intellectual property portfolio;
- hire additional clinical, scientific and commercial personnel;
- establish a commercial manufacturing source and secure supply chain capacity sufficient to provide commercial quantities of any product candidates for which we may obtain regulatory approval;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- establish a sales, marketing and distribution infrastructure and/or enter into partnership arrangements to commercialize any products for which we may obtain regulatory approval; or
- add administrative, operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts, and to support our being a public reporting company.

Components of Results of Operations

Revenue

To date, we have not generated any revenue from product sales, collaborations with other companies, government grants or any other source, and do not expect to generate any revenue in the foreseeable future. If our product development efforts for our product candidates are successful and result in regulatory approval, we may generate revenue in the future from product sales. We cannot predict if, when, or to what extent we will generate revenue from the commercialization and sale of our product candidates. We may never succeed in obtaining regulatory approval for any of our product candidates.

Cost of Revenue

To date, we have not generated any revenue and thus have no cost of revenue. If our development efforts for our product candidates are successful and result in regulatory approval, we may generate revenue in the future from

product sales and have corresponding cost of revenue. We cannot predict if, when, or to what extent we will incur costs from revenue from the commercialization and sale of our product candidates. If we are successful at commercialization, the cost of revenues would include all costs directly related to providing the commercial asset, which would consist primarily of labor, material, facilities, warehousing and other overhead expenses. Cost of revenues would also include depreciation expense related to certain equipment used as part of the commercial asset.

Operating Expenses

Research and Development Expenses

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

- employee-related expenses, including salaries, related benefits and stock-based compensation, for employees engaged in research and development functions;
- expenses incurred in connection with the clinical development of our product candidates, including under agreements with third parties, such as consultants and Clinical Research Organizations ("CROs");
- the cost of manufacturing and storing drug products for use in our preclinical studies and clinical trials, including under agreements with third parties, such as consultants and Clinical Manufacturing Organizations ("CMOs");
- facilities, depreciation and other expenses, which include direct or allocated expenses for rent and maintenance of facilities and insurance;
- costs related to compliance with regulatory requirements; and
- payments made under third-party licensing agreements.

We recognize external development costs based on an evaluation of the progress toward completion of specific tasks using information provided to us by our service providers. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf, and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual costs. Nonrefundable advance payments for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. Such amounts are recognized as an expense when the goods have been delivered or the services have been performed, or when it is no longer expected that the goods will be delivered, or the services rendered.

Our direct research and development expenses consist primarily of external costs, such as fees paid to outside consultants, CROs, CMOs and research laboratories in connection with our clinical development, quality assurance and quality control processes, manufacturing, and clinical development activities. Our direct research and development expenses also include fees incurred under third-party license agreements. We use our employee and infrastructure resources across multiple research and development projects. We do not allocate employee costs and costs associated with our facilities, including depreciation or other indirect costs, to specific product candidates because these costs are deployed across multiple programs and, as such, are not separately classified. We use internal resources primarily to conduct manufacturing and clinical development activities. These employees work across multiple programs and, therefore, we do not track our costs by product candidate.

Clinical development activities are central to our business model. We do not believe that our historical costs are indicative of the future costs associated with these programs, nor do they represent the costs of other future programs we may initiate. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We have some control over the timing of these expenses, but costs may be difficult to control once clinical trials have commenced.

The successful development and commercialization of our product candidates are highly uncertain. At this time, we cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary to complete the

preclinical and clinical development of any of our product candidates. Additionally, because of the risks inherent in novel treatment discovery and development, we cannot reasonably estimate or know:

- the timing and progress of preclinical and clinical development activities;
- the number and scope of clinical programs that we decide to pursue;
- our ability to maintain our current development programs and to establish new ones;
- establishing an appropriate safety profile with IND-enabling studies;
- successful patient enrollment in, and the initiation and completion of, clinical trials;
- the successful completion of clinical trials with safety, tolerability and efficacy profiles that are satisfactory to the FDA or any comparable foreign regulatory authority;
- the receipt of regulatory approvals from applicable regulatory authorities;
- the timing, receipt and terms of any marketing approvals from applicable regulatory authorities;
- our ability to establish new licensing or collaboration arrangements;
- establishing agreements with third-party manufacturers for clinical supply for our clinical trials and commercial manufacturing, if any of our product candidates is approved;
- development and timely delivery of clinical-grade and commercial-grade drug formulations that can be used in our clinical trials and for commercial launch;
- obtaining, maintaining, defending and enforcing patent claims and other intellectual property rights;
- launching commercial sales of our product candidates, if approved, whether alone or in collaboration with others;
- maintaining a continued acceptable safety profile of the product candidates following commercialization; or
- the effect of competing technological and market developments.

A change in the outcome of any of these variables with respect to the development of our product candidates could significantly change the costs and timing associated with the development of that product candidate.

Acquired In-Process Research and Development

We include costs to acquire or in-license product candidates in acquired in-process research and development expenses (“IPR&D”). When we acquire the right to develop and commercialize a new product candidate, any up-front payments, or any future milestone payments that relate to the acquisition or licensing of such a right are immediately expensed as acquired in-process research and development in the period in which they are incurred. These costs are immediately expensed provided that the payments do not also represent processes or activities that would constitute a “business” as defined under GAAP, or provided that the product candidate has not achieved regulatory approval for marketing and, absent obtaining such approval, has no alternative future use. Royalties owed on future sales of any licensed product will be expensed in the period the related revenues are recognized.

General and Administrative Expenses

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

We anticipate that our general and administrative expenses will increase in the future as a result of accounting, audit, legal, regulatory, compliance, and director and officer insurance costs as we pursue the development of our product pipeline, as well as investor and public relations expenses associated with being a public company.

Interest Income

Interest income consists of bank interest earned on our cash and cash equivalents.

Fair Value Change in Warrant Liabilities

The fair value change in warrant liabilities is attributed to the change in fair value of Series A Warrants and the Series B Warrants (as defined further below).

Other Expense

Other expense primarily reflects losses on sale of fixed assets and translations of foreign currency.

Income Taxes

Since our inception, we have not recorded any income tax benefits for the NOLs we have incurred in each year or for our earned research and development tax credits, as we believe, based upon the weight of available evidence, that it is more likely than not that all of our NOL carryforwards and tax credits will not be realized. As of December 31, 2022, we had federal, state and foreign NOLs carryforwards of $1.4 million, $0.8 million, and $0.7 million, respectively, which may be available to offset future income tax liabilities and begin to expire, in 2043 for state carryforwards and in 2028 for the foreign carryforwards. As of December 31, 2022, we also had federal and state research and development tax credit carryforwards of $24,000 and $2,000, respectively, which may be available to offset future tax liabilities and each begin to expire in 2043. We have recorded a full valuation allowance against our net deferred tax assets at each balance sheet date.

Results of Operations

Comparison of the Years Ended December 31, 2022 and December 31, 2021

The following table summarizes our results of operations for the years ended December 31, 2022 and December 31, 2021 (in thousands):

	For the Year Ended December 31,		
	2022	2021	Change
Operating expenses:			
Research and development	$ 2,778	$ 6,546	$ (3,768)
Acquired in-process research and development	8,210	—	8,210
General and administrative	8,640	8,752	(112)
Total operating expenses	19,628	15,298	4,330
Loss from operations	(19,628)	(15,298)	(4,330)
Interest income	—	14	(14)
Financing expense	(2,191)	—	(2,191)
Change in fair value of warrant liabilities	7,935	—	7,935
Other expense	(83)	—	(83)
Loss before income taxes	(13,967)	(15,284)	1,317
Provision for income taxes	—	—	—
Net loss	$ (13,967)	$ (15,284)	$ 1,317

Research and Development Expenses

Research and development expenses were $2.8 million for the year ended December 31, 2022 as compared to $6.5 million for the year ended December 31, 2021. The $3.8 million decrease was primarily related to reduced clinical trial activity and drug manufacturing costs of approximately $2.7 as we completed our ANA 001 clinical trial and reduced payroll, consulting and overhead costs of approximately $1.1 million.

Acquired In-process Research and Development (IPR&D)

IPR&D for the year ended December 31, 2022 amounted to $8.2 million and was attributable to the acquisition of intellectual property rights under the 2022 License Agreement. Given that no processes or activities constituting a "business" were acquired and since none of the rights underlying the 2022 License Agreement had alternative future uses or had reached a stage of technological feasibility, the acquisition was recorded as IPR&D and was based on the fair value of the 2,200 shares of Series A Preferred Stock issued to Dong-A pursuant to the terms and conditions of the 2022 License Agreement. There was no IPR&D for the year ended December 31, 2021.

General and Administrative Expenses

General and administrative expenses were $8.6 million for the year ended December 31, 2022, compared to approximately $8.7 million for the year ended December 31, 2021. The decrease of $0.1 million was primarily due to decreases in payroll, insurance and overhead of $0.5 million, $0.4 million and $0.1 million, respectively, offset by increases in legal and professional fees of $0.7 million, attributed mostly to the pursuit of business opportunities, and by an increase in stock compensation of $0.2 million.

Interest Income

Interest income for the year ended December 31, 2022 was nominal. Interest income for the year ended December 31, 2021 was $14,000 related to our cash deposits.

Financing Expense

We incurred approximately $2.2 million in financing expense during the year ended December 31, 2022 representing the portion of the transaction costs allocated to the issuance of the Series A Warrants and Series B Warrants described further below. We did not incur financing expense during the year ended December 31, 2021.

Change in fair value of warrant liabilities

The change in fair value of warrant liabilities resulted in a gain of $7.9 million for the year ended December 31, 2022, primarily resulting from the fluctuation of the underlying stock price of our common stock at issuance compared to December 31, 2022.

Other Expense

During year ended December 31, 2022, we recorded approximately $0.1 million of other expense primarily related to the loss on sale of fixed assets and losses on translations of foreign currency. Other expense for the year ended December 31, 2022 was nominal.

Liquidity and Capital Resources

Recent Financing

On September 14, 2022, we entered into the Securities Purchase Agreement with Dong-A. Pursuant to the Securities Purchase Agreement, Dong-A agreed to purchase shares of our Series A Preferred Stock and warrants to purchase shares of our common stock (collectively, the "Dong-A Financing") concurrent to a qualified financing resulting in gross proceeds of at least $15 million exclusive of the Dong-A Financing.

On November 8, 2022, we closed on an underwritten public offering (the "2022 Public Offering") of units with gross proceeds of approximately $17.3 million. The underwritten public offering was comprised of (1) 3,147,003 Class A Units, priced at a public offering price of $3.00 per Class A Unit, with each Class A Unit consisting of one share of common stock, a Series A Warrant (the "Series A Warrants") to purchase one share of common stock for no additional consideration that expires on the one year anniversary following the initial exercise date and a Series B Warrant (the "Series B Warrants") to purchase one share of common stock for no additional consideration that expires on the five year anniversary following the initial exercise date, and (2) 2,602,997 Class B Units, priced at a public offering price of $3.00

per Class B Unit, with each Class B Unit consisting of one share of Series B convertible preferred stock (the "Series B Preferred Stock"), convertible into one share of common stock, one Series A Warrant and one Series B Warrant.

The 2022 Public Offering satisfied the definition of a Qualified Financing as defined by the Securities Purchase Agreement and on November 8, 2022, we closed on the Dong-A Financing, and issued an additional 1,500 shares of Series A Preferred Stock, 5,000,000 Series A Warrants and 5,000,000 Series B Warrants. The Company received gross proceeds in the amount of $15.0 million from Dong-A in connection with the Dong-A Financing.

Net proceeds, of the 2022 Public Offering and Dong-A Financing, after deducting underwriter's fees and related offering expenses were $28.6 million.

On October 1, 2021, we entered into a securities purchase agreement (the "October 2021 Securities Purchase Agreement") with several institutional investors for the purchase and sale in a registered direct offering ("Registered Offering") of 4,307,693 shares of our common stock, at a purchase price of $3.25 per share for gross proceeds of approximately $14.0 million. The October 2021 Securities Purchase Agreement also provides for a concurrent private placement of warrants to purchase our common stock (the "October 2021 Warrants") with the purchasers in the October 2021 Registered Offering. Net proceeds, after deducting placement agent fees and expenses, related offering expenses, was $12.8 million.

On January 18, 2021, we entered into a Securities Purchase Agreement (the "2021 Purchase Agreement") with certain institutional and accredited investors, pursuant to which we, in a private placement (the "2021 Private Placement"), agreed to issue and sell an aggregate of 2,500,000 shares (the "2021 Shares") of our common stock, par value $0.001 per share at a purchase price of $4.00 per share, and warrants to purchase an aggregate of 2,500,000 shares of common stock (the "2021 Warrants"), resulting in total gross proceeds to us in the amount of $10.0 million. Net proceeds, after deducting placement agent fees and relating offering expenses, were $9.1 million.

Cash Flows

The following table summarizes our sources and uses of cash for each of the periods presented:

	For the Year Ended December 31,	
	2022	2021
	(in thousands)	
Net cash used in operating activities	$ (11,712)	$ (15,134)
Net cash provided by (used in) investing activities	8	(586)
Net cash provided by financing activities	28,681	22,026
Net increase in cash	$ 16,977	$ 6,306

Operating Activities

During the year ended December 31, 2022, cash used from operating activities was approximately $11.7 million, consisting of our net loss of approximately $14.0 million, offset by non-cash expenses in the aggregate of $1.2 million and by $2.2 million in financing expense related to financing costs attributed to the issuance of the Series A and Series B Warrants reclassified to *Financing Activities*, and consisting of our working capital cash usage in the amount of approximately $1.1 million. The non-cash expenses related primarily to IPR&D in the amount of $8.2 million from the 2022 License Agreement, and $0.9 million in stock offset by a $7.9 million fair value change in the warrant liabilities. Lastly, the change in working capital consisted primarily of decreases in our accrued liabilities associated with fluctuations of our operating expenses under the normal course of business.

During the year ended December 31, 2021 operating activities used $15.1 million of cash, primarily consisting of our net loss of $15.3 million and a net decrease of accounts payable and accrued expenses of $1.0 million, offset by stock-based compensation and other non-cash charges of $0.7 million and $0.4 from a decrease in prepaid expenses and other current assets.

Investing Activities

Cash provided by investing activities was approximately $8,000 during the year ended December 31, 2022 related to the sale of equipment.

During the year ended December 31, 2021, net cash used in investing activities was $0.6 million. Investing activities during the period consisted mainly of cash paid for transaction costs associated with the 2020 merger with ANA. Purchases of property and equipment in the amount of $3,000 comprised the balance of investing activities during the period.

Financing Activities

During the year ended December 31, 2022, net cash provided by financing activities was $28.7 million, consisting of gross proceeds from the Dong-A Financing and the 2022 Public Offering of $32.3 million, offset by $3.6 million of issuance costs.

During the year ended December 31, 2021, net cash provided by financing activities was $22.0 million, consisting of gross proceeds from our 2021 Private Placement and 2021 Registered Offering of $24.0 million, offset by $2.1 million of issuance costs, and $0.1 million received from the exercise of stock options.

Funding Requirements

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

As of December 31, 2022, we had an accumulated deficit of $95.8 million. Our net losses were $14.0 million and $15.3 million for the years ended December 31, 2022 and 2021, respectively. We expect to continue to incur significant expenses and increasing operating losses for at least the next several years. We expect that our expenses and capital requirements will increase substantially in connection with our ongoing activities, particularly if and as we:

- pursue clinical development for any of our current product candidates;
- initiate preclinical studies and clinical trials with respect to any of our current product candidates and indications and any future product candidates or indications that we may pursue;
- acquire or in-license other product candidates and/or technologies;
- develop, maintain, expand and protect our intellectual property portfolio;
- hire additional clinical, scientific and commercial personnel;
- establish a commercial manufacturing source and secure supply chain capacity sufficient to provide commercial quantities of any product candidates for which we may obtain regulatory approval;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- establish a sales, marketing and distribution infrastructure and/or enter into partnership arrangements to commercialize any products for which we may obtain regulatory approval; or
- add administrative, operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts, and to support our being a public reporting company

As of December 31, 2022, we had cash of $33.4 million. We expect that our cash will be adequate to fund our operations into 2024. We will need to continue to raise additional funds until we are able to commercialize our products which would generate sufficient revenues to fund our operations. Our future operating activities, coupled with our plans to raise capital or issue debt financing, may provide additional liquidity in the future, however these actions are not solely within our control and we are unable to predict the ultimate outcome of these actions to generate the liquidity ultimately required.

Contractual and Other Obligations

Lease Commitments

Boston Leases:

On May 14, 2021, we entered into a non-cancelable operating lease for its corporate headquarters located in Boston Massachusetts. The agreement, effective August 1, 2021, had a six month term, and rental costs of approximately $3,000 per month prior to the application of certain rent concessions granted by the landlord in the amount of approximately $2,000 over the term of the lease. We've since entered into amendments to this lease which reduced the size of our office space and extend the term to expire in March 2023 for rental costs of approximately $1,000-$2,000 per month.

License Agreements

We are party to license agreements with respect to certain of our product candidates that would obligate us to pay royalties with respect to revenue from such product candidates and milestone payments upon achievement of certain development milestones. As of the date hereof, we do not expect to achieve such milestones in the near term, but we would have to obtain additional capital to pay such milestone payments.

Other Obligations

We enter into contracts in the normal course of business with various third parties for clinical trials, preclinical research studies, and testing, manufacturing, and other services and products for operating purposes. These contracts provide for termination upon notice. Payments due upon cancellation generally consist only of payments for services provided or expenses incurred, including non-cancellable obligations of our service providers, up to the date of cancellation. These payments have not been included separately within these contractual and other obligations disclosures.

Critical Accounting Estimates

Our consolidated financial statements are prepared in accordance with U.S. GAAP. The preparation of our consolidated financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, costs, and expenses, and related disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of expenses during the reporting period. On an on-going basis, our management evaluates its estimates, including those related to accounting for clinical trials, income taxes including the valuation allowance for deferred tax assets, accrued expenses, warrant liabilities, contingencies and stock-based compensation. We base our estimates on historical experience, known trends and events, and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgements about the carrying values of assets and liabilities. Actual results could differ from those estimates. Changes in estimates are reflected in reported results in the period in which they become known.

While our significant accounting estimates are described in more detail in Note 2 to our consolidated financial statements included elsewhere in this report, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our consolidated financial statements.

Research and Development Expenses

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

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued research and development expenses. This process involves reviewing open contracts and purchase orders, communicating with applicable personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual costs. Certain of our service providers invoice us in arrears for services performed, on a pre-determined schedule or when contractual milestones are met; however, some service providers require advance payments. We make estimates of our accrued and prepaid expenses as of each balance sheet date in the consolidated financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of these estimates with the service providers and make adjustments, if necessary. Examples of estimated accrued research and development expenses include fees paid to:

- vendors in connection with preclinical development activities;
- CROs and investigative sites in connection with preclinical studies and clinical trials; and
- CMOs in connection with the production of preclinical and clinical trial materials.

We base the expense recorded related to external research and development on our estimates of the services received and efforts expended pursuant to quotes and contracts with multiple CMOs and CROs that supply, conduct and manage preclinical studies and clinical trials on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the expense. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, we adjust the accrual or the amount of prepaid expenses accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too high or too low in any particular period.

Acquired In-Process Research and Development Expenses

We include costs to acquire or in-license product candidates in acquired in-process research and development expenses. These costs are immediately expensed provided that the payments do not also represent processes or activities that would constitute a “business” as defined under GAAP or provided that the product candidate has not achieved regulatory approval for marketing and absent obtaining such approval, has no alternative future use. Royalties owed on future sales of any licensed product will be expensed in the period the related revenues are recognized.

Stock-Based Compensation

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

The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option-pricing model, which uses as inputs the fair value of our common stock and assumptions we make for the volatility of the common stock, the expected term of the stock options, the risk-free interest rate for a period that approximates the expected term of the stock options and the expected dividend yield.

Warrant Liabilities

As part of the Dong-A Financing and the 2022 Public Offering, we issued the Series A Warrants and Series B Warrants. We accounted for the Series A and Series B warrants as liabilities at fair value as certain provisions excluded equity accounting treatment for these instruments. Additionally, issuance costs allocated to the Series A Warrants and Series B Warrants classified as liabilities are expensed as incurred and reflected as financing expense in the accompanying consolidated statements of comprehensive loss.

Recently Issued Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations disclosed in Note 2 to our consolidated financial statements included in Part II, Item 8 *"Consolidated Financial Statements and Supplementary Data"* of this report.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 8. CONSOLIDATED FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

INDEX TO FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

Shareholders and Board of Directors
NeuroBo Pharmaceuticals, Inc.
Boston, Massachusetts

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of NeuroBo Pharmaceuticals, Inc. (the "Company") as of December 31, 2022 and 2021, the related consolidated statements of operations and comprehensive loss, mezzanine equity and stockholders' equity and cash flows for each of the years then ended, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2022 and 2021, and the results of its operations and its cash flows for each of the years then ended**,** in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the consolidated financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Accrual for Research and Development Costs Related to Clinical Trial Activities

As described in Note 3 to the consolidated financial statements, the Company's accrued external research and development expenses balance was $109,000 at December 31, 2022. This accrual includes liabilities for clinical trial activities such as clinical studies and certain manufacturing costs. Clinical studies are primarily managed internally, with the assistance of contract research organizations. The accrual for clinical trial activities is based on an estimate of the percentage of activities completed to date, contractual rates, and amounts invoiced and paid to date.

We identified the determination of the accrual for research and development costs related to clinical trial activities as a critical audit matter. When estimating clinical trial expenses, the Company considers several factors including clinical trial budgets, contract amendments and the progress toward completion. Auditing these elements involves especially challenging auditor judgment due to the nature and extent of audit effort required to address these matters.

The primary procedures we performed to address the critical audit matter included:

- Obtaining an understanding of management's process for estimating the accrual for clinical trial activities.
- For certain contract research organizations, testing the completeness and accuracy of the underlying billing information received from the contract research organizations used in determining the clinical trial accrual.
- For certain clinical trial studies, assessing the Company's estimates of the activities completed to date by (i) inspecting original contract terms, change orders and the expected timeline for the related study, (ii) discussing the status of the clinical trials with certain members of management and project teams and (iii) evaluating the payments made and the invoices received after December 31, 2022 for proper application in the determination of the accrual.
- Testing the completeness of the Company's clinical trial accruals by evaluating i) publicly available information (such as press releases and public databases that track clinical trials) ii) board of directors' materials regarding the status of clinical trials and inquiring of clinical staff to gain an understanding of the status of certain on-going clinical trials.

Accounting for 2022 Private Placement and Public Offering

As discussed in Note 7, the Company entered into two financing transactions during the year that included the issuance of equity securities and warrants.

We identified the accounting for the 2022 Private Placement and Public Offering, including the evaluation for potential embedded derivatives, classification of the preferred stock, and the treatment of the warrants as a critical audit matter. The application of the accounting guidance applicable to the 2022 Private Placement and Public Offering transaction are complex, and therefore, applying such guidance to the contract terms requires significant management judgment. Auditing these elements involved especially complex auditor judgment due to the nature of the terms of the financing transactions and the effort required to address these matters, including the extent of specialized skills and knowledge needed.

The primary procedures we performed to address this critical audit matter included:

- Inspecting the agreements associated with each financing transaction and evaluating the completeness and accuracy of the Company's technical accounting analysis and application of the relevant accounting literature.
- Utilizing personnel with specialized knowledge and skills in technical accounting to assist in assessing management's analysis of the financing transactions, including the evaluation for potential embedded derivatives and classification of the related warrants including: (i) evaluating the contracts to identify relevant terms that affect the recognition in the financial statements, and (ii) assessing the appropriateness of conclusions reached by management.

We have served as the Company's auditor since 2019.

/s/ BDO USA, LLP

Boston, Massachusetts
March 30, 2023

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

	December 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash	$ 33,364	$ 16,387
Prepaid expenses	168	197
Total current assets	33,532	16,584
Right-of-use assets and other	—	105
Property and equipment, net	2	110
Total assets	$ 33,534	$ 16,799
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 708	$ 830
Accrued liabilities	280	1,301
Warrant liabilities	10,796	—
Lease liability, short-term	—	26
Total current liabilities	11,784	2,157
Lease liability, long-term	—	45
Total liabilities	11,784	2,202
Commitments and contingencies (Note 4)		
Stockholders' equity		
Preferred stock, $0.001 par value per share; 10,000,000 shares authorized as of December 31, 2022 and December 31, 2021; no shares issued or outstanding as of December 31, 2022 and December 31, 2021.	—	—
Common stock, $0.001 par value per share, 100,000,000 shares authorized as of December 31, 2022 and December 31, 2021; 25,436,019 and 888,693 shares issued and outstanding as of December 31, 2022 and December 31, 2021, respectively.	25	1
Additional paid–in capital	117,520	96,420
Accumulated other comprehensive income	—	4
Accumulated deficit	(95,795)	(81,828)
Total stockholders' equity	21,750	14,597
Total liabilities and stockholders' equity	$ 33,534	$ 16,799

See accompanying notes.

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

	For the Year Ended December 31,	
	2022	2021
Operating expenses:		
Research and development	$ 2,778	$ 6,546
Acquired in-process research and development	8,210	—
General and administrative	8,640	8,752
Total operating expenses	19,628	15,298
Loss from operations	(19,628)	(15,298)
Other income (expense)		
Interest income	—	14
Financing expense	(2,191)	—
Change in fair value of warrant liabilities	7,935	—
Other expense	(83)	—
Total other income	5,661	14
Loss before income taxes	(13,967)	(15,284)
Provision for income taxes	—	—
Net loss	(13,967)	(15,284)
Other comprehensive loss, net of tax	(4)	(10)
Comprehensive loss	$ (13,971)	$ (15,294)
Loss per share:		
Net loss per share, basic and diluted	$ (5.43)	$ (19.81)
Weighted average shares of common stock outstanding:		
Basic and diluted	2,573,624	771,422

See accompanying notes.

NeuroBo Pharmaceuticals, Inc.
Consolidated Statements of Mezzanine Equity and Stockholders' Equity
(in thousands, except share amounts)

	Series A Preferred Stock		Series B Preferred Stock		Common Stock		Additional Paid–In Capital	Accumulated Comprehensive Income	Accumulated Deficit	Total Equity
	Shares	Amount	Shares	Amount	Shares	Amount				
Balance at January 1, 2021	—	$ —	—	$ —	655,662	$ 1	$ 73,732	$ 14	$ (66,544)	$ 7,203
Issuance of common stock and warrants in connection with public offering	—	—	—	—	226,935	—	24,000	—	—	24,000
Transaction costs in connection with public offering	—	—	—	—	—	—	(2,089)	—	—	(2,089)
Exercise of stock options	—	—	—	—	6,096	—	115	—	—	115
Stock–based compensation	—	—	—	—	—	—	662	—	—	662
Foreign currency translation adjustment	—	—	—	—	—	—	—	(10)	—	(10)
Net loss	—	—	—	—	—	—	—	—	(15,284)	(15,284)
Balance at December 31, 2021	—	—	—	—	888,693	1	96,420	4	(81,828)	14,597
Issuance of Series A Preferred Stock in Private Offering and License Agreement	3,700	10,630	—	—	—	—	—	—	—	—
Issuance of common stock and Series B preferred stock in connection with public offering	—	—	2,602,997	3	3,147,003	3	5,528	—	—	5,534
Transaction costs in connection with private offering and public offering	—	(959)	—	—	—	—	(499)	—	—	(499)
Conversion of Series A preferred stock to common stock	(3,700)	(9,671)	—	—	12,333,333	12	9,659	—	—	9,671
Conversion of Series B preferred stock to common stock	—	—	(2,602,997)	(3)	2,602,997	3	—	—	—	—
Issuance of stock from exercise of warrants	—	—	—	—	6,463,993	6	5,558	—	—	5,564
Stock–based compensation	—	—	—	—	—	—	854	—	—	854
Foreign	—	—	—	—	—	—	—	(4)	—	(4)

currency translation adjustment										
Net loss	—	—	—	—	—	—		—	(13,967)	(13,967)
Balance at December 31, 2022	—	$ —	—	$ —	25,436,019	$ 25	$117,520	$ —	$ (95,795)	$ 21,750

See accompanying notes.

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

	For the Year Ended December 31,	
	2022	**2021**
Operating activities		
Net loss	$ (13,967)	$ (15,284)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	854	662
Non-cash lease expense	8	24
Depreciation	20	48
Loss on sale of property and equipment	75	—
Acquired in-process research and development	8,210	—
Transaction costs allocated to issuance of warrants	2,191	—
Change in fair value of warrant liabilities	(7,935)	—
Change in operating assets and liabilities:		
Prepaid expenses and other assets	64	396
Accounts payable	(202)	(1,162)
Accrued and other liabilities	(1,030)	182
Net cash used in operating activities	(11,712)	(15,134)
Investing activities		
Transaction costs in connection with asset acquisitions	—	(583)
Purchases of property and equipment	—	(3)
Sale of property and equipment	8	—
Net cash provided by (used in) investing activities	8	(586)
Financing activities		
Proceeds from issuance of common shares, preferred shares and warrants	32,250	24,000
Payment of issuance costs	(3,569)	(2,089)
Exercise of stock options	—	115
Net cash provided by financing activities	28,681	22,026
Net increase in cash	16,977	6,306
Net foreign exchange difference	—	(8)
Cash at beginning of period	16,387	10,089
Cash at end of period	$ 33,364	$ 16,387
Supplemental non-cash investing and financing transactions:		
Modification of right-of-use asset and associated lease liability	$ 62	$ —
Unpaid issuance costs	$ 80	$ —
Reclass of warrant liabilities upon exercise of warrants	$ 5,564	$ —

See accompanying notes.

NeuroBo Pharmaceuticals, Inc.
Notes to Consolidated Financial Statements
(Dollar Amounts in Thousands, Except Per Share Amounts)

1. The Company and Basis of Presentation

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

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

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

The Company had previously focused its efforts on four therapeutic programs: ANA001, NB-01, NB-02 and gemcabene.

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

Basis of presentation and consolidation principles

The accompanying financial statements were prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP")

The consolidated financial statements of the Company include a South Korean subsidiary, NeuroBo Co., Ltd., which is fully owned by the Company. All significant intercompany accounts and transactions have been eliminated in the preparation of the financial statements.

Reverse Stock Split

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

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

Liquidity

From its inception through December 31, 2022, the Company has devoted substantially all of its efforts to drug discovery and development and conducting clinical trials. The Company has a limited operating history and the sales and income potential of the Company's business and market are unproven. Successful transition to attaining profitable operations is dependent upon achieving a level of revenues adequate to support the Company's cost structure. The Company has experienced net losses and negative cash flows from operating activities since its inception and had an accumulated deficit of $95.8 million as of December 31, 2022. These conditions previously raised substantial doubt about the Company's ability to continue as a going concern.

To date, the Company has raised capital principally through private placements and public offerings of convertible preferred stock, common stock and warrants The Company will need to continue to raise a substantial amount of funds until it is able to generate revenues to fund its development activities.

As of December 31, 2022, the Company had $33.4 million in cash. The Company believes that its existing cash will be sufficient to fund its operations for at least the next 12 months from the date these financial statements are issued. The Company will need to continue to raise additional funds until it is able to generate sufficient revenues to fund its development activities. The Company’s future operating activities, coupled with its plans to raise capital or issue debt financing, may provide additional liquidity in the future, however these actions are not solely within the control of the Company and the Company is unable to predict the ultimate outcome of these actions to generate the liquidity ultimately required.

2. Summary of Significant Accounting Policies

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, expenses, and related disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of expenses during the reporting period. The most significant estimates in the Company's consolidated financial statements relate to accrued expenses and the fair value of stock-based compensation and warrant issuances. The Company bases its estimates on historical experience and on various other assumptions that are believed to be reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results could differ from those estimates. Changes in estimates are reflected in reported results in the period in which they become known.

Concentrations

Credit Risk

Financial instruments that potentially subject the Company to a concentration of credit risk consist of cash. The Company’s cash is principally held by one financial institution in the United States. Amounts on deposit may at times exceed federally insured limits. Management believes that the financial institution is financially sound, and accordingly, minimal credit risk exists with respect to the financial institution. As of December 31, 2022, the Company had deposits in excess of federally insured amounts by $32.9 million.

Supplier Risk

On September 14, 2022, the Company entered into an exclusive license agreement (the “2022 License Agreement”) with Dong-A ST Co., Ltd. (“Dong-A”), which requires Dong-A to be the sole manufacturer for the production of DA-1241 and DA-1726. If any issues arise in the manufacturing and the Company is unable to arrange for alternative third-party manufacturing sources, or unable to find an alternative third party capable of reproducing the existing manufacturing method or unable to do so on commercially reasonable terms or in a timely manner, the Company may not be able to complete development of DA-1241 or DA-1726.

Fair Value of Financial Instruments

The Company's financial instruments principally include cash, prepaid expenses, right of use assets, accounts payable, accrued liabilities, lease liabilities and warrant liabilities. The carrying amounts of cash, prepaid expenses and other current assets, accounts payable, and accrued liabilities are reasonable estimates of their fair value because of the short maturity of these items. See Note 10 - *Fair Value Measurements*.

Warrant Liabilities

The Company accounts for its warrants as liabilities at fair value if equity accounting treatment is precluded due to provisions existing within the warrant agreements. The change in fair value of the warrant liabilities are recognized as a fair value change in warrant liabilities in the consolidated statements of operations and comprehensive loss and as an operating item in the statement of cash flows. Additionally, issuance costs associated with warrants initially classified as liabilities are expensed as incurred and reflected as financing costs in the accompanying consolidated statements of operations and comprehensive loss.

General and Administrative Expenses

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

Research and Development Costs

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

Acquired In-Process Research and Development

The Company includes costs to acquire or in-license product candidates in acquired in-process research and development expenses ("IPR&D"). When the Company acquires the right to develop and commercialize a new product candidate, any up-front payments, or any future milestone payments that relate to the acquisition or licensing of such a right are immediately expensed as acquired in-process research and development in the period in which they are incurred. These costs are immediately expensed provided that the payments do not also represent processes or activities that would constitute a "business" as defined under GAAP, or provided that the product candidate has not achieved regulatory approval for marketing and absent obtaining such approval, has no alternative future use. Royalties owed on future sales of any licensed product will be expensed in the period the related revenues are recognized.

Income Taxes

The Company utilizes the liability method of accounting for income taxes as required by ASC 740, *Income Taxes*. Under this method, deferred tax assets and liabilities are determined based on differences between financial reporting and the tax basis of assets and liabilities and are measured using enacted tax rates and laws that will be in effect when the differences are expected to reverse. Currently, there is no provision for income taxes, as the Company has incurred operating losses to date, and a full valuation allowance has been provided on the net deferred tax assets.

Stock-Based Compensation

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

Leases

The Company accounts for leases under Accounting Standards Update ("ASU") No. 2016-02, *Leases* (Topic 842) ("ASU 2016-02"). The Company assesses its contracts at inception to determine whether the contract contains a lease, including evaluation of whether the contract conveys the right to control an explicitly or implicitly identified asset for a period of time. The Company has recognized right-of-use assets and lease liabilities that represent the net present value of future operating lease payments utilizing a discount rate corresponding to the Company's incremental borrowing rate and amortized over the remaining terms of the leases. For operating leases of a short-term nature, i.e., those with a term of less than twelve months, the Company recognizes lease payments as an expense on a straight-line basis over the remaining lease term.

Property and Equipment

Property and equipment is recorded at cost and reduced by accumulated depreciation. Depreciation expense is recognized over the estimated useful lives of the assets using the straight-line method. The estimated useful life for property and equipment ranges from three to five years. Tangible assets acquired for research and development activities and that have an alternative use are capitalized over the useful life of the acquired asset. Estimated useful lives are periodically reviewed, and when appropriate, changes are made prospectively. When certain events or changes in operating conditions occur, asset lives may be adjusted and an impairment assessment may be performed on the recoverability of the carrying amounts. Maintenance and repairs are charged directly to expense as incurred.

Foreign Currency Translation

The foreign subsidiary uses the South Korean Won (KRW) as its functional currency. The Company translates the assets and liabilities of its foreign operation into U.S. dollars based on the rates of exchange in effect as of the transaction date. The resulting adjustments from the translation process are included in accumulated other comprehensive (loss) income in the accompanying consolidated balance sheets.

Certain transactions of the Company are settled in foreign currency and are thus translated to U.S. dollars at the rate of exchange in effect at the end of each month. Gains and losses resulting from the translation are included in other income or expense in the accompanying consolidated statements of operations and comprehensive loss.

Patent Costs

Costs related to filing and pursuing patent applications are expensed as incurred, as recoverability of such expenditures is uncertain. These costs are included in general and administrative expenses.

Comprehensive Loss

Comprehensive loss is comprised of net loss and other comprehensive income or loss. Comprehensive loss includes net loss as well as other changes in stockholders' equity that result from transactions and economic events other than those with stockholders. Comprehensive loss currently consists of net loss and changes in foreign currency translation adjustments.

(Dollar Amounts in Thousands, Except Per Share Amounts)

Segment Information

Operating segments are components of an enterprise for which separate financial information is available and is evaluated regularly by the Company's chief operating decision maker in deciding how to allocate resources and assessing performance. The Company's chief operating decision maker is its Chief Executive Officer. The Company's Chief Executive Officer views the Company's operations and manages its business in one operating segment, which is principally the business of development and commercialization of therapeutics.

Recent Accounting Pronouncements Adopted

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

In June 2016, the FASB issued ASU 2016-13, *"Financial Instruments – Credit Losses"*. The ASU sets forth a "current expected credit loss" (CECL) model which requires the Company to measure all expected credit losses for financial instruments held at the reporting date based on historical experience, current conditions, and reasonable supportable forecasts. This replaces the existing incurred loss model and is applicable to the measurement of credit losses on financial assets measured at amortized cost and applies to some off-balance sheet credit exposures. This ASU is effective for calendar year 2023 for smaller reporting companies. The Company adopted this new guidance on January 1, 2023, and the adoption did not have a material impact on the Company's consolidated financial statements.

3. Balance Sheet Detail

Property and Equipment

Property and equipment consist of the following:

	December 31 2022	December 31, 2021
Research and development equipment	$ -	$ 158
Office equipment	30	63
Total property and equipment	30	221
Less accumulated depreciation	(28)	(111)
Property and equipment, net	$ 2	$ 110

Accrued liabilities

Accrued liabilities consist of the following:

	December 31, 2022	December 31, 2021
External research and development expenses	$ 109	$ 854
Payroll related	100	376
Professional services	23	59
Other	48	12
Total	$ 280	$ 1,301

4. Commitments and Contingencies

Operating Leases

Boston Leases

Effective August 1, 2021, the Company entered into a non-cancelable operating lease for its corporate headquarters located in Boston Massachusetts. This agreement had a six month term, and rental costs of approximately $3 per month prior to the application of certain rent concessions granted by the landlord in the amount of approximately $2 over the term of the lease. In December 2021, the Company signed an amendment to its corporate headquarters lease to extend the term until March 31, 2022 for rental costs of approximately $1 per month. In February 2022, April 2022, August, 2022 and December, 2022 the Company signed amendments to extend the lease term until June 30, 2022, September 30, 2022, December 31, 2022 and March 31, 2023, respectively.

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

No assets and liabilities were recognized for the corporate headquarters leases at December 31, 2022 and 2021. Due to the short-term nature of the leases, the Company recognized lease payments as an expense on a straight-line basis over the remaining lease term. For the years ended December 31, 2022 and 2021, expense under the corporate headquarters leases in the aggregate was $16 and $48, respectively.

Lease in Korea:

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

The operating lease was subject to a deposit, base rent payments and additional charges for utilities and other common costs. For the years ended December 31, 2022 and 2021, the Company recorded non-cash expense of $8 and $24, respectively, related to the Korea Lease. During the year ended December 31, 2022 and 2021, the Company made cash payments of $11 and $32, for amounts included in the measurement of lease liabilities.

License Agreement with Dong-A ST

On September 14, 2022, the Company and Dong-A, a related party, and greater than 5% shareholder, entered into the 2022 License Agreement, pursuant to which, subject to the conditions set forth therein, the Company ultimately received an exclusive global license (other than in the Republic of Korea) to two proprietary compounds for specified indications. The 2022 License Agreement covers the rights to DA-1241 for treatment of NASH and DA-1726 for treatment of obesity and NASH. Under the 2022 License Agreement, Dong-A will be eligible to receive (i) 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; (ii) commercial-based milestone payments, dependent upon the achievement of specific commercial developments; and (iii) single digit royalties on net sales received by the Company from the commercial sale of products covering DA-1241 or DA-1726. See Note 5, *2022 License Agreement.*

As of December 31, 2022, no milestone or royalty payments had been accrued as there were no potential milestones yet considered probable.

Gemphire Contingent Value Rights Agreement

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

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

As of the December 31, 2022 and 2021, no milestones had been accrued as there were no potential payments under the CVR Agreement or the CVR Amendment that were yet considered probable.

Pfizer License Agreement

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

The Company agreed to make milestone payments totaling up to $37 million upon the achievement of certain milestones, including the first new drug application (or its foreign equivalent) in any country, regulatory approval in each of the United States, Europe and Japan, the first anniversary of the first regulatory approval in any country, and upon achieving certain aggregate sales levels of Gemcabene. Future milestone payments under the Pfizer Agreement, if any, are not expected to begin for at least several years and extend over a number of subsequent years.

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

The Pfizer Agreement will expire upon expiration of the Royalty Term. On expiration (but not earlier termination), the Company will have a perpetual, exclusive, fully paid-up, royalty-free license under the licensed patent rights and related data to make, use, develop, commercialize, import and otherwise exploit the clinical product candidate Gemcabene. Either party may terminate the Pfizer Agreement for the other party's material breach following a cure period or immediately upon certain insolvency events relating to the other party. Pfizer may immediately terminate the Pfizer Agreement in the event that (i) the Company or any of its affiliates or sublicenses contests or challenges, or supports or assists any third party to contest or challenge, Pfizer's ownership of or rights in, or the validity, enforceability or scope of any of the patents licensed under the Pfizer Agreement or (ii) the Company or any of its affiliates or sublicensees fails to achieve the first commercial sale in at least one country by April 16, 2024.

Furthermore, upon termination of the Pfizer Agreement by Pfizer for any of the foregoing reasons, the Company grants Pfizer a non-exclusive, fully paid-up, royalty free, worldwide, transferrable, perpetual and irrevocable license to use any

(Dollar Amounts in Thousands, Except Per Share Amounts)

intellectual property rights arising from the development or commercialization of Gemcabene by the Company and any trademarks identifying Gemcabene and agrees to transfer regulatory filings and approvals to Pfizer or permit Pfizer to cross-reference and rely on such regulatory filings and approvals for Gemcabene. The Company may terminate the Pfizer Agreement for convenience upon 90 days' written notice and payment of an early termination fee of $3.0 million.

As of December 31, 2022 and 2021, there was sufficient uncertainty with regard to both the outcome of the clinical trials and the ability to obtain sufficient funding to support any of the cash milestone payments under the license agreement, and as such, no liabilities were recorded related to the Pfizer Agreement.

ANA Merger Milestone Payments

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

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

Sales Milestones:

Milestone Event – Worldwide Cumulative Net Sales of a Niclosamide Product equal to or greater than:		**Milestone Payment**
$500 million	$	9.0 million
$1 billion	$	13.5 million
$3 billion	$	36.0 million
$5 billion	$	72.0 million

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

As of the December 31, 2022 and 2021, no Royalty Payments had been accrued as there were no potential milestones yet considered probable.

YourChoice License Agreement

In connection with the 2020 Merger, the Company assumed the license agreement between ANA and Your Choice Therapeutics, Inc. (the "YourChoice Agreement"). Prior to the 2020 Merger, YourChoice Therapeutics, Inc. granted to ANA, during the term of the YourChoice Agreement, an exclusive, worldwide, fee-bearing license derived from the licensed intellectual property throughout the world. The fees due under the YourChoice Agreement include royalty payments of 0.5% of annual worldwide net sales of each Niclosamide Product (as defined in the 2020 Merger Agreement) and milestone payments in the aggregate of $19.5 million. The first milestone payment due is $5 million upon first receipt of Marketing Approval (as defined in the 2020 Merger Agreement) for the FDA for any Nicolsamide Product (as defined by the 2020 Merger Agreement), followed by sales milestones of $1 million, $1.5 million, $4 million, and $8 million if worldwide cumulative net sales of a Nicolsamide Product are equal or greater than $500 million, $1 billion, $3 billion, and $5 billion, respectively. The term of the YourChoice Agreement will expire on the

expiration or invalidation of the last of the licensed patents under the YourChoice Agreement. As of December 31 2022 and 2021, there was sufficient uncertainty with regard to both the outcome of the clinical trials and the ability to obtain sufficient funding to support any of the cash milestone payments under the YourChoice Agreement, and as such, no liabilities were recorded related to the YourChoice Agreement.

Contingencies

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

5. Dong-A License Agreement

On September 14, 2022, the Company and Dong-A entered into the 2022 License Agreement, pursuant to which, the Company received an exclusive global license (except for the territory of the Republic of Korea and certain other jurisdictions) to two proprietary compounds for specified indications upon meeting certain financing milestones. The 2022 License Agreement covers the rights to DA-1241 for treatment of NASH and DA-1726 for treatment of obesity and NASH. The 2022 License Agreement also provides that the Company may develop DA-1241 for the treatment of T2D. Under the terms of the 2022 License Agreement, (i), the Company agreed to pay Dong-A an upfront payment to be settled with 2,200 shares of a new series of preferred stock designated as “Series A Convertible Preferred Stock”, par value $0.001 per share (the “Series A Preferred Stock**”**), upon completion of a financing (see Note 7 – Stockholder’s Equity). The Series A Preferred Stock issued in connection with the 2022 License Agreement was recorded as IPR&D expense in the amount of $8.2 million based on the fair market value of the Series A Preferred Stock. The 2022 License Agreement did not include any processes or activities constituting a “business” were acquired and since none of the rights underlying the Dong-A License Agreement had alternative future uses or had reached a stage of technological feasibility.

The term of the 2022 License Agreement continues on a product-by-product and country-by country basis until the later of (i) the fifth anniversary of the first commercial sale of such product in such country, (ii) the expiration or termination of the last valid patent claim that covers a product in such country and (iii) the loss of regulatory exclusivity for such product in such jurisdiction. Either Dong-A or the Company may terminate the 2022 License Agreement (i) if the other party is in material breach of the agreement and has not cured or started to cure the breach within 60 days of notice of such breach; provided that if the breach cannot be cured within the 60-day period and the breaching party started to remedy the breach, if such breach is not cured within 90 days of receipt of written notice, (ii) if the other party is subject to a bankruptcy or insolvency event (subject to a 30-day cure period in the case of a petition for bankruptcy), or (iii) in the event the Company had failed to complete the public offering as further described in Note 7 -Stockholders’ Equity by December 31, 2022 (or January 31, 2023 under specified circumstances set forth in the 2022 License Agreement).

None of the milestone or royalty payments under the 2022 License Agreement were triggered as of December 31, 2022.

Shared Services Agreement

On September 14, 2022, in conjunction with the Dong-A License Agreement, the Company entered into a shared services agreement with Dong-A (the “Shared Services Agreement”). The Shared Services Agreement provides that Dong-A may provide technical support, pre-clinical development, and clinical trial support services on terms and conditions acceptable to both parties. In addition, the Shared Services Agreement provides that Dong-A will manufacture all of the Company’s clinical requirements of DA-1241 and DA-1726.

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 the Company which is not cured within 30 days.

As of December 31, 2022, the Company did not incur any research and development expenses under the Shared Services Agreement.

6. Beijing SL License Agreement

Beijing SL License and Collaboration Agreement

Upon the close of the 2019 Merger, the License and Collaboration Agreement (the "Beijing SL Agreement") with Beijing SL Pharmaceutical Co., Ltd. ("Beijing SL")(the "Beijing SL Agreement") was assumed by the Company, pursuant to which the Company granted Beijing SL an exclusive royalty-bearing license to research, develop, manufacture and commercialize pharmaceutical products comprising, as an active ingredient, Gemcabene in mainland China, Hong Kong, Macau and Taiwan (each, a "region", and collectively, the "Territory"). The terms of the Beijing SL Agreement include payments based upon achievement of milestones and royalties on net product sales. Under the Beijing SL Agreement, the Company has variable consideration in the form of milestone payments. As of December 31, 2022, no revenue under the Beijing SL Agreement has been recognized.

Under the terms of the Beijing SL Agreement, Beijing SL will be responsible, at its expense, for developing and commercializing products containing Gemcabene (each, a "Licensed Product") in the Territory, with certain assistance from the Company. To the extent mutually agreed to in writing, the Company and Beijing SL will collaborate on the Phase 3 clinical trial for homozygous familial hypercholesterolemia or other clinical trials with the Company as the sponsor designed to enroll patients both inside and outside the Territory (a "Global Study"), but Beijing SL will be responsible, at its expense, for the conduct of any Global Study to the extent solely in the Territory, subject to the Company's final decision making authority, and the Company will be responsible, at its expense, for the conduct of any Global Study to the extent solely outside of the Territory. Under a territory development plan, the parties shall develop Licensed Products with respect to the Territory. Beijing SL will be responsible for development activities, including non-clinical and clinical studies directed at obtaining regulatory approval of the Licensed Product in the Territory. Beijing SL has agreed to use commercially reasonable efforts to commercialize the Licensed Products for each indication that receives regulatory approval in the Territory and shall prepare and present a commercialization plan that shall be subject to approval by the joint steering committee.

Pursuant to the Beijing SL Agreement, Beijing SL was to make a non-refundable upfront gross payment of $2.5 million to the Company within 45 days of the effective date of the Beijing SL Agreement; the upfront payment was received in October 2019 and such funds were fully expended prior to the close of 2019 Merger. Additionally, with respect to each Licensed Product, the Company is eligible to receive (i) payments for specified developmental and regulatory milestones (including submission of a new drug application to China's National Medical Product Administration, dosing of the first patient in a phase 3 clinical trial in mainland China and regulatory approval for the first and each additional indication of a Licensed Product in the Territory) totaling up to $6 million in the aggregate and (ii) payments for specified global net sales milestones of up to $20 million in the aggregate multiplied by the ratio of the net sales of a Licensed Product sold by Beijing SL in the Territory divided by the global net sales of a Licensed Product, which net sales milestone payments are payable once, upon the first achievement of such milestone.

Beijing SL is also obligated to pay the Company tiered royalties ranging from the mid-teens to twenty percent on the net sales of all Licensed Products in the Territory until the latest of (a) the date on which any applicable regulatory exclusivity with respect to such Licensed Product expires in such region, (b) the expiration or abandonment of the last valid patent claim or joint patent claim covering such Licensed Product in each region and (c) the fifth anniversary of the first commercial sale of such Licensed Product in such region (the "Royalty Term"). Future milestone payments under the Beijing SL Agreement, if any, are not expected to begin for at least one year and will extend over a number of subsequent years. The Company cannot determine the date on which Beijing SL's potential royalty payment obligations to the Company would expire because Beijing SL has not yet developed any Licensed Products under the Beijing SL Agreement and therefore the Company cannot at this time identify the date of the first commercial sale or the periods of any regulatory exclusivity or patent claims with respect to any Licensed Product.

On a Licensed Product-by-Licensed Product and region-by-region basis upon the expiration of the Royalty Term, the license granted to Beijing SL shall be deemed perpetual, fully paid-up and royalty free with respect to such Licensed Product in such region. Either party may terminate the Agreement (x) with written notice in the event of the other party's material breach following a cure period or (y) if the other party becomes subject to certain insolvency proceedings. In

addition, the Company may terminate the agreement in its entirety if Beijing SL or its affiliates or sublicensees commence a proceeding challenging the validity, enforceability or scope of any of the Company's patents.

To the extent rights granted to Beijing SL under the Beijing SL Agreement are controlled by the Company pursuant to the Pfizer Agreement, such rights are subject to the terms and conditions of such agreement with Pfizer, and Beijing SL has agreed to comply with such terms and conditions.

The Beijing SL Agreement contemplates that Beijing SL and the Company shall, no later than twelve months prior to the anticipated date of the first commercial sale of a Licensed Product, if any, negotiate in good faith and execute a commercial supply agreement, pursuant to which Beijing SL shall purchase from the Company, and the Company shall use commercially reasonable efforts to supply, Gemcabene or Licensed Product for clinical or commercial purposes, as applicable, until manufacturing and regulatory transfers are complete.

Each of the Company and Beijing SL has agreed to indemnify the other party against certain losses and expenses relating to the development or commercialization of a Licensed Product by the indemnifying party, the negligence or willful misconduct of the indemnifying party or its directors, officers, employees or agents or a breach of the indemnifying party's representations, warranties or covenants.

7. Stockholders' Equity

Common Stock

The voting, dividend, and liquidation rights of the holders of the common stock are subject to and qualified by the rights, powers, and preferences of the holders of the preferred stock when outstanding. The holders of the common stock are entitled to one vote for each share of common stock held at all meetings of stockholders. Common stockholders are entitled to receive dividends at the sole discretion of the board of directors of the Company. There have been no dividends declared on common stock to date as of December 31, 2022. In the event of any liquidation, dissolution, or winding-up of the Company, the holders of common stock shall be entitled to share in the remaining assets of the Company available for distribution post preferential distributions made to holders of the Company's preferred stock.

Preferred Stock

The rights of the Series A Preferred Stock and Series B Preferred Stock (as defined further below), collectively, the "Preferred Stock", while outstanding were as follows:

Dividends. Holders of the Preferred Stock were entitled to receive dividends on shares of the Preferred Stock equal (on an as-if-converted-to common-stock basis) to the amount paid on shares of the common stock.

Voting Rights. **T**he Preferred Stock had no voting rights. However, as long as any shares of Preferred Stock were outstanding, the Company could not, without the affirmative vote of the holders of a majority of the then outstanding shares of the Preferred Stock, (a) alter or change adversely the powers, preferences or rights given to the Preferred Stock or amend its Certificate of Designation, (b) amend other charter documents in any manner that could have adversely affected any rights of the holders, (c) increase the number of authorized shares of Preferred Stock, or (d) enter into any agreement with respect to any of the foregoing. In addition, the Series A Preferred Stock could have voted on any matter that authorized, created and/or issued any funded indebtedness (other than indebtedness already incurred); sold or transferred, other than in the ordinary course of its business, mortgaged, assigned, pledged, leased, granted a security interest in, or encumbered any of the Company's assets.

Liquidation. The Preferred Stock while outstanding in the event of a liquidation, dissolution or winding-up of the Company, collectively a "Liquidation", had the following rights:

> *Series A Preferred Stock***:** Upon any Liquidation of the Company, whether voluntary or involuntary**,** after the satisfaction in full of the debts of the Company and the payment of any liquidation preference owed to the holders of shares of capital stock of the Company ranking senior to the Series A Preferred Stock upon liquidation, but before any distribution or payment out of the assets of the Company shall be made to the holders of any junior

securities, including common stock, an amount in cash per share equal to the amount per share in cash payable to the holder if the shares of Series A Preferred Stock were converted immediately prior to the Liquidation into shares of common stock.

Series B Preferred Stock: Upon any Liquidation of the Company, whether voluntary or involuntary, the holders shall be entitled to receive out of the assets, whether capital or surplus, of the Company the same amount that a holder of common stock would receive if the Series B Preferred Stock were fully converted (disregarding for such purposes any conversion limitations hereunder) to common stock which amounts shall be paid pari passu with all holders of common stock.

Conversion.

Series A Preferred Stock:

- Automatic Conversion. On the first Trading Day after the Company obtains the stockholder approval, all outstanding shares of the Series A Preferred Stock would, without any further action by holders and whether or not any certificates representing such shares are surrendered to the Company or the Transfer Agent, automatically be converted into such number of shares of common stock as determined by dividing the stated value of $10,000 per share by the conversion price then in effect (the “Automatic Conversion”). The conversion price upon an Automatic Conversion for the Series A Preferred Stock was equal to $3.00 per share.

- Special Cash Payout Provisions: Unless and until stockholder approval was obtained, the holder did not have the right to acquire shares of common stock issuable upon conversion of the Series A Preferred Stock, and the Company was not required to issue shares of common stock issuable upon conversion of the Series A Preferred Stock in excess of the Share Cap as defined (the "Conversion Restriction"). Notwithstanding the foregoing, if the Automatic Conversion had not occurred by the nine (9)-month anniversary of the original issuance date, the holder would have been entitled to submit a request to the Company for the conversion of all, but not less than all, of holder's shares of Series A Preferred Stock that were subject to the Conversion Restriction that would have exceeded the Share Cap; provided, that, in lieu of the Conversion Shares that would have otherwise been deliverable upon conversion but for the Conversion Restriction, the Company would have instead delivered to such holder for each share of common stock that would have been so otherwise delivered an amount of cash equal to the volume weighted average price (“VWAP”) per share of common stock on the trading day immediately preceding the date such request is made. If the Company failed to make any required cash payment by the required deadline on any share of Series A Preferred Stock, then the holder thereof would have been entitled to receive cumulative cash dividends on each such share at a rate per annum of 5.00% on the stated value ("Default Cash Dividends"). Default Cash Dividends, if any, would have accumulated on a daily basis.

Series B Preferred Stock

- Conversions at Option of Holder. Each share of Series B Preferred Stock was convertible, at any time at the option of the holder thereof, into that number of shares of common stock (subject to certain limitations) determined by dividing the stated value of $3.00 per share by the conversion price in effect. The conversion price for the Series B Preferred Stock was equal $3.00 per share.

Fundamental Transaction. If, at any time while shares of the Preferred Stock were outstanding, the Company, directly or indirectly, in one or more related transactions effected any merger or consolidation of the Company, the holder of the Preferred Stock would have had the right to receive, for each conversion share that would have been issuable upon such conversion immediately prior to the occurrence of such Fundamental Transaction as defined, the number of shares of common stock of the successor or acquiring Company or of the Company, if it is the surviving Company, and any additional consideration (the "Alternate Consideration") receivable as a result of such Fundamental Transaction by a holder of the number of shares of the common stock for which shares of the Preferred Stock would have been

convertible immediately prior to such Fundamental Transaction. If holders of the common stock were given any choice as to the securities, cash or property to be received in a Fundamental Transaction, then the holder of the Preferred Stock would have been given the same choice as to the Alternate Consideration it would have received upon any conversion of shares of the Preferred Stock following such Fundamental Transaction.

2022 Private Placement and Public Offering

On September 14, 2022, the Company entered into a Securities Purchase Agreement with Dong-A (the "Dong-A Securities Purchase Agreement"). Pursuant to the Dong-A Securities Purchase Agreement, Dong-A agreed to purchase from the Company shares of its Series A Preferred Stock and warrants to purchase shares of its common stock, equivalent to those to be issued in the Qualified Financing (as hereafter defined), (collectively, the "Dong-A Financing") concurrent with and contingent upon a qualified financing resulting in gross proceeds of at least $15 million exclusive of the Dong-A Financing (the "Qualified Financing").

On November 8, 2022, the Company closed on an underwritten public offering (the "2022 Public Offering") of units with gross proceeds of approximately $17.3 million. The underwritten public offering was comprised of (1) 3,147,003 Class A Units, priced at a public offering price of $3.00 per Class A Unit, with each Class A Unit consisting of one share of common stock, a Series A Warrant (the "Series A Warrants") to purchase one share of common stock for a purchase price of $3.00 per share that expires on the one year anniversary following the initial exercise date and a Series B Warrant (the "Series B Warrants") to purchase one share of common stock, for a purchase price of $3.00 per share that expires on the five year anniversary following the initial exercise date, and (2) 2,602,997 Class B Units, priced at a public offering price of $3.00 per Class B Unit, with each Class B Unit consisting of one share of Series B convertible preferred stock (the "Series B Preferred Stock"), convertible into one share of common stock, one Series A Warrant and one Series B Warrant. The Series A Warrants and the Series B Warrants, (collectively, the " Public Warrants") were to only be exercisable upon stockholder approval, and each Warrant was to be exchangeable for one share of common stock for no additional consideration.

The 2022 Public Offering met the definition of a Qualified Financing as defined by the Dong-A Securities Purchase Agreement; therefore, on November 8, 2022, the license under the Dong-A License Agreement became effective, and the Company issued to Dong-A 2,200 shares of Series A Preferred Stock. In addition, the Company closed on the Dong-A Financing, and issued an additional 1,500 shares of Series A Preferred Stock, 5,000,000 warrants substantially similar to the Series A Warrants and 5,000,000 warrants substantially similar to the Series B Warrants (the "Dong-A Warrants"). The Company received gross proceeds in the amount of $15.0 million in connection with the Dong-A Financing.

The Series A Preferred Stock was initially classified outside of stockholders' equity due to a contingent redemption feature if stockholder approval of the Series A Preferred Stock had not been secured within nine months from the date of issuance. Stockholder approval was secured on December 22, 2022, at which time, all of the Series A Preferred Stock was automatically converted into 12,333,333 shares of common stock.

The Series B Convertible Preferred Stock was classified in permanent equity upon issuance as there were no other provisions precluding equity treatment. As of December 31, 2022, all of the 2,602,997 shares of the Series B Preferred Stock had been converted into 2,602,997 shares of common stock.

The public Warrants and the Dong-A Warrants (together, the "2022 Warrants"), upon their issuance were not exercisable unless and until stockholder approval was granted as required under Nasdaq rules. The Company accounts for these warrants as a liability at fair value as certain provisions precluded equity accounting treatment for these instruments.

As the 2022 License Agreement and Dong-A Financing were both contingent and based on the terms of a Qualified Financing, the Company combined these two transactions along with the 2022 Public Offering (collectively, the "2022

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Transaction") when allocating gross consideration and issuance costs. The table below lists the aggregate consideration received by the Company in the 2022 Transaction:

	Consideration received	Classification
Dong-A License Agreement	$ 8,210	Acquired in-process research and development
Dong-A Financing	15,000	Cash
2022 Public Offering	17,250	Cash
Total	$ 40,460	

The consideration received was first allocated to the 2022 Warrants at their fair value on the date of issuance. The remainder of the consideration from the 2022 Transaction was allocated to the Series A Preferred Stock and Series B Preferred Stock (collectively the "Preferred Stock"), and to the common stock based on their relative fair values on the date of issuance. Issuance costs in connection with 2022 Transaction in the amount of $3.6 million were allocated to each instrument based on the amount of consideration allocated to each instrument. Issuance costs attributed to the Warrants in the amount of $2.2 million were recorded as financing expense in the accompanying consolidated statements of operations and comprehensive loss. The remainder of the issuance costs were recorded in additional paid-in capital.

The fair value of the Series A Preferred Stock was probability weighted for stockholder approval to convert to common stock. In the approval scenario, the fair value was calculated using the underlying stock price multiplied by the number of common shares to be issued on conversion as adjusted for a 90% probability factor, a volatility rate of 101%, a discount for a lack of marketability of 11%, a risk free rate of 3.7% and a remaining term of 0.1 years. In the non-approval scenario, the fair value was calculated using the underlying share price as adjusted for a 10% probability factor, a volatility rate of 107%, a risk free rate of 4.6% and a remaining term of 0.8 years. A credit risk factor was also used to discount the future value of the Series A Preferred Stock as applicable. The concluded fair value of the Series A Preferred Stock upon issuance was approximately $3,732 per share.

The fair value of the Series B Preferred Stock was equal to the underlying common stock fair value as the shares were readily convertible at the time of issuance on a one-for-one basis.

The fair value of the 2022 Warrants was determined using a Monte Carlo simulation. However, due to the cashless exercise provision of the 2022 Warrants rendering the exercise price effectively at zero, the calculated price per share of the Warrants was equal to that of a share of common stock prior to taking into account the probability factor of stockholder approval factor at 90%. The concluded fair value of the 2022 Warrants was $24.3 million in the aggregate on their issuance date.

October 2021 Registered Direct Offering

On October 1, 2021, the Company entered into a Securities Purchase Agreement (the "October 2021 Securities Purchase Agreement") with several institutional investors for the purchase and sale in a registered direct offering of 4,307,693 shares of the Company's common stock, at a purchase price of $3.25 per share for gross proceeds of approximately $14.0 million (the "October 2021 Registered Offering").

The October 2021 Securities Purchase Agreement also provides for a concurrent private placement of warrants to purchase the Company's common stock (the "October 2021 Warrants") with the purchasers in the October 2021 Registered Offering. The October 2021 Warrants will be exercisable for up to an aggregate of 4,307,693 shares of common stock. The October 2021 Warrants will have an exercise price of $3.75 per share, will be exercisable commencing six months from the issuance date (the "Initial Exercise Date"), and will expire three and one-half years following the Initial Exercise Date. The fair value of the 2021 Warrants was $4.1 million and was based on the Black-Scholes pricing model. Input assumptions used were as follows: a risk-free interest rate of 0.5%; expected volatility of 80.0%; expected life of 3.5 years; expected dividend yield of 0%; and the underlying traded stock price. The relative fair value attributable to the stock and warrants was $9.8 million and $4.2 million, respectively. The 2021 Warrants were classified in stockholders' equity as the number of shares were fixed and determinable, no cash settlement required and no other provisions precluding equity treatment.

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Issuance costs in connection with the October 2021 Registered Direct Offering were $1.2 million which included cash commissions equal to $1.0 million and legal and other fees of $0.2 million.

2021 Private Placement

On January 21, 2021, the Company closed on a Securities Purchase Agreement (the "2021 Purchase Agreement") with certain institutional and accredited investors, pursuant to which the Company, in a private placement ("2021 Private Placement"), agreed to issue and sell an aggregate of 2,500,000 shares of the Company's common stock at a purchase price of $4.00 per share, and warrants to purchase an aggregate of 2,500,000 shares of the Company's common stock (the "2021 Warrants"), resulting in total gross proceeds to the Company of $10.0 million, before deducting placement agent fees and offering expenses. The 2021 Warrants have an initial exercise price of $6.03 per share. The 2021 Warrants are exercisable beginning six months following the date of issuance and will expire five and one-half years following such date. The fair value of the 2021 Warrants was $7.5 million and was based on the Black-Scholes pricing model. Input assumptions used were as follows: a risk-free interest rate of 0.5%; expected volatility of 76.0%; expected life of 5.5 years; expected dividend yield of 0%; and the underlying traded stock price. The relative fair value attributable to the stock and warrants was $6.3 million and $3.7 million, respectively. The 2021 Warrants were classified in stockholders' equity as the number of shares were fixed and determinable, no cash settlement required and no other provisions precluding equity treatment.

Issuance costs in connection with the 2021 Private Placement were $0.9 million which included cash commissions equal to $0.7 million and legal and other fees of $0.2 million.

Warrants

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

	Number of Warrants:			
Warrant Issuance	**December 31, 2022**	**December 31, 2021**	**Exercise Price**	**Expiration Date**
March 2017	-	1,315	$ 7,800.00	March 2022
July 2018	48	48	$ 5,602.50	July 2028
April 2020	1,252	1,252	$ 375.00	April 2025
January 2021	83,338	83,338	$ 180.90	July 2026
October 2021	143,597	143,597	$ 112.50	April 2025
November 2022 Series A	6,768,837	-	$ 0.00	December 2023
November 2022 Series B	8,267,170	-	$ 0.00	December 2027
Total	15,264,242	229,550		

The warrants outstanding as of December 31, 2022 are all exercisable. In addition, the 2022 Warrants have a cashless exercise provision whereby one warrant can be exchanged for one share of common stock for no additional consideration, which renders the $3.00 per share exercise price to be $0.00. During the year ended December 31, 2022, 3,981,163 Series A Warrants and 2,482,830 Series B Warrants were exchanged for shares of the Company's common stock.

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8. Stock-Based Compensation

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

	Year Ended December 31,	
	2022	2021
General and administrative	$ 854	$ 662

Stock Options

In December 2019, in connection with the 2019 Merger, the Company assumed a previously adopted stock option plan (the "2018 Plan") and adopted the 2019 Equity Incentive Plan (the "2019 Plan"). In addition, in November 2021, the Company adopted the 2021 Inducement Plan, and in December 2022, the Company adopted the 2022 Equity Incentive Plan (the "2022 Plan"). The 2018 Plan, 2019 Plan, 2021 Inducement Plan and 2022 Plan provide for the grant of stock options, restricted stock and other equity awards of the Company's common stock to employees, officers, consultants, and directors. On May 11, 2022, the Company terminated the 2018 Plan. As of the date of termination, there were no outstanding awards under the 2018 Plan.

Evergreen provision

Under the 2022 Plan, the shares reserved automatically increase on January 1st of each year, for a period of not more than five years commencing on January 1, 2023 and ending on (and including) January 1, 2027, to an amount equal to the lesser of 5% of the common shares outstanding as of January 1, or a lesser amount as determined by the Board.

On January 1, 2022, 35,549 shares were added to the 2019 Plan as a result of the evergreen provision associated with the 2019 Plan. With the adoption of the 2022 Plan, no additional shares may be added to or grants awarded from the 2019 Plan.

As of December 31, 2022, 5,078,721, 33,333 and 15,938 shares were authorized under the 2022 Plan, the 2021 Inducement Plan, and 2019 Plan, respectively, prior to the issuance of any shares under these plans.

Options expire within a period of not more than ten years from the date of grant. During the years ended December 31, 2022 and 2021, 5,995 and 22,555 stock options were granted, respectively, to employees and directors with service conditions. The options granted with service conditions vest over a period between one year and three years.

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The following table summarizes the Company's stock option plan activity for the years ended December 31, 2022 and 2021 as follows:

	Number of Options	Weighted Average Exercise Price	Weighted-Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in thousands)
Outstanding at January 1, 2021	30,676	$ 108.32	8.5	$ —
Granted	22,555	$ 67.80	—	$ —
Exercised	(6,096)	$ 17.90	—	$ 364
Forfeited/Cancelled	(14,637)	$ 57.89	—	$ —
Outstanding at December 31, 2021	32,498	$ 119.72	9.3	$ —
Granted	5,995	$ 17.83	—	$ —
Exercised	-	$ —	—	$ —
Forfeited/Cancelled	(2,000)	$ 181.20	—	$ —
Outstanding at December 31, 2022	36,493	$ 99.62	8.5	$ -
Vested and expected to vest at December 31, 2022	36,493	$ 99.62	8.5	$ -
Options exercisable at December 31, 2022	17,903	$ 146.70	8.1	$ -

The weighted average fair value per share of options granted during the year ended December 31, 2022 and 2021 was $12.43 and $43.55, respectively.

The following table summarizes the Company's unvested stock options as of and for the year ended December 31, 2022:

	Number of Options	Weighted Average Grant Date Fair Value
Nonvested at January 1, 2022	25,725	$ 59.09
Granted	5,995	$ 12.43
Vested	(12,018)	$ 64.90
Forfeited/Cancelled	(1,112)	$ 117.26
Nonvested as of December 31, 2022	18,590	$ 36.81

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

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

(Dollar Amounts in Thousands, Except Per Share Amounts)

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

	Year Ended December 31,	
	2022	2021
Expected stock price volatility	80.7-85.2 %	79.0-80.4 %
Expected life of options (years)	5.5-5.8	5.8
Expected dividend yield	— %	— %
Risk free interest rate	1.72-3.08 %	0.93-1.33 %

During the years ended December 31, 2022 and 2021, 12,018 and 3,164 stock options vested, respectively. The weighted average fair value per share of options vesting during the years ended December 31, 2022 and 2021 was $64.90 and $163.64, respectively During the years ended December 31, 2022 and 2021, 2,000 and 14,637 stock options were forfeited, respectively. During the year ended December 31, 2021, $364 was recognized in income by option holders as a result of stock option exercises. As of December 31, 2022, 5,091,500 shares in the aggregate were available for future issuance under the 2022 Plan and the 2021 Inducement Plan.

Unrecognized stock-based compensation cost for the stock options issued under the 2019 Plan, the 2021 Inducement Plan, and the 2022 Plan was $0.5 million as of December 31, 2022. The unrecognized stock-based expense is expected to be recognized over a weighted average period of 0.8 years.

9. Net Loss Per Share of Common Stock

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

The basic net loss per share calculation includes the 2022 Warrants given that these instruments are exchangeable into common stock for which no additional consideration is required from the holder. The following potential shares of common stock were not considered in the computation of diluted net loss per share as their effect would have been anti-dilutive:

	Year Ended December 31	
	2022	2021
Stock options	36,493	32,498
Warrants	228,235	229,550

10. Fair Value Measurements

The Company follows accounting guidance that emphasizes that fair value is a market-based measurement, not an entity specific measurement. Fair value is defined as “the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date.” Fair value measurements are defined on a three level hierarchy:

Level 1 inputs: Unadjusted quoted prices for identical assets or liabilities in active markets;

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Level 2 inputs: Quoted prices for similar assets and liabilities in active markets, quoted prices in markets that are not active, or inputs which are observable, whether directly or indirectly, for substantially the full term of the asset or liability;

Level 3 inputs: Unobservable inputs that reflect the Company's own assumptions about the assumptions market participants would use in pricing the asset or liability in which there is little, if any, market activity for the asset or liability at the measurement date.

There were no financial instruments measured on a recurring basis as of December 31, 2021.

The fair value of financial instruments measured on a recurring basis as of December 31, 2022 are as follows:

	As of December 31, 2022			
Description	**Total**	**Level 1**	**Level 2**	**Level 3**
Liabilities:				
Warrant liabilities	$ 10,796	$ —	$ —	$ 10,796
Total liabilities at Fair Value	$ 10,796	$ —	$ —	$ 10,796

The fair value of the 2022 Warrants was determined using a Monte Carlo simulation. This valuation technique involves a significant amount of estimation and judgment. In general, the assumptions used in calculating the fair value of the common stock warrant liability represent management's best estimate, but the estimate involves inherent uncertainties and the application of significant management judgment.

Input assumptions were as follows:

	As of December 31, 2022
Stock Price	$ 0.72
Exercise Price	—
Risk free interest rate	3.9-4.6 %
Volatility	94-103 %
Remaining term (years)	1.0-5.0

Due to the cashless exercise provision of the 2022 Warrants rendering the exercise price effectively at zero, the calculated price per share of the 2022 Warrants was equal to that of a share of common stock

The following table provides a roll-forward of the warrant liabilities measured at fair value for the year ended December 31, 2022:

	Year Ended December 31 2022
Balance at beginning of period	$ —
Issuance of 2022 warrants	24,295
Change in fair value of warrant liabilities	(7,935)
Reclass of warrant liabilities upon exercise of warrants	(5,564)
Balance at end of period	$ 10,796

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11. Income Taxes

The effective tax rate for the years ended December 31, 2022 and 2021 was zero percent. A reconciliation of income tax computed at the statutory federal income tax rate to the provision (benefit) for income taxes included in the accompanying consolidated statements of operations and comprehensive loss is as follows:

	For the Year Ended December 31, 2022	2021
Income tax (benefit) provision at federal statutory rate	21.0 %	21.0 %
State income tax, net of federal benefit	7.2	3.5
Valuation allowance	188.6	(26.2)
Research credits	1.2	2.5
Provision to tax return	-	(1.0)
Transaction costs	(3.3)	-
Change in fair value of warrant liabilities	11.9	-
Section 382 limitation adjustment attributes	(225.1)	-
Other	(1.5)	0.2
Effective tax rate	- %	- %

Loss before provision for taxes for the years ended December 31, 2022 and 2021 consisted of the following:

	Year Ended December 31, 2022	2021
Loss before Income taxes:		
Domestic	$ (14,559)	$ (14,954)
Foreign	592	(330)
	$ (13,967)	$ (15,284)

The components of income tax provision (benefit) consisted of the following for the years ended December 31, 2022 and 2021:

	Year Ended December 31, 2022	2021
Tax Provision (Benefit):		
Current		
Domestic	$ —	$ —
Foreign	—	—
Total current tax provision (benefit)	—	—
Deferred		
Domestic	26,183	(3,932)
Foreign	148	(81)
Total deferred tax provision (benefit)	26,331	(4,013)
Change in valuation allowance - Domestic	(26,183)	3,932
Change in valuation allowance - Foreign	(148)	81
Total tax provision (benefit)	$ —	$ —

Significant components of the Company's deferred tax assets and liabilities are summarized in the tables below as of (in thousands):

	Year Ended December 31, 2022	2021
Deferred tax assets:		
Federal and state operating loss carryforwards	$ 370	$ 19,904
Foreign operating loss carryforwards	176	324
Acquired intangibles	3,095	1,683
Stock-based compensation	467	276
Lease liability	-	17
Capitalized R&D Costs	278	7,023
Other	16	44
Research and development credit carryforwards	26	1,483
	4,428	30,754
Valuation allowance - Domestic	(4,252)	(30,410)
Valuation allowance - Foreign	(176)	(324)
Total deferred tax assets, net of valuation allowance	-	20
Deferred tax liabilities:		
ROU asset	-	(18)
Other	-	(2)
Net deferred tax assets	$ —	$ —

As of December 31, 2022 and 2021, the Company had deferred tax assets of approximately $4.4 million and $30.8 million, respectively. Realization of the deferred tax assets is primarily dependent upon future taxable income, if any, the amount and timing of which are uncertain. The Company has had significant pre-tax losses since its inception. The Company has not yet generated revenues and faces significant challenges to becoming profitable. Accordingly, the deferred tax assets have been fully offset by a valuation allowance of $4.4 million and $30.8 million as of December 31, 2022 and 2021, respectively. U.S. deferred tax assets will continue to require a valuation allowance until the Company can demonstrate their realizability through sustained profitability or another source of income.

As of December 31, 2022 and 2021, the Company's federal net operating loss carryforwards were approximately $1.5 million and $81.8 million, respectively. The Company had federal research credit carryforwards as of December 31, 2022 and 2021 of approximately $24 thousand and $1.0 million, respectively. The Federal net operating losses were incurred after December 31, 2017 and therefore, will not expire. As of December 31, 2022 and 2021, the Company had state net operating loss carryforwards of approximately $65 thousand and $42.6 million, respectively. The Company had state research credit carryforwards of $2 thousand and $0.6 million as of December 31, 2022 and 2021, respectively. The state net operating loss carryforwards and state research credit carryforwards will begin to expire in 2043, if not utilized. Lastly, the Company had foreign net operating loss carryforwards of approximately $0.7 million and $1.3 million as of December 31, 2022 and 2021, respectively. The foreign net operating loss carryforwards will begin to expire in 2028.

Utilization of the net operating loss carryforwards and credits may be subject to a substantial annual limitation due to the ownership change limitations provided by Section 382 of the Internal Revenue Code of 1986, as amended, and similar state provisions. Generally, in addition to certain entity reorganizations, the limitation applies when one or more "5-percent shareholders" increase their ownership, in the aggregate, by more than 50 percentage points over a 36-month testing period, or beginning the day after the most recent ownership change, if shorter. The annual limitation may result in the expiration of net operating losses and credits before utilization. As a result of the public stock offering and private placement offering during the fourth quarter of 2022, a Section 382 ownership change occurred with an annual limitation of $0. Because of the 2022 ownership change and corresponding limitation, approximately $99.0 million and $48.5 million of federal and state net operating loss carryforwards, respectively, were written off, with a corresponding offset to the Company's full valuation allowance. Additionally, approximately $1.2 million and $0.6 million of federal and

state research credit carryforwards, respectively, were written off, with a corresponding offset to the Company's full valuation allowance.

The Company recognizes interest and/or penalties related to uncertain tax positions in income tax expense. There were no uncertain tax positions as of December 31, 2022 and 2021, and as such, no interest or penalties were recorded to income tax expense.

The Company's corporate returns are subject to examination beginning with the 2018 tax year for federal and state jurisdictions, and beginning with the 2019 tax year for one foreign jurisdiction.

12. Related Party Transactions

Agreements with Dong-A

On September 28, 2018, NeuroBo entered into a five year manufacturing and supply agreement with Dong-A, a greater than 5% shareholder, for the manufacturing and supply of NB-01 drug substance and placebos for the purpose of research and development to be used in Phase 3 clinical trials (the "Manufacturing Agreement"). There were no manufacturing related costs under the Manufacturing Agreement for the years ended December 31, 2022 or 2021.

The Manufacturing Agreement will automatically terminate in the event that the license agreement with Dong-A is terminated for any reason. In addition, each of Dong-A and NeuroBo may terminate the Manufacturing Agreement (1) upon the material breach by the other party, if the breach is not cured within a specified number of days after receiving notice from the terminating party, or if the breach cannot reasonably be cured within such period and the breaching party has not started to remedy the breach within such period and diligently endeavored to cure the breach within a reasonable time thereafter, or (2) in the event that (i) the other party is the subject of a petition for bankruptcy, reorganization, or arrangement and the same is not dismissed within thirty days thereof, (ii) a receiver or trustee is appointed for all or a substantial portion of the assets of the other party, or (iii) the other party makes an assignment for the benefit of its creditors.

On June 7, 2020, the Company entered into a manufacturing and supply agreement (the "Manufacturing and Supply Agreement") with Dong-A for the manufacturing and supply of NB-02 drug product and placebo for the purpose of research and development of NB-02, including but not limited to, the use in the first NB-02 human clinical trial to be conducted by the Company. Under the terms of the Manufacturing and Supply Agreement, upon receipt of a purchase order from the Company no later than 270 days prior to the requested delivery date, Dong-A has agreed to produce for the Company tablets of the NB-02 drug substance and placebos at a specified supply price. The Company is obligated to manufacture, or have manufactured, and supply to Dong-A the active pharmaceutical ingredients which are necessary to manufacture the NB-02 drug product. The Manufacturing and Supply Agreement has a five year term, subject to earlier termination under certain circumstances.

13. Defined Contribution Plan

The Company adopted a 401(k) defined contribution plan in November 2018, effective as of January 1, 2019, for all employees over age 21. Employees can defer up to 90% of their compensation through payroll withholdings into the plan subject to federal law limits. Discretionary employer matches vest over a six-year period beginning on the second anniversary of an employee's date of hire. Employee contributions and any employer matching contributions made to satisfy certain non-discrimination tests required by the Internal Revenue Code are 100% vested upon contribution. No matching contributions were made during the years ended December 31, 2022 and 2021.

14. Subsequent Events

Since December 31, 2022, 345,333 Series A Warrants and 1,395,333 Series B Warrants were exchanged for shares of the Company's common stock.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

As required by Rules 13a-15(b) and 15d-15(b) under the Exchange Act, our management, with the participation of our principal executive officer ("PEO") and principal financial officer ("PFO"), evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of the end of the period covered by this annual report for the Company. Based upon that evaluation, our PEO and PFO concluded that our disclosure controls and procedures were not effective as of the end of the period covered by this annual report, as a result of material weaknesses in our internal control over financial reporting, which is discussed further below.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of financial statements for external purposes in accordance with U.S. generally accepted accounting principles. Internal control over financial reporting includes those policies and procedures that: (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and Board; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Management has assessed the effectiveness of our internal control over financial reporting as of December 31, 2022. The scope of management's assessment regarding the Company's internal control over financial reporting includes the criteria set forth by the Internal Control Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of The Treadway Commission. As a result of material weaknesses, management has concluded that our internal control over financial reporting was not effective as of December 31, 2022.

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

Remediation Efforts to Address the Material Weaknesses

We are in the process of remediating, but have not yet remediated, the material weaknesses related to lack of segregation of duties, logical access and lack of supervision and review over financial reporting as described above. Under the oversight of the audit committee, management is developing a detailed plan and timetable for the implementation of

appropriate remedial measures to address the material weaknesses. As of the date of this report, we are taking or intend to take the following actions:

- we will enhance the controls over disbursements, separating the functions of initiating and approving to two separate individuals;
- we will implement enhanced controls relative to the review and oversight of the accounting for review of journal entries, cash disbursements and financial reporting.
- we will restrict administrator rights to only those individuals who require access.

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

This annual report does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our registered public accounting firm pursuant to rules of the SEC that permit us to provide only management's report in this Annual Report on Form 10-K.

Inherent Limitations of Disclosure Controls and Procedures and Internal Control over Financial Reporting

Our management, including our PEO and PFO, does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the control. The design of any system of controls is also based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

Changes in Internal Control Over Financial Reporting

Other than the remediation activities listed above, there have been no changes in our internal control over financial reporting during the quarter ended December 31, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

On March 29, 2023, Dr. Richard Kang provided notice of his resignation from the Board of Directors of the Company, effective immediately due to time constraints related to his other positions. Dr. Kang's resignation was not the result of any disagreement with the Company regarding the Company's operations, policies or practices.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Directors and Executive Officers

The Board is divided into three classes. Members of each class serve staggered three-year terms. The terms of office of directors in Class I, Class II and Class III expire at the annual meetings of stockholders to be held in 2023, 2024 and 2025, respectively. The following table provides information as to each person who is, as of the filing hereof, a director and/or executive officer of the Company.

Name	Position(s)	Age
Andrew Koven	Class II Director and Chair of the Board	65
Hyung Heon Kim	Class II Director	47
Jason L. Groves	Class II Director	52
Na Yeon (Irene) Kim	Class I Director	47
D. Gordon Strickland	Class I Director	76
Michael Salsbury	Class III Director	73
Joseph Hooker	Interim Chief Executive Officer and President	70

Business Experience and Background of Directors and Executive Officer

Mr. Andrew Koven-Mr. Koven has served as a member of our Board since July 2021, and Chair of our Board since January 2022. Mr. Koven is the Lead Independent Director of Kala Pharmaceuticals, Inc., a public biopharmaceutical company focused on the discovery, development and commercialization of innovative therapies for diseases of the eye. He has served as the Lead Independent Director of Kala Pharmaceuticals, Inc. since December 2018 and as a member of the Kala board of directors since September 2017. Mr. Koven was, until his retirement in January 2019, the President and Chief Business Officer of Aralez Pharmaceuticals Inc., or Aralez, a public specialty pharmaceutical company, and served in that role with the company's predecessor, Pozen Inc., commencing in June 2015. Prior to joining Pozen, Mr. Koven served as Executive Vice President, Chief Administrative Officer and General Counsel of Auxilium Pharmaceuticals Inc., a public specialty biopharmaceutical company, from February 2012 until January 2015, when it was acquired by Endo International plc. Mr. Koven served as President and Chief Administrative Officer and a member of the board of directors of Neurologix, Inc., a company focused on the development of multiple innovative gene therapy development programs, from September 2011 to November 2011. Before Neurologix, Mr. Koven served as Executive Vice President and Chief Administrative and Legal Officer of Inspire Pharmaceuticals, Inc., a public specialty pharmaceutical company, from July 2010 until May 2011 when it was acquired by Merck & Co., Inc. Previously, Mr. Koven served as Executive Vice President, General Counsel and Corporate Secretary of Sepracor Inc. (now Sunovion), a public specialty pharmaceutical company, from March 2007 until February 2010 when it was acquired by Dainippon Sumitomo Pharma Co., Ltd. Prior to joining Sepracor, Mr. Koven served as Executive Vice President, General Counsel and Corporate Secretary of Kos Pharmaceuticals, Inc., a public specialty pharmaceutical company, from August 2003 until its acquisition by Abbott Laboratories (now AbbVie) in December 2006. Mr. Koven began his career in the pharmaceutical industry first as an Assistant General Counsel and then as Associate General Counsel at Warner-Lambert Company from 1993 to 2000, followed by his role as Senior Vice President and General Counsel at Lavipharm Corporation from 2000 to 2003. From 1986 to 1992 he was a corporate associate at Cahill, Gordon & Reindel in New York. From 1992 to 1993 he served as Counsel, Corporate and Investment Division, at The Equitable Life Assurance Society of the U.S. Mr. Koven holds a Master of Laws (LL.M.) Degree from Columbia University School of Law and a Bachelor of Laws (LL.B.) Degree and Bachelor of Arts Degree in Political Science from Dalhousie University. Our Board believes that Mr. Koven's extensive experience in the pharmaceutical industry qualifies him to serve as a director.

Mr. Hyung Heon Kim- Mr. Kim has served as a member of our Board since July 2021. Mr. Kim is the General Counsel and a Vice President of Dong-A ST and Dong-A Socio Group, a Korean-based group of companies mainly engaged in the research, development, production and sale of pharmaceuticals, medical devices and APIs. Mr. Kim has

served as General Counsel of Dong-A ST since January 2018 and as a Vice President of Dong-A ST since December 2020. Mr. Kim previously served as Executive Director of Dong-A ST from January 2018 through December 2020. Prior to his roles with Dong-A ST, Mr. Kim was Head of International Legal Affairs for Dong-A Socio Holdings Co., Ltd., a Korean-based holdings company for the Dong-A Socio group of companies from 2012 to 2018. Since April 2021, Mr. Kim has served as a director of AnaPath Services GmbH, a private Swiss-based provider of scientific research and development services, and STP America Research Corp, a private New Jersey-based research and development company. Prior to joining Dong-A Socio Group, Mr. Kim served as legal counsel to SK Energy Co., Ltd. and SK Innovation Co., Ltd. from 2008 to 2011. Mr. Kim received his Bachelor of Law degree from Soongshil University in Korea, and obtained his Juris Doctor from Washington University School of Law. Our Board believes that Mr. Kim's experiences gained as General Counsel and Head of International Legal Affairs to an established pharmaceutical group of companies qualify him to serve as a director.

Mr. Jason L. Groves, Esq. has served a member of our Board since December 2019. Since July 2022, he has served as the Chief Legal Officer and Corporate Secretary of Medifast, Inc. (NYSE: MED), a publicly held leading manufacturer and distributor of clinically-proven, healthy-living products and programs. After joining Medifast in 2009, Mr. Groves has held several executive management positions, most recently serving as Executive Vice President and General Counsel of Medifast, Inc. from 2011 to July 2022. Mr. Groves was a Medifast, Inc. director from 2009 to 2015, serving on the Audit Committee from 2009 to 2011. Prior to joining Medifast, Mr. Groves was Assistant Vice President of Government Affairs for Verizon Maryland, where he was responsible for the company’s legislative policy and government affairs. A United States Army veteran, Mr. Groves was a direct-commissioned Judge Advocate in the United States Army Judge Advocate General’s (JAG) Corps. As a JAG officer, he practiced law and had the distinction of prosecuting criminal cases in the District Court of Maryland as a Special Assistant United States Attorney. Over the course of three years, he received two Army Achievement Medals and one Army Commendation Medal. Mr. Groves completed nine years with the Anne Arundel Medical Center Board of Trustees, chairing their international captive insurance company board for eight years. Mr. Groves received his Bachelor of Science degree, *cum laude*, in Hospitality Management from Bethune-Cookman University, and obtained his Juris Doctor from North Carolina Central University School of Law. Our Board believes that Mr. Grove’s experience serving as an independent director, audit committee member, and chief legal officer of a large public corporation while assisting with the initial international introduction of such corporation’s products qualify him to serve as a director.

Mr. Groves was nominated in accordance with the terms of the Voting Agreement and each of the E&H Funds and Dong-A ST voted their shares in favor of the election of Mr. Groves.

Ms. Na Yeon (“Irene”) Kim has served as a member of our Board since December 2019 and served as the Chair of our Board from December 2019 to January 2021. Prior to December 2019, she had served on the Board of Private NeuroBo since April 2018. Ms. Kim also currently serves as the Chief Executive Officer of E&Investment, Inc., a South Korean venture capital firm specializing in investments in life sciences companies, a position she has held since March 2018. From October 2015 until March 2018, Ms. Kim was a Representative Director for The SEED Investment Co., Ltd. (formerly known as OST Investment Co., Ltd.), a South Korean investment and fund manager specializing in investments in life sciences companies, and from January 2015 until December 2017, Ms. Kim served as member of the board of directors of Macrogen, Inc., a South Korean, publicly-traded biotechnology company specializing in precision medicine and biotechnology. Ms. Kim also served as an officer of AJUIB Investment, Inc., a venture capital firm headquartered in South Korea specializing in investments in life-science companies from August 2014 until September 2015. Ms. Kim focuses on investment opportunities in a number of industries, particularly in the field of BioPharma, and has more than 15 years of accumulated experience of investment in private equity/venture capital markets. As an investor representative, Ms. Kim has successfully managed more than $400 million in private equity and venture capital funds. Ms. Kim holds an M.S. and B.S. in biomolecular engineering, as well as an M.B.A. from Yonsei University in Korea. Our Board believes that Ms. Kim’s specialized knowledge in building value in life sciences companies and her extensive investment management experience qualify her to serve as a director.

Mr. D. Gordon Strickland- has served a member of our Board since January 2022. He served as Chairman of Ampex Corporation, a publicly traded technology company, from March 2012 until June 2019. He also served as Ampex’s Chief Executive Officer from February 2007 to March 2012. Prior to Ampex, he served as President and Chief Executive Officer of Cardiff Holdings, a privately held producer of credit, debit, loyalty and other cards by Brookside

Equity Partners from March 2012 to August 2013. Prior to Cardiff Holdings, Mr. Strickland was the chairman of Medical Resources, a public operator of diagnostic imaging centers. Mr. Strickland was also president and CEO of MCSi, Inc, a technical integrator of audio visual products, from March 2003 until March 2004. Prior to MCSi, Mr. Strickland was the president and CEO of Capitol Wire, Inc, an internet based news and information service provider from September 1999 until August 2002 and had leadership roles with Kerr Group, a manufacturer of glass containers and plastic packaging, from June 1986 until August 1997, including serving as the president and CEO, and as Senior Vice President, Finance and Chief Financial Officer. Mr. Strickland has over 35 years of experience as a senior executive and board member with public and private companies. Mr. Strickland received an M.B.A. from the Wharton School of the University of Pennsylvania and a B.A from Yale University. Our Board believes that Mr. Strickland's experience serving as Chairman and Chief Executive Officer of a publicly traded company, Ampex, qualifies him to serve as a director.

Mr. Michael Salsbury has served a member of our Board since December 2019. He has served as Counsel to Current Health Inc., a provider of remote care management products and services, since May 2021. Current Health was acquired by Best Buy Co., Inc. (BBY) in November 2021. From September 2017 to May 2022, Mr. Salsbury has served as Counsel to Verisma Systems, Inc., a provider of cloud-based automated disclosure management systems; and from February 2013 to July 2017, he served as Secretary and General Counsel to Best Doctors, Inc., a provider of expert medical opinions. Best Doctors was acquired by Teladoc Health, Inc. (TDOC) in July 2017. Mr. Salsbury has more than 25 years' experience as a senior executive with public and private companies and private law practice. Mr. Salsbury received a J.D. and M.B.A. from University of Virginia and a B.A. from Dartmouth College. Our Board believes that Mr. Salsbury's legal expertise and his experience serving as general counsel and secretary of a Fortune 100 corporation qualifies him to serve as a director.

Mr. Joseph Hooker has served as our Interim Chief Executive Officer and President since January 2023. Prior to joining NeuroBo, Mr. Hooker was an independent consultant and advised on an ad hoc basis for leading management consultancies and various pharmaceutical companies with respect to clinical trials, CROs and program management. From May 2019 through October 2020, Mr. Hooker was Sr. Director of Clinical Operations/Program Leader Rare Disease, Oncology for X4 Pharmaceuticals, Inc., where he led a cross functional global program team pre-clinical through development and commercialization including strategic planning, oversight, execution of clinical operations and the management of staff. From March 2018 to March 2019, Mr. Hooker served as Director, Program Leadership at Biogen, where he led programs and clinical development for gene therapy, ALS, ophthalmology, rare orphan disease and CNS. From September 2017 through February 2018 he served as Senior Director, Clinical Operations at Pierian Bioscience, where he built, developed and led clinical operations for an oncology device program. He also served as chief operating officer of MedAvante-ProPhase from March 2017 to August 2017. Mr. Hooker served as Head, Clinical Operations for Sandoz Biopharmaceuticals, division of Novartis, from February 2014 to May 2015. Mr. Hooker began his pharmaceutical career as Senior Clinical Trial Manager and project leader at DuPont-Merck Pharmaceuticals, and also served at various times in clinical trial management roles at Shire Pharmaceuticals, Cephalon Pharmaceuticals, Quintiles and Novo Nordisk. Mr. Hooker received a BA from Rutgers University and an MBA from Rider University.

Code of Business Conduct and Ethics

Our Board has adopted a code of business conduct and ethics that applies to all of our employees, officers and directors, including our Chief Executive Officer, Chief Financial Officer and other executive officers. We intend to disclose future amendments to certain provisions of our code of business conduct and ethics, or waivers of these provisions, on our website, http://www.neurobopharma.com.The full text of our code of conduct is posted on the investor relations section of our website at http://neurobopharma.com/corporate-governance/highlights.

Audit Committee

Our Board has established an audit committee, which is comprised of Mr. Strickland, Mr. Koven and Mr. Groves, with Mr. Strickland serving as chair of the committee. Each member of our audit committee meets the requirements for independence under the current Nasdaq and SEC rules and regulations and is financially literate. In addition, our Board has determined that Mr. Strickland qualifies as an "audit committee financial expert" as defined in Item 407(d)(5)(ii) of Regulation S-K promulgated under the Securities Act based on his serving as chief executive officer of multiple

companies as described above. This designation does not impose on either of them any duties, obligations or liabilities that are greater than are generally imposed on members of our audit committee and our Board.

Delinquent Section 16(a) Reports

Section 16(a) of the Exchange Act requires that the Company's directors, executive officers and persons who beneficially own more than 10% of a registered class of its equity securities, file with the SEC reports of ownership and changes in ownership of its common stock and other equity securities. Executive officers, directors and greater than 10% beneficial owners are required by SEC regulation to furnish the Company with copies of all Section 16(a) reports that they file. Based solely on the Company's review of such filed forms and representations from our directors and executive officers that no other forms were required, to our knowledge, other than a Form 4 filed by D. Gordon Strickland on February 2, 2022, which was filed two days after the required filing date, all of the Company's Directors and executive officers, and other persons who owned more than 10% of the Company's outstanding common stock, fully complied with the reporting requirements of Section 16(a) during fiscal year 2022.

ITEM 11. EXECUTIVE COMPENSATION

Executive Officer Compensation

The following tables and accompanying narrative disclosure discuss the compensation awarded to, earned by, or paid to:

- Dr. Ben Gil Price, our former President, and Chief Executive Officer

Dr. Price was our sole executive officer for the year ended December 31, 2022.

Summary Compensation Table for 2022

The following table presents summary information regarding the total compensation for services rendered in all capacities that was earned by our named executive officer during the fiscal years ended December 31, 2022 and 2021.

NAME AND PRINCIPAL POSITION	YEAR	SALARY ($) (4)	BONUS ($)	OPTION AWARDS ($)(1)	TOTAL ($)
Gil Price (2)	2022	400,000	100,000	—	500,000
Former President, and Chief Executive Officer	2021	66,154	—	854,122	920,276

(1) Reflects the aggregate grant date fair value of options granted during the fiscal year ended December 31, 2021, as computed in accordance with ASC 718. The assumptions applicable to the determination of grant date fair value of the stock options granted to Dr. Price in 2022 can be found in Note 8 of the Notes to Consolidated Financial Statements – Stock-Based Compensation in this Annual Report on Form 10-K.

(2) Dr. Price was appointed as our President and Chief Executive Officer effective November 15, 2021. Dr. Price resigned as our Chief Executive Officer effective January 12, 2023.

Narrative Disclosure to Summary Compensation Table

Agreements with Our Named Executive Officer

We have entered into written agreements with our named executive officer.

On November 3, 2021, the Company and Dr. Price entered into an employment agreement (the "Price Employment Agreement"). The Price Employment Agreement has an initial term (the "Initial Term") of one year beginning on

November 3, 2021 and automatically renews for an additional one year period at the end of the Initial Term a (a "Renewal Term") provided that at least 60 days prior to the expiration of the Initial Term or any Renewal Term the Board does not notify Dr. Price of its intention not to renew. Dr. Price resigned from the Company effective January 12, 2023.

In connection with Dr. Price's departure, on January 16, 2023, the Company and Dr. Price entered into a Separation and Release Agreement (the "Separation Agreement"). Pursuant to the terms and conditions of the Separation Agreement, in exchange for granting and not revoking a release agreement, Dr. Price will be entitled to receive from the Company (i) severance pay in an amount equal to $100,000, payable in substantially equal installments in accordance with the Company's payroll practice over three months, beginning on the first payroll date after Dr. Price's release of the Company becomes effective and irrevocable and (ii) an amount equal to $100,000 as Dr. Price's annual bonus for 2022, payable on the first payroll date after Dr. Price's release of the Company becomes effective and irrevocable.

Pursuant to the terms of the Employment Agreement, and as approved by the independent members of the Board on November 3, 2021, Dr. Price was granted, effective as of his first day of full-time employment with the Company (the "Grant Date"), a non-qualified stock option to purchase 20,555 shares of the Company's common stock pursuant to the terms of a stock option award agreement (the "New Hire Option") under the Inducement Plan as an inducement material to Dr. Price becoming an employee of the Company in accordance with Nasdaq Listing Rule 5635(c)(4). The New Hire Option has a ten-year term and vests as to 8,888 of the shares underlying the stock option on the first anniversary of the Grant Date and as to the remaining 11,667 of the shares on the second anniversary of the Grant Date. The New Hire Option granted to Dr. Price has an exercise price per share equal to the closing price of the Company's common stock on the Grant Date.

Outstanding Equity Awards at Fiscal Year-End 2022

The following table sets forth information regarding outstanding stock options held by our executive officer as of December 31, 2022:

NAME	NUMBER OF SECURITIES UNDERLYING UNEXERCISED OPTIONS EXERCISABLE (#)	NUMBER OF SECURITIES UNDERLYING UNEXERCISED OPTIONS UNEXERCISABLE (#)	OPTION EXERCISE PRICE ($)	OPTION EXPIRATION DATE
Dr. Gil Price	8,888	11,667 (2)	61.20	November 3, 2031

(1) All of the outstanding stock option awards were granted under the NeuroBo 2021 Inducement Plan.
(2) Subject to continued service: options were to vest on the second anniversary of the vesting commencement date.

Non-Employee Director Compensation

Our non-employee directors receive a mix of cash and share-based compensation intended to encourage non-employee directors to continue to serve on our Board, further align the interests of the directors and stockholders, and attract new

non-employee directors with outstanding qualifications. Directors who are employees or officers of the Company do not receive any additional compensation for Board service.

The following table provides compensation information for the fiscal year ended December 31, 2022 for each member of our Board.

Name	Fees Earned or Paid in Cash ($)	Option Awards ($) (5)	Total ($)
Ms. Na Yeon (Irene) Kim	45,784	6,663	52,447
Jason Groves	134,131	6,663	140,794
Michael Salsbury	136,989	6,663	143,652
Andrew Koven	200,267	6,663	206,930
D. Gordon Strickland (1)(4)	123,539	34,574	158,113
Richard Kang (2)	38,556	6,663	45,219
Hyung Heon Kim	54,217	6,663	60,880
Douglas Swirsky (3)	3,611	—	3,611

(1) Mr. Strickland was appointed to the Board effective January 27, 2022
(2) Dr. Kang resigned from the Board effective March 29, 2023.
(3) Mr. Swirsky resigned from the Board effective January 14, 2022
(4) Mr. Strickland was granted an option to purchase 1,333 shares at an exercise price of $30.60 in January 2022. Each option vests, subject to continuing service, in 36 monthly installments beginning February 28, 2022. The amount reported reflects the aggregate grant date fair value of the option granted to Mr. Strickland during the fiscal year ended December 31, 2022, as computed in accordance with ASC 718.
(5) All current board members were granted an option to purchase 666 shares at an exercise price of $14.18 per share in June 2022. Each option vests, subject to continuing service in June 2023. The amount reported reflects the aggregate grant date fair value of the options granted during the fiscal year ended December 31, 2022, as computed in accordance with ASC 718.
(6) As of December 31, 2022, Ms. Kim, Mr. Groves, Mr. Salsbury and Mr. Koven have 2,666 options outstanding, Mr. Strickland has 1,999 options outstanding, and Mr. Kim and Dr. Kang have 666 options outstanding.

In January 2022, the compensation committee recommended and our Board approved the Company's Amended and Restated Non-Employee Director Compensation Policy (the "Amended Non-Employee Director Compensation Policy"). Under the Amended Non-Employee Director Compensation Policy, all of our non-employee directors receive an annual cash retainer of $40,000 for Board service except for the Chair of the Board who will receive an annual cash retainer of $75,000. A lead independent director, if applicable, would receive a total of $60,000. In addition, directors receive an additional cash retainer for serving as a committee chair or member as follows:

	Audit Committee	Compensation Committee	Nominating and Corporate Governance Committee
Committee Chair	$18,000	$12,000	$8,000
Committee Member (other than the Chair)	9,000	6,000	4,000

In addition, non-employee directors are entitled to an initial grant for a nonstatutory stock option to acquire 1,333 shares of the Company's common stock pursuant to the terms and conditions of the Company's 2022 Equity Incentive Plan (the "Plan"), which will vest in a series of three successive equal annual installments over the three-year period measured from the date of grant, subject to the director's service to the Company through each applicable vesting date. In accordance with the Amended Non-Employee Director Compensation Policy, each non-employee director will also be eligible to be granted, immediately following the Company's annual meeting of stockholders, a nonstatutory stock option to purchase 666 shares of Company common stock (the "Annual Grant"). Each Annual Grant will vest upon the earlier of the one (1) year anniversary of the grant date or the day prior to the Company's next annual

meeting occurring after the grant date, subject to such non-employee director's service to the Company through the vesting date. Vesting will be accelerated upon a Corporate Transaction (as defined in the Plan) The nonstatutory stock options are subject to the terms and conditions of the Plan and its related agreements. Additionally, pursuant to the Restated Non-Employee Director Compensation Policy, non-employee directors may elect to receive a restricted stock unit award in lieu of the cash compensation payable.

Under the Company's prior Non-Employee Director Compensation Policy, which was in effect prior to the amendment, director compensation was as follows:

- Annual cash compensation of $20,000 per year;
- $20,000 per year for service on a committee, irrespective of the number of committees;
- $35,000 additional per year of service for the Chair of the Board;
- $20,000 additional per year for service for each of the Chair of the Nomination Committee and the Compensation Committee; and
- $40,000 per year additional for service for each of the Chair of the Audit Committee; and
- Option to purchase 2,000 shares, vested monthly over 36 months upon election as a director;

In September 2021, the Board formed a transaction committee of the Board consisting of 4 members of the Board to review a licensing transaction presented to the Board. Pursuant to the authorizing resolution, the Board approved the following compensation for the members of the Board serving on such transaction committee: a monthly fee in the amount of $5,000 per month (for each calendar month or portion thereof that such member serves on the transaction committee) and $800 per meeting of the transaction committee attended by such member.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The following table sets forth information regarding beneficial ownership of our common stock, as of March 25, 2023 by:

- each person, or group of affiliated persons, known by us to beneficially own more than 5% of our common stock;
- each of our named executive officers;
- each of our directors; and
- all of our current executive officers and directors as a group.

The table lists applicable percentage ownership based on 27,176,685 shares of common stock outstanding as of March 25, 2023. In addition, the rules include shares of our common stock issuable pursuant to the exercise of stock options and warrants that are either immediately exercisable or exercisable within 60 days of March 25, 2023. These shares are deemed to be outstanding and beneficially owned by the person holding those options for the purpose of computing the percentage ownership of that person, but they are not treated as outstanding for the purpose of computing the percentage ownership of any other person.

We have determined beneficial ownership in accordance with the rules of the SEC. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting power or investment power with respect to those securities. Unless otherwise indicated, the persons or entities identified in this table have sole voting and investment power with respect to all shares shown as beneficially owned by them, subject to applicable community

property laws. Except as otherwise noted below, the address for each person or entity listed in the table is c/o NeuroBo Pharmaceuticals, Inc., 200 Berkeley Street, 19th Floor, Boston, Massachusetts, 02116.

NAME OF BENEFICIAL OWNER	SHARES BENEFICIALLY OWNED NUMBER	PERCENT
Greater than 5% stockholders		
Dong-A ST Co., Ltd. (1)	12,429,353	45.7 %
Directors and Named Executive Officers		
Andrew Koven, Chair of the Board of Directors (3)	1,111	*
Na Yeon (Irene) Kim, Director (2)(3)	204,013	*
Jason Groves, Director (3)	2,000	*
Michael Salsbury, Director (3)	2,000	*
Hyung Heon Kim, Director	—	—
Richard Kang, Former Director	—	—
D. Gordon Strickland, Director (3)	592	*
Joseph Hooker, Interim Chief Executive Officer and President	—	—
Gil Price, Former President and Chief Executive Officer	8,888	—
All current executive officers and directors as a group (7 persons)	218,604	*

* Represents beneficial ownership of less than one percent.

(1) Based solely on the Company's review of a filing made on an amendment to Schedule 13D on December 30, 2022 with the SEC. Dong-A ST Co., Ltd. is a South Korean corporation. The address of Dong-A ST Co., Ltd. Is 64, Cheonho-daero, Dongdaemun-gu, Seoul, Republic of Korea.

(2) Based solely on the Company’s review of a filing made on an amendment to Schedule 13D on July 25, 2022 with the SEC. The amendment to the Schedule 13D was filed by The E&Healthcare Investment Fund II (“Fund II”), The E&Healthcare Investment Fund No. 6 (“Fund 6”), The E&Healthcare Investment Fund No. 7 (“Fund 7”), E&Investment, Inc. (“GP”), and Na Yeon Kim. Fund II beneficially owns 96,351 shares of common stock, Fund 6 beneficially owns 37,373 shares of common stock, Fund 7 beneficially owns 62,159 shares of common stock and GP, as the general partner of each of Fund II, Fund 6 and Fund 7, owns 1,459 shares of common stock and may be deemed to beneficially own 200,554 shares of common stock. Ms. Kim has been granted stock options to purchase up to 2,000 shares of common stock in respect of her service on the Board, all of which are exercisable of March 25, 2023. Ms. Kim, as the Chief Executive Officer of GP, may be deemed to hold shared voting and dispositive power over a total of 204,013 shares of Common Stock. The business address of Ms. Kim and the address of the principal office of the person and entities noted in this footnote is 16th floor, Yeoksam I-Tower, 326, Teheran-ro, Gangnam-gu, Seoul, Republic of Korea 06211.

(3) Represents shares underlying outstanding stock options that are vested or will become vested within 60 days of March 25, 2023.

Securities Authorized for Issuance Under Equity Compensation Plans

The following table presents information as of December 31, 2022 with respect to compensation plans under which shares of our common stock may be issued.

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (#)(a)	Weighted-average exercise price of outstanding options, warrants and rights ($) (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (#)(c)	
Equity compensation plans approved by security holders	15,938	149.16	5,078,721	(1)(2)
Equity compensation plans not approved by security holders	20,555	61.20	12,778	(3)
Total	36,493	99.62	5,091,500	

(1) The number of shares of common stock remaining available for future issuance represent shares available for issuance under the 2022 Plan.

(2) The 2022 Plan provides that the number of shares that may be issued under the 2022 Plan shall be increased on the first day of each fiscal year by an amount equal to the lesser of (i) 5% of the number of outstanding shares of Common Stock on such date and (ii) an amount determined by the Administrator.

(3) Our only equity compensation plan not approved by our security holders is our 2021 Inducement Plan. A total of 33,333 shares of common stock of the Company have been reserved for issuance under the Inducement Plan, subject to adjustment for stock dividends, stock splits, or other changes in the Company's common stock or capital structure. The Inducement Plan was approved by the Compensation Committee without stockholder approval pursuant to Nasdaq Stock Market Listing Rule 5635(c)(4), and is to be utilized exclusively for the grant of stock awards to individuals who were not previously an employee or non-employee director of the Company (or following a bona fide period of non-employment with the Company) as an inducement material to such individual's entry into employment with the Company, within the meaning of Nasdaq Listing Rule 5635(c)(4). The Inducement Plan is administered by the Board. Stock awards under the Inducement Plan may only be granted by: (i) the Compensation Committee or (ii) another committee of the Board composed solely of at least two members of the Board who meet the requirements for independence under the Nasdaq Stock Market Listing Rules (the foregoing subsections (i) and (ii) are collectively referred to as the "Committee"). Under the 2021 Inducement Plan, the Committee may choose to grant (i) nonstatutory stock options, (ii) stock appreciation rights, (iii) restricted stock awards, (iv) restricted stock unit awards, (v) performance stock awards, (vi) performance cash awards, and (vii) other stock awards to eligible recipients, with each grant to be evidenced by an award agreement setting forth the terms and conditions of the grant as determined by the Committee in accordance with the terms of the Inducement Plan.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

Certain Relationships and Related Party Transactions

The following includes a summary of transactions since January 1, 2021 to which we have been a party, in which the amount involved in the transaction exceeded $120,000, and in which any of our directors, executive officers or, to our knowledge, beneficial owners of more than 5% of our capital stock or any member of the immediate family of any of the foregoing persons had or will have a direct or indirect material interest.

Recent Transactions with Dong-A ST Co., Ltd.

License Agreement

On September 14, 2022, we entered into a License Agreement with 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 "2022 License Agreement"). The 2022 License Agreement covers the rights to a compound referred to as DA-1241 for treatment of NASH and a compound referred to as DA-1726 for treatment of obesity and NASH. We may also develop DA-1241 for the treatment of T2D. The 2022 License Agreement became effective on November 8, 2022. As of March 24, 2023, Dong-A ST was the beneficial owner of more than 5% of our capital stock.

Under the terms of the 2022 License Agreement, Dong-A (i) received an upfront payment of 2,200 shares of Series A Preferred Stock under the terms of the Securities Purchase Agreement (as defined below); (ii) is eligible to receive single digit royalties on net sales received by us from the commercial sale of products covering DA-1241 or DA-1726; (iii) is eligible to receive commercial-based milestone payments, dependent upon the achievement of specific commercial developments; and (iv) is eligible to receive regulatory milestone payments of up to $178 million for DA-1726 and $138 million for DA-1241, dependent upon the achievement of specific regulatory developments.

Securities Purchase Agreement

On September 14, 2022, in connection with the 2022 License Agreement, we entered into the Securities Purchase Agreement with Dong-A. Pursuant to the Securities Purchase Agreement, upon the consummation of the 2022 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 the Dong-A Warrants.

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

Shared Services Agreement

On September 14, 2022, in connection with the 2022 License Agreement, we and Dong-A entered into 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.

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.

Manufacturing Agreement with Dong-A ST

On September 28, 2018, our predecessor entered into a five year manufacturing and supply agreement with Dong-A ST for manufacturing and supply of NB-01 drug substance and placebos for the purpose of research and development to be used in Phase 3 clinical trials (the "Manufacturing Agreement"). Under the terms of the Manufacturing Agreement, Dong-A ST has agreed to produce for NeuroBo a specified number of tablets of the NB-01 drug substance and placebos at a supply price to be determined at the time of each individual order. In addition, prices were set for stability testing of the NB-01 drug substance and placebo. The Company incurred no such expenses for the years ended December 31, 2022 and 2021.

The Manufacturing Agreement will automatically terminate in the event that the license agreement with Dong-A ST is terminated for any reason. In addition, each of Dong-A ST and NeuroBo may terminate the Manufacturing Agreement (1) upon the material breach by the other party, if the breach is not cured within a specified number of days after receiving notice from the terminating party, or if the breach cannot reasonably be cured within such period and the breaching party has not started to remedy the breach within such period and diligently endeavored to cure the breach within a reasonable time thereafter, or (2) in the event that (i) the other party is the subject of a petition for bankruptcy, reorganization, or arrangement and the same is not dismissed within thirty days thereof, (ii) a receiver or trustee is appointed for all or a substantial portion of the assets of the other party, or (iii) the other party makes an assignment for the benefit of its creditors.

Director Independence

Our common stock is listed on Nasdaq. Under the rules of Nasdaq, independent directors must comprise a majority of a listed company's board of directors. In addition, the rules of Nasdaq require that, subject to specified exceptions, each member of a listed company's audit, compensation and nominating and corporate governance committees be independent. Under the rules of Nasdaq, a director will only qualify as an "independent director" if, in the opinion of that company's board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. Additionally, compensation committee members must not have a relationship with us that is material to the director's ability to be independent from management in connection with the duties of a compensation committee member.

Audit committee members must also satisfy the independence criteria set forth in Rule 10A-3 under the Exchange Act. In order to be considered independent for purposes of Rule 10A-3, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the board of directors or any other board of directors committee: (i) accept, directly or indirectly, any consulting, advisory or other compensatory fee from the listed company or any of its subsidiaries; or (ii) be an affiliated person of the listed company or any of its subsidiaries.

Our Board has undertaken a review of the independence of each director and considered whether each director has a material relationship with us that could compromise his or her ability to exercise independent judgment in carrying out his or her responsibilities. As a result of this review, our Board affirmatively determined that Na Yeon (Irene) Kim, Jason Groves, Michael Salsbury, Andrew Koven Hyung Heon Kim, D. Gordon Strickland and Douglas Swirsky, who was a member of the board through January 2022, are "independent directors" as defined under the applicable rules and regulations of the SEC and the listing requirements and rules of Nasdaq. The Board determined that Richard Kang, our former Chief Executive Officer, President, Interim Chief Financial Officer, Secretary and Treasurer, who served as a director until his resignation on March 29, 2023, was not independent. In making this determination, our Board considered the current and prior relationships that each non-employee director has with us and all other facts and circumstances that our Board deemed relevant in determining each non-employee director's independence, including the participation by our non-employee directors, or their affiliates, in certain financing transactions by the Company and the beneficial ownership of our common stock by each non-employee director.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Service Fees Paid to the Independent Registered Public Accounting Firms

The Audit Committee has considered the scope and fee arrangements for all services provided by BDO USA, LLP, taking into account whether the provision of non-audit-related services is compatible with maintaining BDO USA, LLP independence. The following table presents fees for professional audit services rendered by BDO USA, LLP for the audit of the annual financial statements for the years ended December 31, 2022 and 2021.

	FISCAL YEAR		FISCAL YEAR	
FEE CATEGORY	2022		2021	
Audit fees	$	571,037	$	343,034
Audit-related fees	$	-	$	-
Tax fees	$	-	$	-
All other fees	$	-	$	-
Total fees	$	571,037	$	343,034

Audit fees consist of fees billed for services relating to the audit of our annual financial statement and review of our quarterly financial statements, services that are normally provided in connection with statutory and regulatory filings or engagements, comfort letters, reports on an issuer's internal controls, and review of documents to be filed with the SEC (e.g. periodic filings, registration statements, and company responses to SEC comment letters).

Audit-related fees are related to other assurance and related services that are traditionally performed by an independent accountant such as employee benefit plan audits, due diligence related to mergers and acquisitions, accounting assistance and audits in connection with proposed or consummated acquisitions, attest services that are not required by statute or regulation, and consultations concerning proposed accounting and reporting standards.

Tax fees relate to permissible services for technical tax advice related to federal and state income tax matters.

Policy on Audit Committee Pre-Approval of Audit and Permissible Non-Audit Services of Independent Registered Public Accounting Firm

Our audit committee generally pre-approves all audit and permitted non-audit and tax services provided by the independent registered public accounting firm. Pre-approval is detailed as to the particular service or category of services and is generally subject to a specific budget. The independent registered public accounting firm and management are required to periodically report to the audit committee regarding the extent of services provided by the independent registered public accounting firm in accordance with this pre-approval, and the fees for the services performed to date. Our audit committee may also pre-approve particular services on a case-by-case basis. All of the services relating to the fees described in the table above were approved by our audit committee.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) The following documents are filed as part of this report:

1. Financial Statements: The information required by this item is contained in Item 8 of this Form 10-K.

2. Financial Statement Schedules:

No financial statement schedules are provided because the information called for is not required or is shown either in the financial statements or notes thereto.

3. The exhibits to this Annual Report are as follows:

EXHIBIT NUMBER	DESCRIPTION OF DOCUMENT
2.1	Agreement and Plan of Merger, dated as of December 31, 2020, by and among the Registrant, Shelby Merger Sub 1, Inc., Shelby Merger Sub 2, LLC, ANA Therapeutics, Inc. and Akash Bakshi (incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K, filed on January 6, 2021).
3.1	Third Amended and Restated Certificate of Incorporation of Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed on August 10, 2016).
3.2	Certificate of Amendment (Reverse Stock Split) to the Third Amended and Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed on December 31, 2019).
3.3	Certificate of Amendment (Name Change) to the Third Amended and Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K, filed on December 31, 2019).

3.4	Certificate of Amendment (Reverse Stock Split) to the Third Amended and Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed on September 12, 2022).
3.5	Second Amended and Restated Bylaws of Registrant (incorporated by reference to Exhibit 3.4 to the Registrant's Annual Report on Form 10-K, filed on March 30, 2020).
3.6	Amendment to Second Amended and Restated Bylaws of Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed on November 4, 2022).
3.7	Certificate of Designation of Preferences, Rights and Limitations, filed with the Delaware Secretary of State on November 4, 2022, with respect to the Series A Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed with the SEC on November 8, 2022).
3.8	Certificate of Designation of Preferences, Rights and Limitations, filed with the Delaware Secretary of State on November 4, 2022, with respect to the Series B Convertible Preferred Stock (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K filed with the SEC on November 8, 2022).
4.1	Form of Common Stock Certificate of the Registrant (incorporated by reference to Exhibit 4.1 to the Registrant's Amendment No. 1 to Registration Statement on Form S-1, filed on June 13, 2016).
4.2	Form of Warrant to Purchase Common Stock (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K, filed on March 13, 2017).
4.3	Warrant to Purchase Stock, dated July 31, 2018, by and between the Registrant and Silicon Valley Bank (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8- K, filed on August 6, 2018).
4.4	Form of Placement Agent's Warrant to Purchase Common Stock (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed with the SEC on April 15, 2020).
4.5	Form of Warrant to Purchase Common Stock (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed with the SEC on January 21, 2021).
4.6	Form of Warrant to Purchase shares of Common Stock (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed with the SEC on October 4, 2021).
4.7	Form of Series A Warrant to purchase shares of common stock (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed with the SEC on November 8, 2022).
4.8	Form of Series B Warrant to purchase shares of common stock (incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K filed with the SEC on November 8, 2022)
4.9	Warrant Agency Agreement, dated as of November 8, 2022, by and between the Registrant and American Stock Transfer and Trust Company LLC (incorporated by reference to Exhibit 4.3 to the Registrant's Current Report on Form 8-K filed with the SEC on November 8, 2022).
4.10	Form of Dong-A Series A Warrant to purchase shares of common stock (incorporated by reference to Exhibit 4.4 to the Registrant's Current Report on Form 8-K filed with the SEC on November 8, 2022)

4.11	Form of Dong-A Series B Warrant to purchase shares of common stock (incorporated by reference to Exhibit 4.5 to the Registrant's Current Report on Form 8-K filed with the SEC on November 8, 2022)
4.12	Description of Securities , filed herewith
10.1#	Form of Indemnification Agreement (incorporated by reference to Exhibit 10.1 to the Registrant's Registration Statement on Form S-1, filed on April 18, 2016).
10.9+	Amended and Restated License Agreement, effective as of August 2, 2018, by and between the Registrant and Pfizer Inc. (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on August 6, 2018).
10.10#	2019 Equity Incentive Plan (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K, filed on December 31, 2019).
10.11+++	License and Collaboration Agreement, dated as of July 23, 2019, by and between the Registrant and Beijing SL Pharmaceutical Co., Ltd. (incorporated by reference to Exhibit 10.6 to the Registrant's Current Report on Form 8-K, filed on July 25, 2019).
10.12	Membership Agreement, dated as of November 11, 2020, by and between WeWork and the Registrant (incorporated by reference to Exhibit 10.15 to the Registrant's Annual Report on Form 10-K, filed on March 30, 2020).
10.13+++	Manufacturing and Supply Agreement, dated as of September 28, 2018, between Dong-A ST Co., Lt. and the Registrant (incorporated by reference to Exhibit 10.36 to the Registrant's Registration Statement on Form S-4, filed on September 3, 2019).
10.14	Lease Agreement, dated as of May 2, 2019, by and between Gyeonggi Urban Innovation Corporation and NeuroBo Co., Ltd. (incorporated by reference to Exhibit 10.40 to the Registrant's Registration Statement on Form S-4, filed on September 3, 2019).
10.15+++	License Agreement, dated as of January 18, 2018, as amended on April 18, 2018 and July 24, 2019, by and between Dong-A ST Co., Ltd. and the Registrant (incorporated by reference to Exhibit 10.42 to the Registrant's Registration Statement on Form S-4, filed on September 3, 2019).
10.16+++	Acquisition Agreement, dated January 18, 2018, as amended on April 18, 2018 and July 24, 2019, by and between Dong-A ST Co., Ltd. and the Registrant (incorporated by reference to Exhibit 10.43 to the Registrant's Registration Statement on Form S-4, filed on September 3, 2019).
10.17++	Contingent Value Rights Agreement, dated as of December 30, 2019, by and among the Registrant, Grand Rapids Holders Representative, LLC, Computershare Inc. and Computershare Trust Company, N.A. (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on December 31, 2019).
10.18	First Amendment to Contingent Value Rights Agreement, dated as of December 30, 2019, by and among the Registrant, Grand Rapids Holders Representative, LLC, Computershare Inc. and Computershare Trust Company, N.A., dated as of March 23, 2021 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on March 24, 2021).
10.19#	Form of Incentive Stock Option Agreement for 2019 Equity Incentive Plan (incorporated by reference to Exhibit 10.31 to the Registrant's Annual Report on Form 10-K, filed on March 30, 2020).

10.20#	Form of Restricted Stock Agreement for 2019 Equity Incentive Plan (incorporated by reference to Exhibit 10.32 to the Registrant's Annual Report on Form 10-K, filed on March 30, 2020).
10.21#	Form of Non-Qualified Stock Option Agreement for 2019 Equity Incentive Plan (incorporated by reference to Exhibit 10.33 to the Registrant's Annual Report on Form 10-K, filed on March 30, 2020).
10.22	Form of Securities Purchase Agreement (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on April 15, 2020).
10.23	Manufacturing and Supply Agreement (NB-02 formerly DA-9803), dated as of June 7, 2020, by and between Dong-A ST Co., Ltd. and the Registrant (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q, filed on August 11, 2020).
10.24	Form of Support Agreement (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on January 6, 2021).
10.25	Form of Lock-Up Agreement (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K, filed on January 6, 2021).
10.26	Form of Securities Purchase Agreement, dated as of October 1, 2021, by and among NeuroBo Pharmaceuticals, Inc. and the purchasers identified on the signature pages thereto. (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed with the SEC on October 4, 2021).
10.27#	NeuroBo Pharmaceuticals, Inc. 2021 Inducement Plan (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed with the SEC on November 4, 2021).
10.28#	Form of Stock Option Grant Notice, Option Agreement and Notice of Exercise under the NeuroBo Pharmaceuticals, Inc. 2021 Inducement Plan (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed with the SEC on November 4, 2021).
10.29#	Employment Agreement entered into on November 3, 2021 by and between NeuroBo Pharmaceuticals, Inc. and Ben Gil Price (incorporated by reference to Exhibit 10.4 to the Registrant's Current Report on Form 8-K filed with the SEC on November 4, 2021).
10.30#	Amended and Restated Non-Employee Director Compensation Policy, dated January 14, 2022 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, as filed on January 28, 2022).
10.31	Amendment to Membership Agreement, dated December 23, 2021, by and between WeWork and the Registrant (incorporated by reference to Exhibit 10.47 to the Registrant's Annual Report on Form 10-K, as filed on March 30, 2022).
10.32	Amendment to Membership Agreement, dated February 9, 2022, by and between WeWork and the Registrant (incorporated by reference to Exhibit 10.48 to the Registrant's Annual Report on Form 10-K, as filed on March 30, 2022).
10.33	Amendment to Membership Agreement, dated April 19, 2022, by and between WeWork and the Registrant (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q, as filed on May 13, 2022).

10.34	Amendment to Membership Agreement, dated August 30, 2022, by and between WeWork and the Registrant (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q, as filed on November 14, 2022).
10.35	License Agreement, dated September 14, 2022, by and between Dong-A ST Co., Ltd. and the Registrant (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, as filed on September 14, 2022).
10.36	Shared Services Agreement, , dated September 14, 2022, by and between Dong-A ST Co., Ltd. and the Registrant (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K, as filed on September 14, 2022).
10.37	Securities Purchase Agreement, dated September 14, 2022, by and between Dong-A ST Co., Ltd. and the Registrant (incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K, as filed on September 14, 2022).
10.38	Registration Rights Agreement, dated September 14, 2022, 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 (incorporated by reference to Exhibit 10.4 to the Registrant's Current Report on Form 8-K, as filed on September 14, 2022).
10.39	Investor Rights Agreement, , dated September 14, 2022, by and between Dong-A ST Co. Ltd. and the Registrant (incorporated by reference to Exhibit 10.5 to the Registrant's Current Report on Form 8-K, as filed on September 14, 2022).
10.40	NeuroBo Pharmaceuticals, Inc. 2022 Equity Incentive Plan, effective as of December 22, 2022 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, as filed on December 22, 2022)
10.41	NeuroBo Pharmaceuticals, Inc. 2022 Equity Incentive Plan Forms of Restricted Stock Unit Agreement and Option Grant Agreements (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K, as filed on December 22, 2022)
10.42	Amendment to Membership Agreement, dated December 14, 2022 by and between WeWork and the Registrant, filed herewith.
10.43	Separation and Release Agreement, dated January 16, 2023, by and between the Registrant and Gil Price (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, as filed on January 18, 2023.)
21.1*	Subsidiaries of the Registrant
23.1*	Consent of BDO USA, LLP
31.1*	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to Exchange Act Rule 13a-14(a) or 15d-14(a), as Adopted Pursuant to Section 302 of the Sarbanes Oxley Act of 2002
32.1**	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS*	Inline XBRL Instance Document
101.SCH*	Inline XBRL Taxonomy Extension Schema Document

101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

#	Indicates management contract or compensatory plan
*	Filed herewith
**	Furnished herewith
+	Registrant has omitted and filed separately with the SEC portions of the exhibit pursuant to a confidential treatment request under Rule 406 promulgated under the Securities Act.
++	Certain schedules and exhibits have been omitted pursuant to Item 601(b)(2) of Regulation S-K. A copy of any omitted schedule and/or exhibit will be furnished to the SEC upon request.
+++	Certain schedules and exhibits have been omitted pursuant to Item 601(a)(5) of Regulation S-K. A copy of any omitted schedule and/or exhibit will be furnished to the SEC upon request. Certain portions of the exhibits that are not material and would be competitively harmful if publicly disclosed have been redacted pursuant to Item 601(b)(10)(iv) of Regulation S-K. Copies of the unredacted exhibits will be furnished to the SEC upon request.

ITEM 16. FORM 10-K SUMMARY

None

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: March 30, 2023

NEUROBO PHARMACEUTICALS, INC.

By: /s/ Joseph Hooker
Joseph Hooker
Interim President and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

SIGNATURE	TITLE	DATE
/s/ Joseph Hooker Joseph Hooker	Interim President and Chief Executive Officer (Principal Executive Officer, Principal Financial Officer and Principal Accounting Officer)	March 30, 2023
/s/ Andrew Koven Andrew Koven	Chair of the Board of Directors	March 30, 2023
/s/ Jason L. Groves Jason L. Groves	Director	March 30, 2023
/s/ Hyung Heon Kim Hyung Heon Kim	Director	March 30. 2023
/s/ Na Yeon (Irene) Kim Na Yeon (Irene) Kim	Director	March 30, 2023
/s/ Michael Salsbury Michael Salsbury	Director	March 30, 2023
/s/ D. Gordon Strickland D. Gordon Strickland	Director	March 30, 2023

DESCRIPTION OF THE REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

General

The following summary describes the securities of NeuroBo Pharmaceuticals, Inc. (the "***Company***") registered under Section 12 of the Securities Exchange Act of 1934, as amended (the "***Exchange Act***"), certain provisions of the Company's certificate of incorporation and bylaws, and certain provisions of Delaware law. Because it is only a summary, it does not contain all of the information that may be important to you.

The Company has one class of securities registered under Section 12 of the Exchange Act, the Company's common stock, par value $0.001 per share ("***Common Stock***").

The Company's authorized capital stock consists of 100,000,000 shares of Common Stock, $0.001 par value per share, and 10,000,000 shares of preferred stock, $0.001 par value per share ("***Preferred Stock***").

On September 12, 2022, the Company completed a 30-for-1 reverse stock split of its Common Stock. As a result of the foregoing, every thirty (30) shares of Common Stock outstanding was automatically changed and reclassified into one (1) share of Common Stock.

In November 2022, the Company's board of directors (the "***Board***") designated 3,700 shares of Preferred Stock as Series A Convertible Preferred Stock, pursuant to a License Agreement with Dong-A ST Co. Ltd. ("***Dong-A***"), dated September 14, 2022 and a Securities Purchase Agreement with Dong-A, dated September 14, 2022. On November 8, 2022, the Company issued 3,700 shares of Series A Convertible Stock to Dong-A. On December 22, 2022, the Company's stockholders approved the conversion of the Series A Preferred Stock and all of the Series A Preferred Stock converted into 12,333,333 shares of Common Stock.

In November 2022, the Board designated 2,602,997 shares of Preferred Stock as Series B Convertible Preferred Stock, all of which were issued and outstanding in accordance with an Underwriting Agreement between the Company and Ladenburg Thalmann & Co. Inc., as part of an underwritten public offering by the Company. As of March 29, 2023, all of the shares of Series B Preferred Stock had been converted into shares of our Common Stock.

Description of Common Stock

The following description of our Common Stock is a summary and does not purport to be complete. It is subject to and qualified in its entirety by reference to our Third Amended and Restated Certificate of Incorporation, as amended (the "***Certificate of Incorporation***") and our Second Amended and Restated Bylaws (the "***Bylaws***"), each of which is incorporated by reference as an exhibit to the Annual Report on Form 10-K of which this Description of Registrant's Securities is a part. We encourage you to read our Certificate of Incorporation, Bylaws, and the applicable provisions of the Delaware General Corporation Law for additional information.

Voting Rights. Holders of Common Stock are entitled to one vote per share on all matters voted on by the stockholders, including the election of directors. The Company's Certificate of Incorporation and Bylaws do not provide for cumulative voting in the election of directors.

Dividend Rights. Holders of Common Stock are entitled to receive dividends, if any, as may be declared from time to time by the Board in its discretion out of funds legally available for the payment of dividends.

Liquidation Rights. In the event of the Company's liquidation, the holders of the Company's Common Stock will be entitled to share ratably in any distribution of the Company's assets after payment of all debts and other liabilities and the preferences payable to holders of shares of Preferred Stock then outstanding, if any.

Applicable Anti-Takeover Provisions

Set forth below is a summary of the provisions of the Certificate of Incorporation and the Bylaws that could have the effect of delaying or preventing a change in control of the Company. The following description is only a summary and it is qualified by reference to the Certificate of Incorporation, the Bylaws and relevant provisions of the Delaware General Corporation Law ("***DGCL***").

Delaware Anti-Takeover Law

The Company is subject to Section 203 of the DGCL. Section 203 generally prohibits a public Delaware corporation such as us from engaging in a "business combination" with an "interested stockholder" for a period of three years following the time that the stockholder became an interested stockholder, unless:

- prior to the time the stockholder became an interested stockholder, the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;
- upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the number of shares outstanding (a) shares owned by persons who are directors and also officers and (b) employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- at or subsequent to the time the stockholder became an interested stockholder, the business combination is approved by the board and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66-2/3% of the outstanding voting stock which is not owned by the interested stockholder.

Section 203 defines a business combination to include:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, lease, exchange, mortgage, pledge, transfer or other disposition (in one transaction or a series of transactions) involving the interested stockholder of 10% or more of the assets of the corporation (or its majority-owned subsidiary);
- subject to exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- subject to exceptions, any transaction involving the corporation that has the effect, directly or indirectly, of increasing the proportionate share of the stock or any class or series of the corporation beneficially owned by the interested stockholder; and
- the receipt by the interested stockholder of the benefit, directly or indirectly (except proportionately as a stockholder of such corporation), of any loans, advances, guarantees, pledges or other financial benefits, other than certain benefits set forth in Section 203, provided by or through the corporation.

In general, Section 203 defines an interested stockholder as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person that is an affiliate or associate of such entity or person.

Charter Documents

The Company's Certificate of Incorporation and Bylaws provide that the Board be divided into three classes of directors, as nearly equal in number as possible, with each class serving a staggered three-year term. The classification system of electing directors may tend to discourage a third-party from making a tender offer or otherwise attempting to obtain control of us since the classification of the board of directors generally increases the difficulty of replacing a majority of directors. In addition, our Certificate of Incorporation and Bylaws:

- provide that any action required or permitted to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and may not be effected by any consent in writing;
- establish advance notice requirements for nominations for election to our Board or for proposing matters that can be acted upon at a stockholder meeting;
- provide that the authorized number of directors may be changed only by resolution of the board of directors; and
- provide that special meetings of our stockholders may be called only by the chairman of the Board, the chief executive officer or the Board pursuant to a resolution adopted by a majority of the total number of authorized directors.

The DGCL provides generally that the affirmative vote of a majority of the shares entitled to vote is required to amend a corporation's bylaws, unless a corporation's certificate of incorporation requires a greater percentage or also confers the power upon the corporation's directors. The Company's Bylaws may be amended or repealed by:

- the affirmative vote of a majority of our directors then in office; or
- the affirmative vote of the holders of at least 66-2/3% of the voting power of all then-outstanding shares of our capital stock entitled to vote generally in the election of directors.

The foregoing provisions of the Certificate of Incorporation may only be amended or repealed by the affirmative vote of a majority of directors and the affirmative vote of the holders of at least 66-2/3% of the voting power of all then-outstanding shares of our capital stock entitled to vote generally in the election of directors.

These and other provisions contained in the Certificate of Incorporation or Bylaws could delay or discourage some types of transactions involving an actual or potential change in control or change in management, including transactions in which stockholders might otherwise receive a premium for their shares over then current prices, and may limit the ability of stockholders to remove current management or approve transactions that stockholders may deem to be in their best interests and, therefore, could adversely affect the price of our common stock.

Exclusive Forum Provision

In accordance with an exclusive forum provision set forth in the Bylaws, unless the Company consents in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if and only if the Court of Chancery of the State of Delaware lacks subject matter jurisdiction, any state court located within the State of Delaware or, if and only if all such state courts lack subject matter jurisdiction, the federal district court for the District of Delaware) shall be the sole and exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: (a) any derivative action or proceeding brought on behalf of the Company, (b) any action asserting a claim of breach of a fiduciary duty owed by any director, officer or other employee of the Company to the Company or the Company's stockholders, (c) any action asserting a claim arising pursuant to any provision of the DGCL, the Certificate of Incorporation or the Bylaws or (d) any action asserting a claim governed by the internal affairs doctrine, in all cases to the fullest extent permitted by law and subject to the court's having personal jurisdiction over the indispensable parties named as defendants. The exclusive forum provision does not

apply to actions brought to enforce a duty or liability created by the Exchange Act, or the Securities Act of 1933, as amended, or any claim for which the federal courts have exclusive jurisdiction.

Listing

Our Common Stock trade on NASDAQ Capital Market under the trading symbol “NRBO”.

Transfer Agent

The Company’s transfer agent is American Stock Transfer and Trust Company, LLC.

wework

AMENDMENT TO MEMBERSHIP AGREEMENT

HI ADAM PERLISH

Please review the Amendment to your Membership Agreement below.

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

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

MEMBER INFORMATION

Primary member: Adam Perlish
adam.perlish@neurobopharma.com
+17034070449

AMENDED MEMBERSHIP DETAILS

WeWork 200 Berkeley

Current Office(s)

19-120 • 2 person office

Membership Fee:
$1,750.00/mo from January 1, 2023

Commitment term

Start date: January 1, 2023
End date: March 31, 2023

MEMBERSHIP FEE SUMMARY

OFFICE	DATES	MEMBERSHIP FEE	DISCOUNT	NET DISCOUNTED FEE
19-120	01/01/2023 - 03/31/2023	$1,750.00	$87.50	$1,662.50

ANNUAL ESCALATION

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

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

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

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

Community Manager's signature

Molly McLaughlin

200 Berkeley Street Tenant LLC

Electronic Signature

Gil Price

Signed on December 14, 2022

WeWork

200 Berkeley Street
Boston, MA, 02116, USA

VAT: 834152702

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

Exhibit 21.1

SUBSIDIARIES OF NEUROBO PHARMACEUTICALS, INC.

Name	**Jurisdiction of Organization**
NeuroBo Therapeutics, Inc.	Delaware
NeuroBo Co., Ltd.	A Korean limited company
ANA Therapeutics, LLC	Delaware

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

NeuroBo Pharmaceuticals, Inc.
Boston, Massachusetts

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (No. 333-252412, 333-220315, 333-217296, 333-256135 and 333-269365), Form S-1 (No. 333-267482) and Form S-8 (No. 333-237535, 333-232667, 333-225435, 333-222675, 333-213946 and 333-213014) of NeuroBo Pharmaceuticals, Inc. of our report dated March 30, 2023, relating to the consolidated financial statements which appear in this Annual Report on Form 10-K.

/s/ BDO USA, LLP
Boston, Massachusetts
March 30, 2023

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER

I, Joseph Hooker, certify that:

1. I have reviewed this annual report on Form 10-K of NeuroBo Pharmaceuticals, Inc.;

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

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

4. I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

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

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

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

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

March 30, 2023

/s/ Joseph Hooker
Joseph Hooker
Interim President and Chief Executive Officer (Principal Executive Officer and Principal Financial Officer)

Exhibit 32.1

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

In connection with the Annual Report of NeuroBo Pharmaceuticals, Inc. (the "Company") on Form 10-K for the year ended December 31, 2022 as filed with the Securities and Exchange Commission (the "Report"), I, Joseph Hooker, Interim President and Chief Executive Officer, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

March 30, 2023 /s/ Joseph Hooker

Joseph Hooker
Interim President, and Chief Executive Officer (Principal Executive Officer and Principal Financial Officer)