2022

Annual Report

to Shareholders

Aravive, Inc.

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 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 THE SECURITIES EXCHANGE ACT OF 1934**
FOR THE TRANSITION PERIOD FROM _____ TO _____
Commission File Number 001-36361

Aravive, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**26-4106690**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

River Oaks Tower
3730 Kirby Drive, Suite 1200
Houston, Texas 77098
(Address of principal executive offices)
(936) 355-1910
(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 each exchange on which registered**
Common stock, par value $0.0001 per share	**ARAV**	**Nasdaq Global Select Market**

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 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, smaller reporting company, or an emerging growth company. See the definition 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 12b-2 of the Exchange Act). Yes ☐ No ☒

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant, based on the closing price of the shares of common stock on The Nasdaq Global Select Market on June 30, 2022, the last business day of the registrant's most recently completed second fiscal quarter, was $19,068,322.

The number of shares of registrant's Common Stock outstanding as of March 10, 2023 was 59,844,850.

Documents incorporated by reference: None

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PART I

GENERAL

Unless otherwise indicated, all references to “Aravive,” “we,” “us,” “our” or the “Company” in this Annual Report on Form 10-K refer to Aravive, Inc. and our wholly owned subsidiary, Aravive Biologics, Inc.

“Aravive®” and our other registered and common law trade names, trademarks and service marks are the property of Aravive, Inc. Other trade names, trademarks and service marks used in this Annual Report on Form 10-K are the property of their respective owners. Solely for convenience, the trademarks and trade names in this Annual Report on Form 10-K may be referred to without the ® and ™ symbols, but such references should not be construed as any indicator that their respective owners will not assert their rights thereto.

We may announce material business and financial information to our investors using our investor relations website at http://ir.aravive.com/investors/financial-information. We therefore encourage investors and others interested in Aravive to review the information that we make available on our website, in addition to following our filings with the Securities and Exchange Commission (the “SEC”), webcasts, press releases and conference calls. Information contained on, or that can be accessed through, our website is not incorporated by reference into this Annual Report on Form 10-K, and you should not consider information on our website to be part of this Annual Report on Form 10-K.

FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains “forward-looking statements” that involve risks and uncertainties. Our actual results could differ materially from those discussed in the forward-looking statements. The statements contained in this report that are not purely historical are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the “Securities Act”) and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Forward-looking statements are often identified by the use of words such as, but not limited to, “anticipate,” “believe,” “can,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “project,” “seek,” “should,” “strategy,” “target,” “will,” “would” and similar expressions or variations intended to identify forward-looking statements. These statements are based on the beliefs and assumptions of our management based on information currently available to management. Such forward-looking statements are subject to risks, uncertainties and other important factors that could cause actual results and the timing of certain events to differ materially from future results expressed or implied by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those identified below and those discussed in the section titled “Risk Factors” included under Part I, Item 1A below. Furthermore, such forward-looking statements speak only as of the date of this report. Except as required by law, we undertake no obligation to update any forward-looking statements to reflect events or circumstances after the date of such statements.

This Annual Report on Form 10-K also contains market data related to our business and industry. These market data include projections that are based on a number of assumptions. If these assumptions turn out to be incorrect, actual results may differ from the projections based on these assumptions. As a result, our markets may not grow at the rates projected by these data, or at all. The failure of these markets to grow at these projected rates may harm on our business, results of operations, financial condition and the market price of our common stock.

Summary Risk Factors

The following is a summary of the key risks relating to the Company. A more detailed description of each of the risks can be found below in Item 1A. Risk Factors.

Risks Related to Our Financial Position And Capital Requirements

- We have a limited operating history and have incurred significant losses since inception. We have only one product candidate, batiraxcept, and no commercial sales.
- We expect to continue to incur significant losses for the foreseeable future and may never achieve or maintain profitability.
- There is uncertainty regarding our ability to maintain liquidity sufficient to operate our business effectively, which raises substantial doubt about our ability to continue as a going concern.
- We will need additional funds to support our operations and such funding may not be available to us at all or on acceptable terms.

- Raising additional funds by issuing securities may cause dilution to existing stockholders, and raising funds through lending and licensing arrangements may restrict our operations or require it to relinquish proprietary rights.
- Our operating results may fluctuate significantly, making our operations difficult to predict.

Risks Related To Our Business

- Changes in general economic conditions, geopolitical conditions, domestic and foreign trade policies, monetary policies and other factors beyond our control may adversely impact our business and operating results.
- Business disruptions could seriously harm our future revenue and financial condition and increase costs and expenses.
- Our reliance on government funding may impose requirements that limit our ability to take certain actions and subject us to potential financial penalties.
- If the agreements underlying the license on which we rely were terminated, or if other rights that may be necessary for commercialization of our intended products cannot be obtained, we would be materially adversely affected.
- If we fail to comply with our obligations in our intellectual property licenses, we could lose important license rights.
- We depend on collaborations with third parties for the development and commercialization of some of our product candidates.
- We rely extensively on our information technology systems and are vulnerable to damage and interruption.
- We may face particular data protection, data security and privacy risks in connection with privacy regulations.
- Any failure to maintain the security of information could expose us to litigation, government enforcement actions and costly response measures, and could disrupt our operations and harm our reputation.
- We currently have only one product candidate, batiraxcept, in clinical development.
- We are dependent on our ability to successfully advance batiraxcept through the various stages of clinical development.
- We have limited experience conducting clinical trials.
- If the actual or perceived therapeutic benefits, or the safety or tolerability profile of batiraxcept, is not equal to or superior to other competing treatments, we may terminate the development of batiraxcept.
- Any problems obtaining the standard of care drugs used in our clinical trials could result in a trial delay or interruption.
- If batiraxcept, requires or would commercially benefit from a companion diagnostic, and if we are unable to obtain regulatory clearance or approval for such a companion diagnostic test we may not realize the full commercial potential of batiraxcept.
- If batiraxcept has undesirable side effects, it may preclude or delay its development.
- If our trials do not show an increase in efficacy or an acceptable adverse event profile, development may be terminated.
- We rely upon one third party to manufacture our drug substance.
- We may be unable to manufacture our product candidate in sufficient quantities for commercialization.
- Changes to our third-party contract manufacturer could adversely impact our timelines and costs.
- We rely on third parties as vendors, manufacturers and for various services, over which we have no control.
- If the third parties perform in an unsatisfactory manner, it may harm our business.
- We may not be able to retain key personnel or attract, retain and motivate qualified personnel.

Risks Related to Clinical Development, Regulatory Approval and Commercialization

- If the results from preclinical studies or clinical trials of our product candidate are unfavorable, further development or commercialization of the product candidate could be terminated or delayed.
- Clinical trials are very expensive, time-consuming, difficult to design and implement and involve an uncertain outcome.
- Enrollment and retention of subjects 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.
- If we are unable to obtain regulatory approval as planned, we may be required to conduct additional clinical trials beyond those that we contemplate, which could increase the expense of obtaining, and delay the receipt of, necessary marketing approvals.
- Fast Track designation for our product candidates may not lead to a faster development, regulatory review or approval process.

- It is possible that we may not be able to obtain or maintain orphan drug designation or exclusivity for our drug candidates.
- We face significant competition from other biotechnology and pharmaceutical companies.
- Batiraxcept may cause adverse effects or have other properties that could delay or prevent our regulatory approval or limit the scope of any approved label or market acceptance.
- Improper activities by our employees, independent contractors, principal investigators, consultants, commercial collaborators, service providers and other vendors could have an adverse effect on our results of operations.
- If we are not able to obtain, or are delayed in obtaining, required regulatory approvals, we will not be able to commercialize, or will be delayed in commercializing batiraxcept, and we may never obtain approval for or commercialize batiraxcept.
- Even if we obtain regulatory approval, we, may face future development and regulatory difficulties.
- Our product candidate may not receive market acceptance by physicians, patients, third-party payors or others.
- Any failures to comply with healthcare regulatory laws could negatively impact our business.
- We are subject to product liability risks which could result in lawsuits that may require us to incur substantial liabilities.
- We will need to establish sales, marketing and distribution.
- Obtaining approval to commercialize batiraxcept outside of the United States will subject us to a variety of risks.
- Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval.

Risks Related to Our Intellectual Property

- We may be unable to obtain and maintain patent protection for batiraxcept, or the scope of any patent protection we do obtain may be insufficient.
- We may be involved in lawsuits to protect or enforce the patents upon which we rely.
- Changes in U.S. patent law could diminish the value of patents and impair our ability to protect our product candidate.
- If a third party claims we are infringing on their intellectual property rights, we could incur significant expenses, or be prevented from further developing or commercializing batiraxcept.
- We may not be able to protect our intellectual property rights throughout the world, which could impair our business.
- We are subject to the possibility that a competitor will discover our trade secrets and that they will be misappropriated or disclosed.
- Our patent protection could be reduced or eliminated for non-compliance with various governmental requirements.
- Intellectual property rights do not necessarily address all potential threats to our competitive advantage.
- We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

Risks Related to the Ownership of Our Common Stock

- Our failure to meet the continued listing requirements of The Nasdaq Global Select Market could result in a delisting of our common stock.
- Our stock price is volatile and may be volatile in the future.
- Our executive officers, directors, entities under their control and principal stockholders can exert significant influence on all matters submitted to stockholders for approval due to their share ownership.
- We incur significant costs as a result of operating as a public company.
- We are currently a “smaller reporting company,” as defined in the Exchange Act and have elected to take advantage of certain of the scaled disclosures available to smaller reporting companies which may make our stock less attractive to investors.
- An active trading market for our common stock may not be maintained.
- If securities or industry analysts do not publish research, or publish inaccurate or unfavorable research, about our business, our stock price and trading volume could decline.
- Provisions in our corporate charter documents and under Delaware law could make an acquisition of us more difficult and may prevent attempts by our stockholders to replace or remove our current management.
- Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for certain disputes between us and our stockholders.

- Our employment arrangements with our executive officers may require us under certain circumstances to pay severance benefits.
- We do not anticipate paying any cash dividends on our common stock in the foreseeable future.

Item 1. Business.

Overview

Aravive, Inc. ("Aravive" or the "Company") was incorporated on December 10, 2008 in the State of Delaware. Aravive Biologics, Inc. ("Aravive Biologics"), our wholly owned subsidiary, was incorporated in 2007. We are a clinical-stage oncology company developing transformative treatments designed to halt the progression of life-threatening diseases, including cancer and fibrosis.

Batiraxcept (formerly AVB-500), is an ultrahigh-affinity, decoy protein that targets the GAS6-AXL signaling pathway. By capturing serum GAS6, batiraxcept starves the AXL pathway of its signal, potentially halting the biological programming that promotes disease progression. AXL receptor signaling plays an important role in multiple types of malignancies by promoting metastasis, cancer cell survival, resistance to treatments, and immune suppression.

Our current development program benefits from the availability of a proprietary serum-based biomarker that has accelerated batiraxcept drug development by allowing us to select a pharmacologically active dose and may potentially identify the cancer patients that have the best chance of responding to batiraxcept.

In our completed Phase 1 clinical trial in healthy volunteers with batiraxcept, we have demonstrated proof of mechanism for batiraxcept in neutralizing GAS6. Importantly, batiraxcept had a favorable safety profile preclinically and in the first in human trial and Phase 1b clinical trial in cancer patients.

In August 2018, the U.S Food and Drug Administration (the "FDA") designated as a Fast Track development program the investigation of batiraxcept, for platinum-resistant recurrent ovarian cancer ("PROC").

In December 2018, we initiated our Phase 1b clinical trial of batiraxcept combined with standard of care therapies in patients with PROC, for which we reported results in July 2020.

In April 2020, we entered into a license and collaboration agreement with WuXi Biologics (Hong Kong) Limited ("WuXi"), the objective of which is to identify and develop novel high-affinity bispecific antibodies against CCN2, also known as connective tissue growth factor ("CTGF"), implicated in cancer and fibrosis and identified from a similar target discovery screen that identified the significance of the AXL/GAS6 pathway in cancer. However, in August 2022, we temporarily halted work on the CTGF program with WuXi in an effort to focus all our resources on ongoing clinical programs.

In November 2020, we entered into the collaboration and license agreement with 3D Medicines Inc. (the "3D Medicines Agreement"), whereby we granted 3D Medicines an exclusive license to develop and commercialize products that contain batiraxcept as the sole drug substance, for the diagnosis, treatment or prevention of human oncological diseases, in China, Taiwan, Hong Kong and Macau (the "Territory").

During the fourth quarter of 2020, we initiated our Phase 1b portion of the Phase 1b/2 trial of batiraxcept in clear cell renal cell carcinoma ("ccRCC") and we dosed our first patient in the trial in March 2021.

During the first quarter 2021, we initiated our registrational Phase 3 trial of batiraxcept in PROC and we dosed our first patient in the trial in April 2021.This global, randomized, double-blind, placebo-controlled trial is designed to evaluate efficacy and safety of batiraxcept at a dose of 15 mg/kg in combination with paclitaxel ("PAC") versus PAC alone.

In May 2021, we announced expansion of batiraxcept development programs into first line pancreatic ductal adenocarcinoma ("PDAC") with the goal of initiating the trial by end of 2021. We dosed our first patient in August 2021.

In June 2021, we announced initial safety, pharmacokinetic ("PK"), and pharmacodynamic ("PD") results from the batiraxcept Phase 1b portion of the Phase 1b/2 clinical trial in ccRCC.

In October 2021, the EMA granted orphan drug designation for batiraxcept for the treatment of PROC, following a recommendation from the Committee for Orphan Medicinal Products.

In November 2021, we announced preliminary data from our Phase 1b trial evaluating batiraxcept in combination with cabozantinib for treatment of ccRCC.

In January 2022, we announced that we had dosed the first patient in the Phase 2 portion of the Phase 1b/2 study of batiraxcept in combination with cabozantinib for treatment of ccRCC.

In March 2022, we announced updated data and new biomarker data from our Phase 1b trial of batiraxcept in ccRCC.

In May 2022, we provided updated data and information at our Key Opinion Leader symposium.

In October 2022, we received a $6 million development milestone payment from 3D Medicines based on the initiation of the global Phase 3 PROC clinical trial in their Territory.

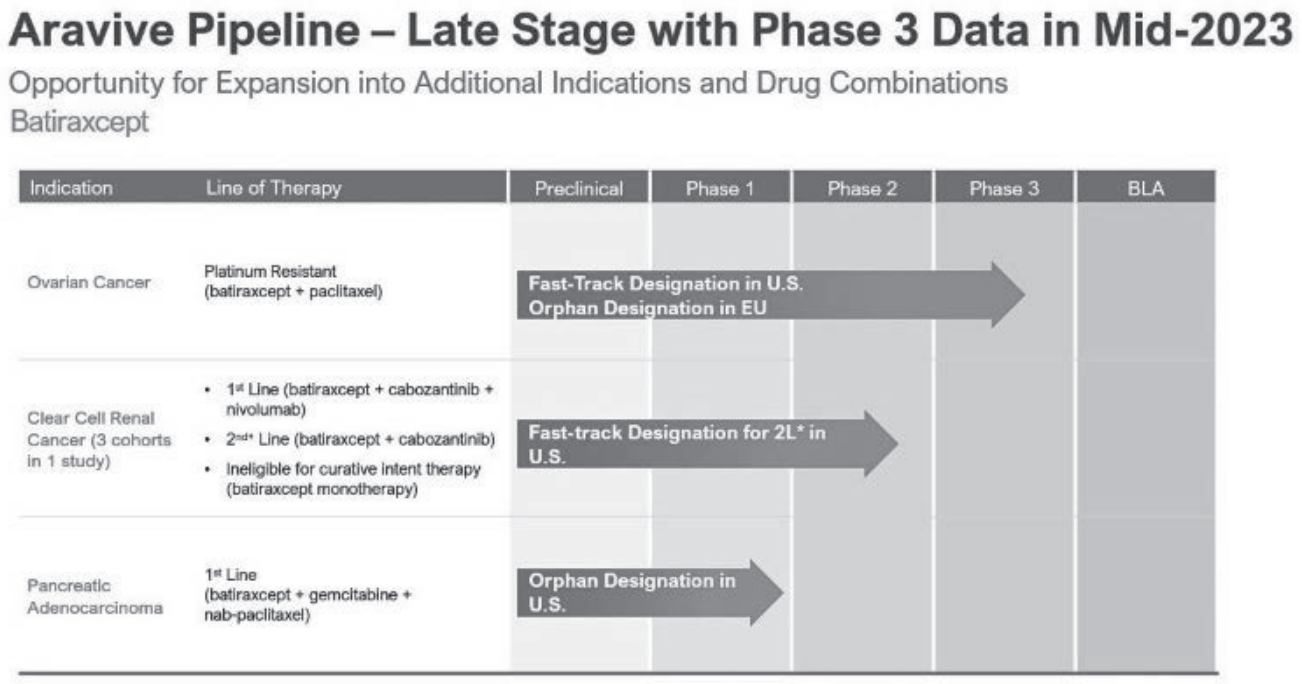
In November 2022, the FDA designated as a Fast Track development program the investigation of batiraxcept for treatment of patients with advanced or metastatic ccRCC who have progressed after 1 or 2 prior lines of systemic therapy that include both immuno-oncology ("IO")-based and vascular endothelial growth factor tyrosine kinase inhibitor ("VEGF-TKI")-based therapies (either in combination or sequentially).

In January 2023, we announced complete enrollment in the global Phase 3 PROC clinical trial.

In February 2023, we presented updated Phase 1b/2 ccRCC data at the 2023 American Society of Clinical Oncology (ASCO) Genitourinary (GU) Cancers Symposium, taking place February 16-18, 2023 in San Francisco and virtually.

In February 2023, we announced that the FDA granted orphan drug designation to batiraxcept for the treatment of PDAC.

Aravive Pipeline



** Specifically, in ccRCC patients who have progressed after 1 or 2 prior lines of systemic therapy that include both immuno-oncology (IO)-based and vascular endothelial growth factor tyrosine kinase inhibitor (VEGF-TKI)-based therapies (either in combination or sequentially)*

First Oncology Indication - Ovarian Cancer and Current Market Opportunity

The decision to select high grade platinum-resistant recurrent ovarian cancer ("PROC") as our first indication was based upon the preclinical data that we generated with batiraxcept in PROC, the fact that high grade serous ovarian cancer tumors are highly AXL positive and the high unmet medical need for effective therapies to treat PROC. In August 2018, the FDA granted Fast Track Designation to batiraxcept for PROC.

Ovarian cancer ranks fifth in cancer deaths among women in the U.S., accounting for more deaths than any other cancer of the female reproductive system. According to the American Cancer Society, it is estimated that in 2023 there will be approximately 19,710 new cases of ovarian cancer diagnosed in the United States and approximately 13,270 ovarian cancer deaths in the United States. A woman's risk of getting ovarian cancer during her lifetime is about 1 in 78. Her lifetime chance of dying from ovarian cancer is about 1 in 108. Due to the nonspecific nature of disease symptoms, currently approximately 70% of ovarian cancer patients are diagnosed with advanced-stage disease, at which point their prognosis is poor. Improving the ability to detect ovarian cancer early is a research priority, given that women diagnosed with localized-stage disease have more than a 90% five-year survival rate.

Decision Resources Group, LLC ("DRG") in its January 2021 Key Findings in Ovarian Cancer, Disease Landscape and Forecast Report estimates the total ovarian cancer market to grow in the major markets (United States, France, Germany, Italy, Spain, the United Kingdom and Japan) at an annual rate of 12.5% from nearly $3 billion in 2019 to nearly $10 billion in 2029.

Treatment of PROC patients (patients whose disease progresses within 6 months of their last platinum-based therapy) on their second- and third-line of therapy consists of a nonplatinum monotherapy as sequential single-agent salvage chemotherapy has been shown to be superior to multiagent chemotherapy in this setting (DRG- December 2019 Ovarian Cancer Disease Landscape and Forecast). Widely used single-agent therapies in this population include gemcitabine, pegylated-liposomal doxorubicin, topotecan, and PAC with or without bevacizumab or Avastin. The median progression free survival ("PFS") rate for patients given standard of care (PAC or doxil/pegylated liposomal doxorubicin ("PLD")) to treat platinum-resistant recurrent ovarian cancer is 3-4 months, with a median overall survival ("OS") of 9-12 months (*A. Davis et al. / Gynecologic Oncology 133 (2014) 624–631*). Adding bevacizumab to the chemotherapy resulted in a median PFS of 6.7 months (*Pujade-Lauraine, et al., J Clin Oncol 32:1302-1308*) but there was no OS benefit (*Stockler MR, et al. J Clin Oncol. 2014 May 1;32(13):1309-16).* In the United States, another treatment option in third-line platinum-resistant/refractory ovarian cancer are poly ADP ribose polymerase inhibitors ("PARPi") which are indicated as a monotherapy for the treatment of patients with deleterious BRCA mutation (germline and/or somatic) with advanced ovarian cancer who have been treated with two or more chemotherapies. There is no standard of care for patients with non-BRCA mutated/ HR proficient ovarian cancer in the fourth- and subsequent-line settings. The majority of these patients have become platinum-resistant and are typically managed with monotherapy chemotherapy treatments.

Data from the Phase 1a and 1b Clinical Trials of Batiraxcept

The safety of batiraxcept was studied in 84 subjects, including 31 healthy volunteers in a Phase 1a clinical trial and 53 PROC patients in a Phase 1b clinical trial (40 in 10 mg/kg cohort, 6 in 15 mg/kg cohort, and 7 in 20 mg/kg cohort).

In December 2018, following a normal healthy volunteer trial that identified a dose of 10mg/kg batiraxcept as sufficient to suppress serum GAS6 levels for a two-week period, we began treating patients in our Phase 1b clinical trial combining 10mg/kg (administered every 2 weeks) batiraxcept with standard-of-care therapies (specifically, PAC or PLD) in patients with PROC. The Phase 1b clinical trial was designed, in part, to confirm the dosing regimen predicated on the Phase 1 trial in healthy volunteers and to identify the dose to investigate in later stage trials. The primary objective of the Phase 1b clinical trial was to assess the safety and tolerability of batiraxcept in combination with PAC or PLD, and secondary objectives were to assess PK and PD (serum GAS6 and soluble AXL ("sAXL") levels), efficacy, and potential immunogenicity of batiraxcept. Exploratory objectives included efficacy endpoints in biomarker (GAS6, AXL) defined populations based on expression of those biomarkers in serum and/or tumor tissue.

Safety Data: Batiraxcept has been generally well-tolerated with no dose-limiting toxicities or unexpected safety signals. There were no batiraxcept-related significant adverse events reported. There were two types of adverse events reported in the Phase 1b PROC trial that were considered related to batiraxcept, as determined by an independent medical monitor: infusion reactions and fatigue. A premedication regimen was designed and implemented during the trial to manage potential infusion reactions.

Pharmacokinetics: Prior data analysis of 31 PROC patients from the 10 mg/kg cohort showed that blood trough levels of batiraxcept taken on Cycle 1 Day 15 ("C1D15") demonstrated statistically significant correlation with clinical activity, as patients who achieved minimal efficacious concentration ("MEC") >13.8 mg/L demonstrated a greater likelihood of response and prolonged PFS. Updated modeling using actual data from all enrolled patients demonstrated that the 20 mg/kg dose is not predicted to improve PFS relative to the 15 mg/kg dose so the dose of 15 mg/kg was selected as the recommended Phase 2 dose or RP2D for batiraxcept.

Clinical Activity: While the Phase 1b clinical trial was a safety trial and not powered to demonstrate efficacy, the investigator-assessed best response according to RECIST V1.1 to batiraxcept across all cohorts supports promising clinical activity. In September 2019, we presented data from the initial 12 patients of the Phase 1b clinical trial in a late breaking oral presentation at the European Society for Medical Oncology Congress in Barcelona and based upon our analysis of the data decided to study higher doses of the drug and expanded the Phase 1b trial to study 15 mg/kg and 20 mg/kg dose levels.

The Phase 1b study data are summarized as follows:

- All doses of batiraxcept (10, 15 and 20mg/kg) were well-tolerated and the safety profile of the combination with PAC or PLD was consistent with the safety profile of PAC or PLD alone. Infusion reactions were noted, likely related to batiraxcept infusion and they were managed by a premedication regimen or by adjusting the infusion time, if necessary.

- Batiraxcept plus PAC appeared to perform better than batiraxcept plus PLD based on response rates: across all cohorts, batiraxcept plus PAC data show an ORR of 35% (8/23, including 2 CRs) compared to ORR of 11% (3/28) in batiraxcept plus PLD.

- While not powered to demonstrate efficacy, drug exposure levels correlated with clinical response as there was a statistically significant relationship between batiraxcept trough levels and PFS, supporting the use of higher dose than 10 mg/kg of batiraxcept. Additionally, batiraxcept combined with PAC had better clinical responses in patients whose trough levels were above the MEC of 13.8 mg/L compared to those patients whose trough levels were below the MEC.

- Batiraxcept holds promise as treatment in combination with PAC for patients who have had multiple lines of therapy or who progressed in less than 3 months following their last platinum-containing regimen compared to published literature (*Bruchim et al, European Journal of Obstetrics & Gynecology and Reproductive Biology 166 (2013) 94–98 and Kobayashi-Kato et al., Cancer Chemotherapy and Pharmacology (2019) 84:33-39 37).*

- Batiraxcept plus chemotherapy appeared to perform better in patients without previous exposure to bevacizumab.

    - In a subgroup analysis of patients who had not been previously exposed to bevacizumab in their prior lines of therapy, batiraxcept plus chemotherapy yielded an ORR of 60% (6/10 including 2 CR) when combined with PAC and an ORR of 19% (3/16) when combined with PLD. For reference, control arms of the third-party AURELIA trial of bevacizumab (NCT00976911) showed ORR of 30.2% (out of 55 patients total) with PAC alone and 7.8% (out of 64 patients total) with PLD alone.

    - Patients who received 10 or 15 mg/kg in combination with PAC and whose trough level was above the MEC of 13.8mg/L demonstrated clinical activity (67% response rate, 7.7 months PFS, and 19.3 months OS) greater than what was reported for PAC alone (bevacizumab naïve) patients in the AURELIA trial: 30.2% ORR (no CR reported); 3.9 months mPFS; and 13.2 months mOS (*Poveda et al, Journal of Clinical Oncology, Vol 33, No 32 (November 10), 2015: pp 3836-3838).*

- Serum levels of sAXL/GAS6 ratio related to response to batiraxcept and may identify PROC patients more likely to respond to batiraxcept chemotherapy combinations.

    - In the entire Phase 1b cohort, patients with a high sAXL/GAS6 ratio had 33% ORR (11/33) versus 0% ORR (0/15) in patients with a low sAXL/GAS6 ratio.

    - This biomarker will be investigated to see if it can be validated for use to enrich the patient population likely to respond.

Clinical Activity Data for 10mg/kg and 15mg/kg Patients whose First Trough Level was Above the MEC of 13.8mg/L

	PAC (N = 10)
Median PFS (months)	7.5
ORR	5 (50% [2 complete responses (20%])
Median Duration of Response ("DoR") among those who responded (months)	7.4
Median OS (months)	19.0

- Batiraxcept treatment alone demonstrated an ability to maintain tumor response. Three patients during the Phase 1b clinical trial maintained their response for 3-6 months following discontinuation of chemotherapy and while remaining on batiraxcept treatment alone. The tumor in one patient in the 15mg/kg group had completely responded (CR) and tumors in the other 2 patients in the 10 mg/kg group had PR while remaining on batiraxcept treatment alone.

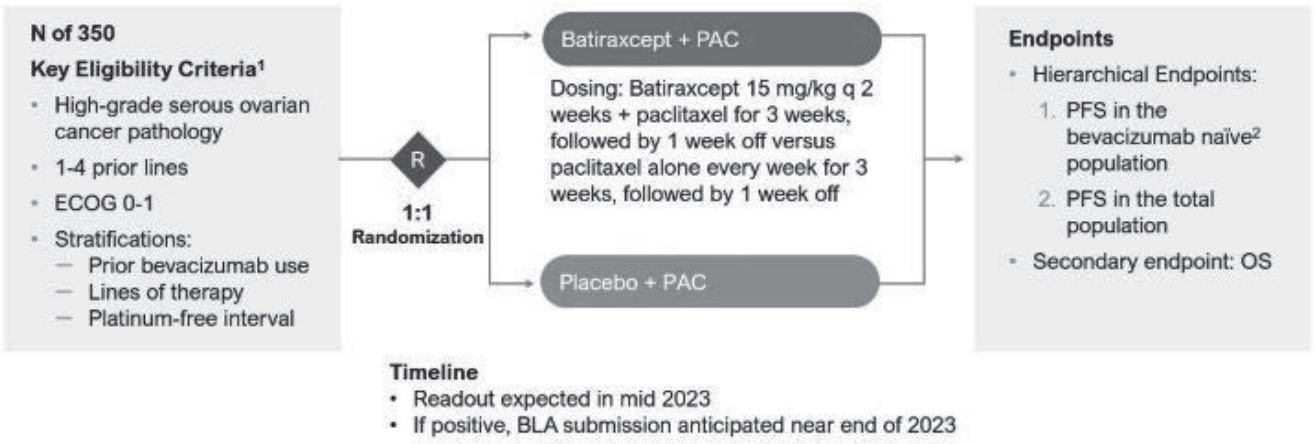
- Two patients whose responses (CR and PR) were maintained on batiraxcept alone for at least 6 months following discontinuation of chemotherapy missed their next dose of batiraxcept (one because she was hospitalized with COVID and one because she wanted to take a vacation) and their tumors showed progression at the next visit. These data suggest the responses these patients experienced were likely attributable to batiraxcept.

Phase 3 Registrational Trial Design in PROC

On November 19, 2020, we announced that we had received guidance from the FDA on a registrational Phase 3 trial design for batiraxcept in PROC. The FDA feedback received was that this trial, if successful, could support full approval of batiraxcept for the treatment of PROC. No further preclinical or clinical pharmacology studies are required at this time. The global, randomized, double-blind, placebo-controlled trial is being conducted at approximately 155 sites in the U.S., Canada, China, and Europe and designed to evaluate efficacy and tolerability of batiraxcept at a dose of 15 mg/kg in combination with PAC in patients with high-grade serous ovarian cancer who have received one to four prior lines of therapy. The pivotal Phase 3 trial initiated in April 2021 and achieved full enrollment of over 360 patients early January 2023. The primary endpoint for the trial is PFS, and secondary endpoints include OS, ORR based on RECIST 1.1, safety and tolerability, DoR, quality of life, clinical benefit rate, and PK and PD profile. Exploratory biomarkers include serum GAS6, serum sAXL and batiraxcept drug levels.

The registration-directed Phase 3 program of batiraxcept in combination with paclitaxel in PROC remains on track. We expect to report topline data from the trial by mid-2023 depending on the time the required number of PFS events occur for data analysis. Chemistry, manufacturing and control ("CMC") work remains on track with the goal of submitting a Biologics License Application ("BLA") by year-end 2023. The global, randomized, double-blind, placebo-controlled Phase 3 trial is evaluating efficacy and tolerability of batiraxcept at a dose of 15 mg/kg in combination with paclitaxel versus placebo in combination with paclitaxel.

Phase 3 batiraxcept -OC-004 Design



[1] Selection of patient population and dose in this trial confirmed by an IST showing lack of benefit outside this patient population and dose of 15mg/kg batiraxcept.
[2] Naive defined as patients who are medically ineligible to receive bevacizumab or who chose not to receive bevacizumab
ECOG = Eastern Cooperative Oncology Group (ECOG) Performance Status, PFS =-progression-free survival, BLA = biologics license application

Second Oncology Indication - ccRCC

ccRCC and Current Market Opportunity

The decision to select ccRCC as our second indication was based upon the strong preclinical data that we generated with batiraxcept and the fact that AXL expression in primary tumors of ccRCC patients has been shown in third party studies as well as our own studies (*Rankin et al, PNAS September 16, 2014 vol. 111 no. 37 13373–13378*), to correlate with aggressive tumor behaviors.

Kidney cancer is a leading cause of cancer-related deaths in the United States and is among the 10 most common cancers in both men and women. Metastasis to distant organs including the lung, bone, liver and brain is the primary cause of death in kidney cancer patients as only 12% of metastatic kidney cancer patients will survive past 5 years. According to the American Cancer Society, it is estimated that there will be approximately 81,800 new cases of kidney cancer and 14,890 people will die from this disease in the United States during 2023.

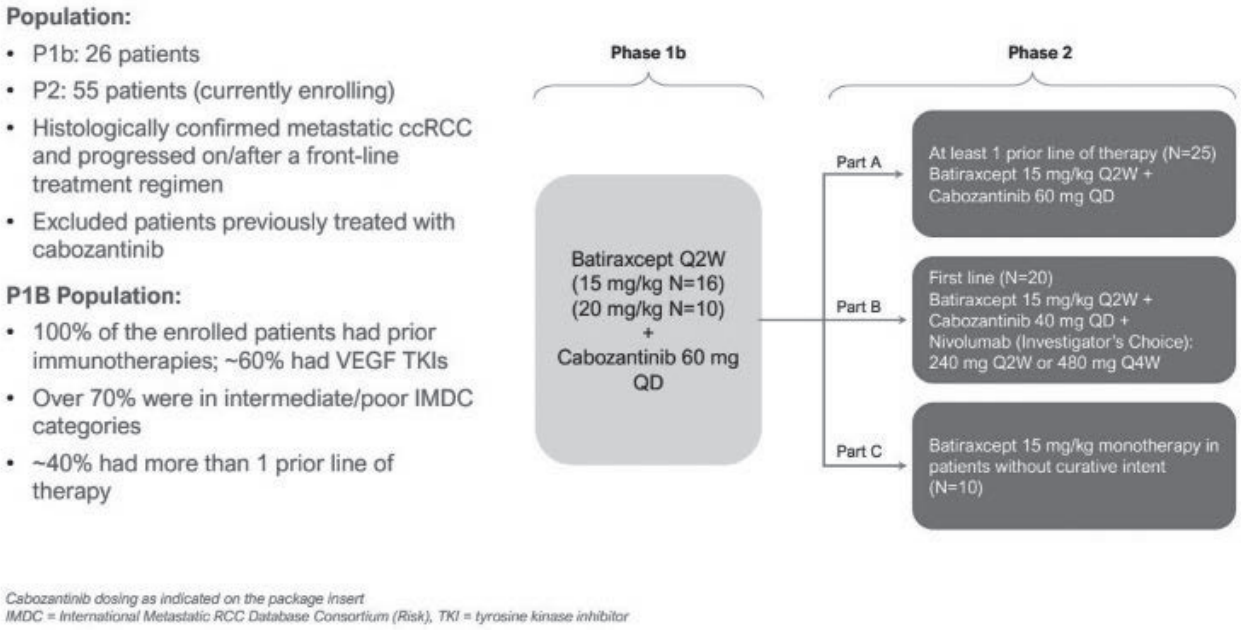
ccRCC is a cancer of the kidney. The name "clear cell" refers to the appearance of the cancer cells when viewed with a microscope. ccRCC occurs when cells in the kidney quickly increase in number, creating a lump (mass). Though the exact cause of ccRCC is unknown, smoking, excessive use of certain medications, and genetic predisposition conditions, e.g., von Hippel Lindau syndrome which involves genetic mutation in VHL, a tumor suppressor gene controlling tumor initiation in ~90% of ccRCC tumors, may contribute to the development of this type of cancer.

Treatment often begins with surgery to remove as much of the cancer as possible, and may be followed by radiation therapy, chemotherapy, biological therapy, or targeted therapy. Most kidney cancer is chemotherapy and radiation resistant, resulting in a large unmet need for treatment options. As reported in Decision Resources Group, LLC's December 2019 Report on The Landscape & Forecast of Renal Cell Carcinoma, nivolumab and cabozantinib have experienced strong uptake as second-line therapies since their FDA approvals (in 2015 and 2016, respectively). However, DRG anticipates that nivolumab's second-line patient shares, across the major markets, will begin to decline from 29-35% in 2018 to 22-27% in 2028, in part owing to its first-line label expansion in combination with ipilimumab and then later as other combination regimens with PD-1/PD-L1 inhibitors enter the first-line setting. In contrast, cabozantinib's second-line patient share as monotherapy is expected to steadily increase over the forecast period as its use in the first-line setting correspondingly declines, and it solidifies its position as the treatment of choice following a first-line immune checkpoint inhibitor combination. By 2023, it is estimated by DRG that cabozantinib will overtake nivolumab as the second-line sales and patient-share leader in all major markets; in 2028, it is expected to earn patient shares of 31-43% across the major markets. Similarly, DRG expects axitinib's second-line patient share will decline over the forecast period, corresponding to the uptake of cabozantinib and the notable uptake of pembrolizumab plus axitinib in the first-line setting; its major-market patient shares will then stabilize to 6-16% between 2024 and 2028. These assumptions in renal cell carcinoma suggest the greatest need may be with respect to second line therapies and in combination with cabozantanib.

Phase 1b/ 2 Clinical Trial

In February 2019, we announced our plans to develop batiraxcept in our second oncology indication, ccRCC. On January 13, 2020, we announced that we had received FDA clearance of our Investigational New Drug Application ("IND") for investigation of batiraxcept, for treatment of patients with advanced or metastatic ccRCC who progressed with or were intolerant to front-line treatment.

Phase 1b/2 Trial Designed to Accelerate Development in ccRCC



Cabozantinib dosing as indicated on the package insert
IMDC = International Metastatic RCC Database Consortium (Risk), TKI = tyrosine kinase inhibitor

The Phase 1b trial is evaluating batiraxcept at doses of 15 mg/kg and 20 mg/kg, plus cabozantinib 60 mg daily in previously treated (2L+) patients with ccRCC. Prior treatment with cabozantinib is not allowed. The primary objective is safety; secondary and exploratory objectives include identification of the recommended Phase 2 dose ("RP2D"), ORR, and DoR. Given baseline levels of serum sAXL/GAS6 correlated to clinical activity in our Phase 1b trial of batiraxcept in PROC, one of the objectives of the ccRCC trial is to correlate baseline sAXL/GAS6 with response in patients with ccRCC treated with batiraxcept plus cabozantinib. We dosed two cohorts of patients, one at the 15 mg/kg dose and the second at 20mg/kg dose. A review of the Phase 1b data demonstrates that 15mg/kg batiraxcept is an appropriate dose to suppress serum GAS6 levels in these patients being treated with cabozantinib and that 20mg/kg batiraxcept does not provide additional clinical activity beyond that seen with 15mg/kg batiraxcept, consistent with the modeling done using the Phase 1b PROC data.

In January 2022, we announced the first patient was dosed in the Phase 2 portion of the ccRCC trial. The Phase 2 portion of the Phase 1b/2 clinical trial of batiraxcept in ccRCC is an open-label study in which 55 patients are anticipated to enroll across three parts. Part A is expected to enroll approximately 25 patients and will investigate batiraxcept 15 mg/kg in combination with cabozantinib in 2L+ ccRCC patients. Part B is expected to enroll approximately 20 patients and evaluate batiraxcept 15 mg/kg in combination with standard of care nivolumab and cabozantinib in first-line ccRCC patients. Part C is expected to evaluate batiraxcept 15 mg/kg monotherapy in approximately 10 patients with ccRCC who are not eligible for curative intent therapies. The primary endpoint of each part of the Phase 2 portion of the trial is ORR and key secondary endpoints include DoR, PFS, and OS. The Phase 2 portion of the ccRCC clinical trial will also explore batiraxcept effects on biomarkers (sAXL and GAS6) in serum.

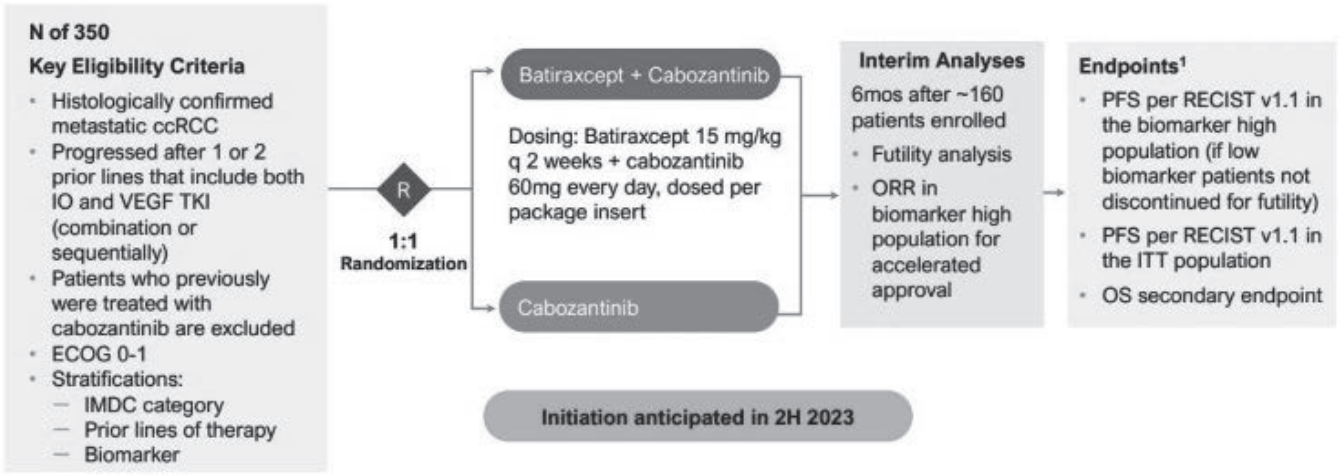
By August 8, 2022, 26 previously treated (2L+) patients with ccRCC had been treated with batiraxcept in the Phase 1b portion of the Phase 1b/2 trial at doses of 15 mg/kg (n=16) and 20 mg/kg (n=10), plus cabozantinib 60 mg daily. There were no dose limiting toxicities observed at either dose. The best overall response rate (ORR, confirmed) in the Intent to treat ("ITT") population was 42%. One of the objectives of the ongoing Phase 1b/2 ccRCC trial is to evaluate the correlation of baseline serum sAXL/GAS6 (biomarker) with radiographic response in patients with ccRCC treated with batiraxcept plus cabozantinib. The best ORR in the biomarker high population was 55%. The 9-month progression-free survival (PFS) rate was 65% in the ITT population and 72% in the biomarker high population. We discussed a registrational path with the FDA that includes use of the sAXL/Gas6 ratio as a basis for a potential accelerated approval.

On November 29, 2022, we announced that the FDA has granted Fast Track Designation to batiraxcept, for treatment of patients with advanced or metastatic ccRCC who have progressed after 1 or 2 prior lines of systemic therapy that include both IO-based and VEGF-TKI-based therapies (either in combination or sequentially).

Fast Track is a process designed to facilitate the development and expedite the review of investigational drugs to treat serious conditions and fill an unmet medical need. Drugs that receive Fast Track designation may be eligible for more frequent communications and meetings with the FDA to discuss the drug's development plan, including the design of the proposed clinical trials, use of biomarkers and the extent of data needed to support approval. Drugs with Fast Track Designation may also qualify for accelerated and priority review of new drug applications if relevant criteria are met.

The Fast Track Designation was based on new data submitted to the agency from the Phase1b portion of the Phase 1b/2 ccRCC study (AVB500-RCC-003; NCT04300140) in September. As of September 26, 2022, 26 previously treated (second line or greater) patients with ccRCC have been treated with batiraxcept in the Phase 1b portion of a Phase 1b/2 trial at doses of 15 mg/kg (n=16) and 20 mg/kg (n=10), plus cabozantinib 60 mg daily. There were no dose limiting toxicities observed at either dose. Clinical data from this study demonstrate that batiraxcept has the potential to increase the clinical activity of cabozantinib in patients with metastatic ccRCC who have progressed following IO- and VEGF-TKI-based therapies (N=14 of the 26 patients) as the ORR was 57% and median PFS was 11.4 months in this population.

Anticipated Batiraxcept Phase 2/3 Trial Design in ccRCC



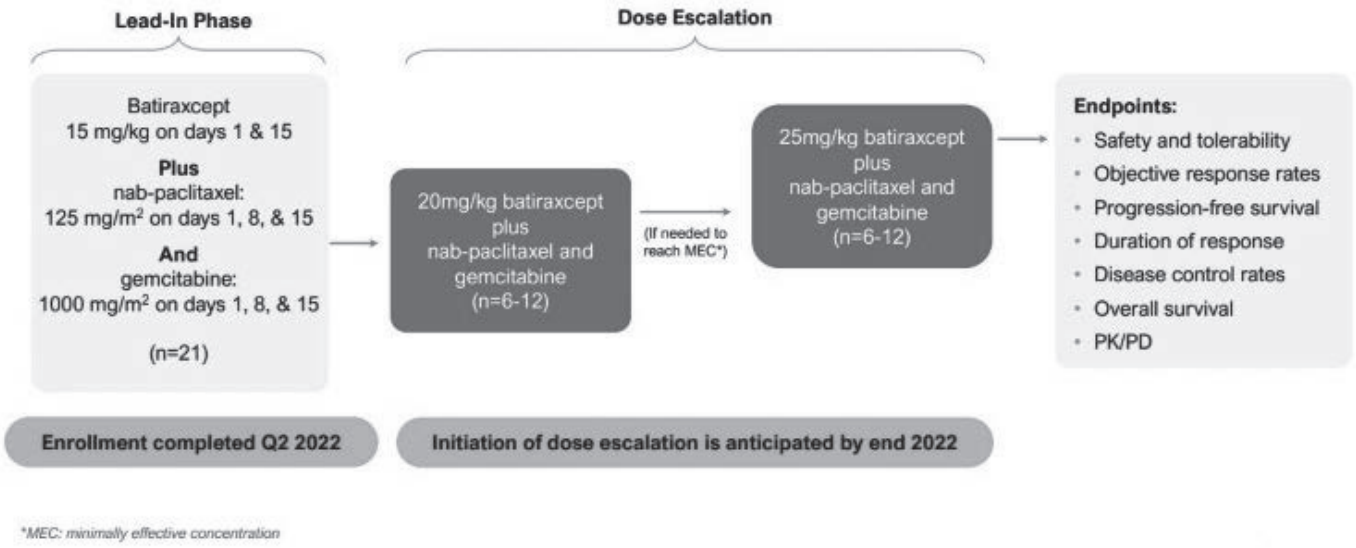
BLA = biologics license application, ECOG = Eastern Cooperative Oncology Group (ECOG) Performance Status, IMDC = International Metastatic RCC Database Consortium (Risk), IO = Immuno-oncology, ITT = intent to treat (population), ORR = Overall response rate, PFS = progression-free survival, TKI = tyrosine kinase inhibitor
1 PFS will be assessed by blinded independent central review (BICR)

Based on data provided in the first quarter of 2022, the FDA recommended an integrated Phase 2/3 study with interim analyses to look at futility in the biomarker low population and ORR for potential accelerated approval with PFS endpoint for full approval. This study design provides an opportunity for both accelerated approval and confirmatory approval in one study and potentially increases the chance for success by allowing the final PFS analysis to be conducted in the ITT and the biomarker high population. Given the most recent data in September and fast-track designation, we plan to also analyze the patients with advanced or metastatic ccRCC who have progressed after both IO-based and VEGF-TKI-based therapies (either in combination or sequentially). The full protocol and statistical plan are in preparation for submission to the FDA.

We expect to report additional data from the Phase 1b portion and preliminary data from the Phase 2 portion of the ccRCC trial mid-2023. We anticipate initiating the registrational Phase 2/3 trial in the second half of 2023.

Third Oncology Indication - PDAC

Phase 1b Design in 1L Pancreatic Adenocarcinoma



The pancreas is a gland about 6 inches long that is shaped like a thin pear lying on its side and it is in the abdomen near the stomach, intestines, and other organs. The pancreas has two main jobs in the body: 1) to make juices that help digest (break down) food; and 2) to make hormones, such as insulin and glucagon, that help control blood sugar levels. Both of these hormones help the body use and store the energy it gets from food. The digestive juices are made by exocrine pancreas cells and the hormones are made by endocrine pancreas cells. About 95% of pancreatic cancers begin in exocrine cells and the most common pancreatic exocrine tumors are called adenocarcinomas.

Pancreatic cancer is the third deadliest cancer in the US and has the highest mortality rate of all cancers, with a five-year survival rate of 11% (*The Surveillance, Epidemiology, and End Results (SEER) Website*)). Few patients are candidates for curative treatment, as the cancer has usually metastasized at the time of diagnosis. Chemotherapy has limited benefit, due to the dense dysplastic stroma impeding delivery and the rapid development of resistance. Immunotherapy also has a limited role as pancreatic cancer has a highly immunosuppressive microenvironment. (*Nevala-Plagemann C, Hidalgo M, Garrido-Laguna I. From state-of-the-art treatments to novel therapies for advanced-stage pancreatic cancer. Nat Rev Clin Oncol. Feb 2020;17(2):108-123. doi:10.1038/s41571-019-0281-6*).The American Cancer Society estimates 64,050 people will be diagnosed with pancreatic cancer and 50,550 people will die of pancreatic cancer in 2023. Per AACR, pancreatic cancer is projected to become the third leading cause of cancer death worldwide by 2025 and the second leading cause of cancer death in the U.S. by 2040(*Rahib L, Wehner MR, Matrisian LM, Nead KT. Estimated Projection of US Cancer Incidence and Death to 2040. JAMA Netw Open. Apr 1 2021;4(4):e214708. doi:10.1001/jamanetworkopen.2021.4708*).

Decision Resources Group, LLC in its December 2019 Pancreatic Cancer Disease Landscape and Forecast reports the first-line metastatic population is the largest drug-treatable population in pancreatic cancer. Correspondingly, the first-line metastatic population had the highest therapy sales ($901 million in 2018, with all but 62 million from the pancreatic exocrine tumor population), accounting for 53% of the total pancreatic cancer therapy market. By 2028, these sales are expected to fall short by more than $100 million ($764 million in 2028), mainly because most products prescribed for metastatic pancreatic adenocarcinoma in the first-line have become generically available and due to failures of several highly anticipated late-phase pipeline drugs. However, there is a clear need for additional therapies and there is a clear trend developing towards a combinatorial approach as a substantial percentage of early-phase studies are being conducted with two or more investigational agents. The addressable population (i.e., eligible to receive gemcitabine + nab-paclitaxel as first-line treatment) across the US and 5 major EU regions is estimated to be approximately 38,000.

On August 9, 2021, we announced that we had dosed the first patient in the Phase 1b portion of our Phase 1b/2 of AVB-500 as a first-line therapy in combination with gemcitabine and nab-paclitaxel (Abraxane®) in patients with advanced or metastatic pancreatic adenocarcinoma eligible to receive gemcitabine and nab-paclitaxel combination therapy. The Phase 1b portion of the clinical trial is evaluating safety, tolerability, PK, PD, and clinical activity in 21 patients dosed with 15 mg/kg of batiraxcept in combination with gemcitabine and nab-paclitaxel.

As of September 20, 2022, 18 patients with PDAC had been treated with 15 mg/kg (Days 1 & 15) + nab-paclitaxel (125 mg/m2 on Days 1, 8, & 15) and gemcitabine (1000 mg/m2 on Days 1, 8, & 15) and have PK data. As has been seen for other Phase 1b cancer studies with batiraxcept, there is a relationship between batiraxcept exposures and clinical activity such that 5 out of the 9 patients in the PDAC study whose batiraxcept levels exceeded the MEC of batiraxcept had a response vs 1 out of 9 patients in the below MEC group. Similarly, the mPFS in the above MEC group was 5.6 months (95% CI 2.1, not evaluable) vs 2.7 months (95% CI 1.1, 5.4) in the below MEC group. In May 2022, we had reported that batiraxcept in combination with gemcitabine and nab-paclitaxel was generally well-tolerated with no unexpected safety signals. Consistent with our other clinical trials, we noted a relationship between clinical activity and batiraxcept drug levels, however highly fibrotic tumors like PDAC may require higher batiraxcept concentrations than platinum-resistant ovarian cancer and clear cell renal cell cancer patients to reach the appropriate batiraxcept drug levels. Due to this characteristic of pancreatic cancer, we are testing higher doses of batiraxcept to see if we can increase the proportion of patients who benefit from the triplet regimen.

In February 2023, the FDA granted orphan drug designation ODD to batiraxcept for the treatment of PDAC.

Investigator Sponsored Trials

In May 2019, we entered into an institution sponsored clinical trial agreement with M.D. Anderson Cancer Center for the use of, and our supply of, batiraxcept, in combination with AstraZeneca Pharmaceuticals LP's medicinal product durvalumab in a Phase 1/2 trial being conducted by the M.D. Anderson Cancer Center for the treatment of patients with platinum-resistant, recurrent epithelial ovarian cancer. Data from this study were presented at the 2022 Society of Gynecological Oncology (SGO) meeting in Arizona: Phase Ib study of AVB S6 500 in Combination with Durvalumab (MEDI4736) in Patients with Platinum Resistant, Recurrent Epithelial Ovarian Cancer (EOC). This study has completed.

In March 2020, we announced that the first patient was dosed in a Phase 1/2 trial for the use of, and our supply of, batiraxcept, in combination with EMD Serono's medicinal product avelumab being conducted by the University of Oklahoma for the treatment of patients with advanced urothelial cancer (COAXIN trial). Data from this study was presented at the 2022 ASCO meeting in Chicago: Phase Ib study of avelumab and novel AXL inhibitor AVB-S6-500 in patients with metastatic urothelial carcinoma (mUC), Abhishek Tripathi, Melissa Clingerman, Riza Celine Fabreo, Adanma Ayanambakkam, Brian Cross, Kelly Lynn Stratton, Michael Cookson, Sumanta K. Pal, and Neeraj Agarwal, Journal of Clinical Oncology 2022 40:16_suppl, 4579-4579. One patient with a complete response remains on study as of end of 2022.

Strategic Collaborations

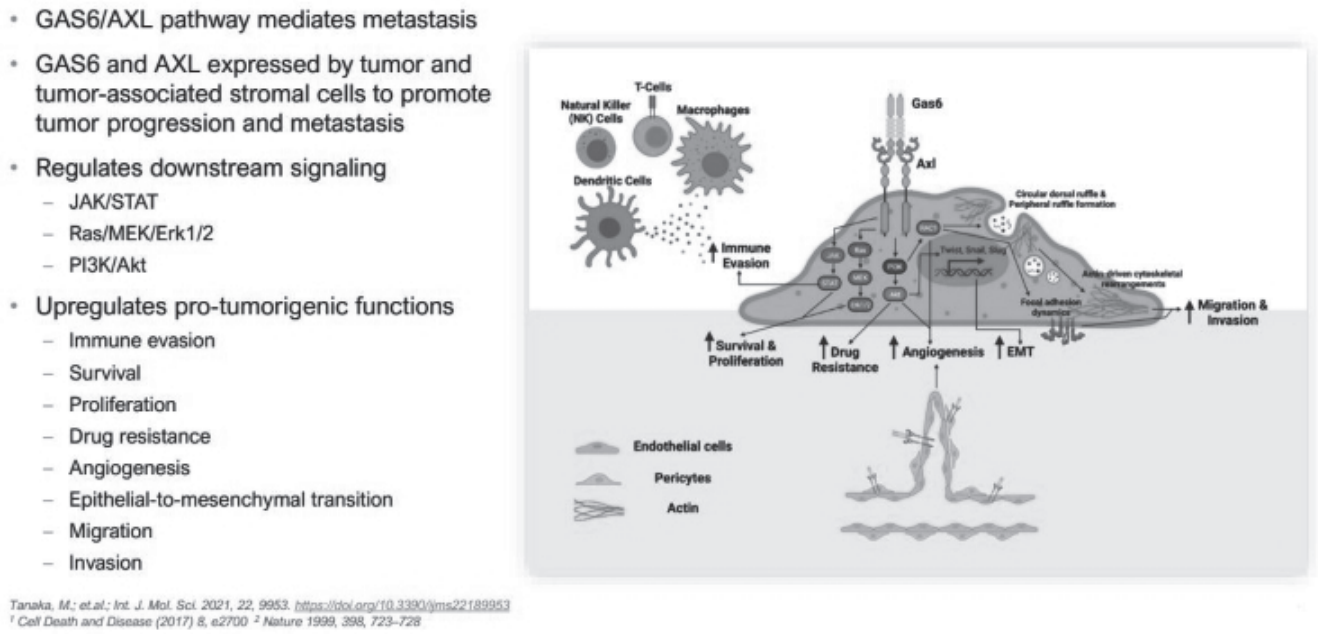
In April 2020, we entered into a license and collaboration agreement with WuXi, the objective of which is to identify and develop novel high-affinity bispecific antibodies against CCN2, also known as CTGF, implicated in cancer and fibrosis and identified from a similar target discovery screen that identified the significance of the AXL/GAS6 pathway in cancer. The goal is to generate a best-in-class therapeutic targeting desmoplasia and tumor growth in the clinic in 2023. In August 2022, we temporarily halted work on the CTGF program with WuXi in an effort to focus all our resources on ongoing clinical programs involving batiraxcept.

On November 6, 2020, we entered into the 3D Medicines Agreement, whereby we granted 3D Medicines an exclusive license to develop and commercialize products that contain batiraxcept as the sole drug substance for the diagnosis, treatment or prevention of human oncological diseases, in the Territory.

GAS6-AXL Pathway

As illustrated in the following graphic, AXL receptor signaling plays an important role in multiple types of malignancies by promoting metastasis, cancer cell survival, resistance to treatments, and immune suppression.

Figure 6: GAS6 and AXL are Overexpressed in Many Cancers and Associated with Tumor Growth, Metastasis, Drug Resistance, and Poor Survival



Tanaka, M.; et.al.; Int. J. Mol. Sci. 2021, 22, 9953. https://doi.org/10.3390/ijms22189953
[1] Cell Death and Disease (2017) 8, e2700 [2] Nature 1999, 398, 723–728

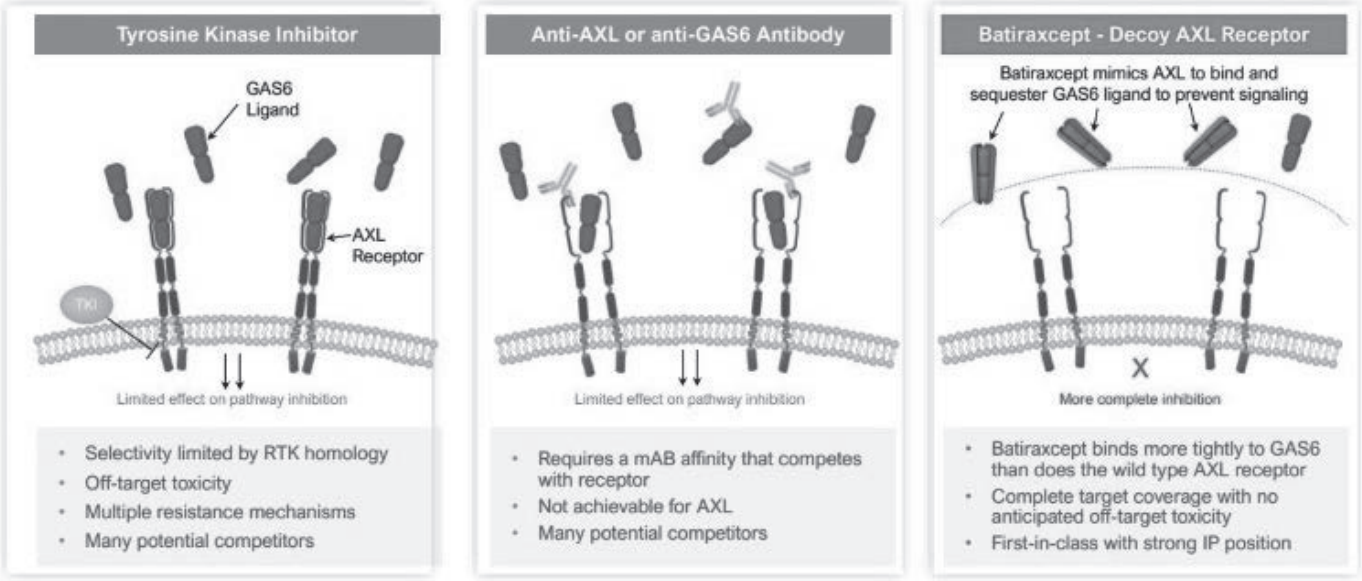
In preclinical studies, we have also identified high AXL expression on tumors resistant to the combination of radiotherapy and immunotherapy and that genetically inactivating AXL in tumors resistant to immunotherapy and radiotherapy restored anti-tumor immune response.

In preclinical studies conducted in Dr. Giaccia's laboratories at Stanford University, Dr. Giaccia was able to demonstrate that the immune response generated by loss of AXL leads to adaptive immune resistance through PD-L1 expression and Treg (regulatory T cells) infiltration. This resulted in tumors that became sensitive to checkpoint immunotherapy when they were previously resistant. Thus, GAS6-AXL pathway inhibitors, in combination with radiation or chemotherapy and immunotherapy, may be a promising treatment regimen and may restore anti-tumor immune response.

Aravive-S6 (AVB-S6)

AVB-S6 is comprised of a family of novel, high-affinity, soluble Fc-fusion proteins, which include batiraxcept, designed to block the activation of the GAS6-AXL signaling pathway by intercepting GAS6 and interfering with its binding to its receptor AXL. AVB-S6 proteins have been engineered to have approximately 50- to 200-times greater affinity for human GAS6 compared to the native AXL receptor, effectively sequestering GAS6 and abrogating AXL signaling. We believe this 'decoy receptor' approach is well suited for AXL inhibition compared to small molecule receptor tyrosine kinase inhibitors or antibodies, as illustrated by the following graphic

Figure 7: Approaches to Inhibiting the GAS6/AXL Signaling Pathway



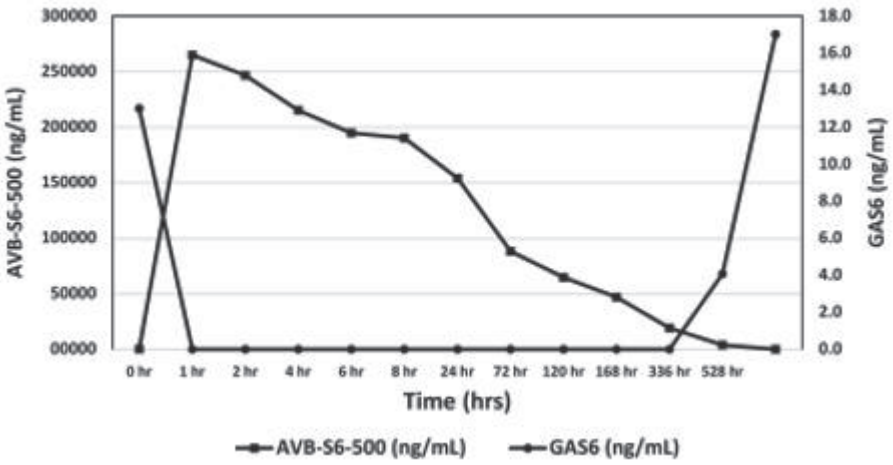
Preclinical Results

Our AVB-S6 proteins have been shown to bind GAS6 with higher affinity than the endogenous AXL protein and inhibit GAS6/AXL signaling. Initial preclinical pharmacology studies were conducted with a variety of engineered AVB-S6 proteins. The preclinical program demonstrated that high GAS6 binding affinity was critical and correlative with the ability of AVB-S6 to inhibit metastasis and disease progression *in vivo*. AVB-S6 proteins have demonstrated significant efficacy in mouse models of metastatic ovarian, breast, renal, and pancreatic cancers.

Biomarker

GAS6 expression in tumors has been reported to be an adverse prognostic factor in several cancers, including urothelial, ovarian, lung adenocarcinoma, gastric cancer, glioblastoma, oral squamous cell carcinoma, liver carcinoma, and renal cell carcinoma. In studies conducted by us, AVB-S6 proteins bind GAS6 with higher affinity than the endogenous AXL protein and prevent GAS6 signaling at the AXL receptor. Preclinical efficacy data for the AVB-S6 program demonstrated a relationship between reduced serum GAS6 and an anti-metastatic effect. We have developed an assay designed to measure GAS6 levels in the blood before and after dosing of our development candidate in humans. In the presence of a pharmacologically active dose of AVB-S6, serum GAS6 has not been detectable. Thus, GAS6 levels in the blood of patients is a PD biomarker that aids AVB-S6 dose selection and potentially serves as a predictive biomarker for response to treatment with AVB-S6. Additionally, our Phase1b PROC clinical trial identified a relationship between sAXL / GAS6 ratios as every patient that responded to treatment, regardless of chemotherapy being administered in combination, had a sAXL / GAS6 of >0.773. We will continue to explore these biomarkers in our other clinical trials.

The following graphic indicates the relationship between batiraxcept protein levels and GAS6 levels in blood from humans participating in the batiraxcept first in human trial.



Manufacturing

Manufacturing of our clinical trial material consists of three main phases, the production of bulk protein (drug substance), formulation/filling operations, and labelling/packaging operations of the finished product. The protein has been manufactured at high yield and with high purity. The clinical bulk drug substance is produced using industry standard manufacturing processes, as is the drug product.

Since September 2017, we have relied on WuXi, a third-party contract manufacturer to manufacture clinical bulk drug substance and drug product of batiraxcept using a cell line and process developed by our contract manufacturer that has been licensed to us on a non-exclusive basis. We have manufactured enough batiraxcept to dose patients through the planned Phase 3 PROC trial, our other ongoing clinical trials and support submission of the anticipated PROC BLA. The clinical bulk drug substance and drug product is manufactured pursuant to the terms of a five-year Master Manufacturing Services Agreement that we entered into with our contract manufacturer in July 2016, which automatically renews for successive one (1) year periods, unless either party provides written notice to the other party of its desire not to renew at least 90 days prior to the expiration of the then-current term. The Master Manufacturing Services Agreement is terminable by us upon 45 days prior written notice, by our contract manufacturer upon 180 days prior written notice provided that all statements of work in progress at such time are completed and upon 60 days prior written notice upon a breach of the terms of the agreement if such breach is not cured within such 60-day period.

We have also contracted with an independent third party located in Texas for the labeling, packaging, and distribution of our injectable protein.

Our personnel have significant technical, manufacturing, analytical, quality and project management experience to execute and manage manufacturing process development, plus oversee the manufacture, testing, quality release, storage and distribution of drug products according to the current Good Manufacturing Practice ("cGMPs"), promulgated by the FDA and other regulatory requirements. The cGMP regulations include requirements relating to the organization of personnel, buildings and facilities, equipment, control of components and drug product containers and closures, production and process controls, packaging and labeling controls, holding and distribution, laboratory controls, records and reports, and returned or salvaged products. Our facilities, and our third-party manufacturers, may be subject to periodic inspections by FDA and local authorities, which include, but are not limited to procedures and operations used in the testing and manufacture of our biological drug candidates to assess our compliance with applicable regulations. Failure to comply with statutory and regulatory requirements subjects a manufacturer to possible legal or regulatory action, including warning letters, the seizure or recall of products, injunctions, and consent decrees causing significant restrictions on or suspending manufacturing operations plus causing possible civil and criminal penalties. These actions could have a material impact on the availability of its biological drug candidates. Similar to contract manufacturers, we may encounter difficulties involving production yields, quality control and quality assurance, as well as shortages of qualified personnel.

Research and Development

We have made and will continue to make substantial investments in research and development. Our research and development expenses totaled approximately $66.9 million and $37.5 million for the years ended December 31, 2022 and 2021, respectively.

In the ordinary course of business, we enter into agreements with third parties, such as CROs, medical institutions, clinical investigators and contract laboratories, to conduct clinical trials and aspects of research and preclinical testing. These third parties provide project management and monitoring services and regulatory consulting and investigative services.

Competition

The biotechnology and pharmaceutical industries are characterized by intense competition to develop new technologies and proprietary products. We face competition from many different sources, including biotechnology and pharmaceutical companies, academic institutions, government agencies, as well as public and private research institutions. Any products that we may commercialize will have to compete with existing products and therapies as well as new products and therapies that may become available in the future.

At this time, there are no FDA or EMA approved therapies targeting GAS6. We believe this mechanism of action represents a novel approach to inhibiting tumor growth and metastasis, as well as addressing tumor immune evasion and resistance to other anticancer agents. Exelixis, Inc. markets cabozantinib, a Tyrosine Kinase Inhibitor which is the only currently marketed compound that inhibits AXL in addition to inhibiting several other kinases. We are aware of a number of companies focused on developing AXL inhibitors in various indications, including BerGenBio ASA, Astellas Pharma Inc., Mirati Therapeutics, Inc., Les Laboratoires Servier, SAS, Eli Lilly and Company, Bristol-Myers Squibb Company, Tolero Pharmaceuticals, Inc., Ignyta, Inc., as well as several companies addressing AXL inhibitors, and PARP 1/2 inhibitors and related signaling pathways.

Our competition may also include companies that are or will be developing therapies for the same therapeutic areas that we are targeting, including ovarian cancer, renal cell carcinoma and pancreatic cancer. Many of our potential competitors, alone or with their strategic partners may have substantially 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. These competitors also compete with us in recruiting and retaining qualified scientific and management personal, establishing clinical trial sites and patient registration for clinical trials, and in acquiring technologies complementary to, or necessary for our programs.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products 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 approval from the FDA or other regulatory agencies for their products more rapidly than we may obtain approval for our product candidates, which could result in our competitors establishing a strong market position before our product is able to enter the market. In addition, our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of generic products.

License Agreement

In 2012, Aravive Biologics entered into an exclusive license agreement with Leland Stanford Junior University ("Stanford University") for intellectual and tangible property rights relating to biologic inhibitors for therapeutic targeting the receptor tyrosine kinase AXL. The license agreement was amended in 2012, 2015 and 2017 to modify certain of the stated milestones and expand the patent rights granted to Aravive Biologics. The term of the license is the length of the last to expire patent. The license agreement grants Aravive Biologics exclusive, worldwide rights to make, use or sell licensed materials based upon the following patent-related rights:

- U.S. patent application: Serial number PCT/US2012/069841, filed December 14, 2012; Serial Number 13/714,875, filed December 14, 2012 ; Serial Number PCT/US2013/074786, filed December 12, 2013; Serial Number 14/650,854, filed June 9, 2015; Serial Number PCT/US2015/066498, filed December 17, 2015; Serial Number 15/535,995, filed June 14, 2017; which patents are jointly owned with Private Aravive and all U.S. patents and foreign patents and patent applications based on the application; as well as all divisionals, continuations, and those claims in continuations-in-parts to the extent they are sufficiently described in the application, and any re-examinations or reissues of the foregoing.

- U.S. patent application: Serial Number PCT/US2011/022125, filed January 21, 2011; Serial Number 13/554,954, filed July 20, 2012; Serial Number 13/595,936, filed August 27, 2012; Serial Number 13/950,111, filed July 24, 2013; Serial Number 14/712,731, filed May 14, 2015; which patents are solely owned by Stanford University, and all U.S. patents and foreign patents and patent applications based on the application; as well as all divisionals, continuations, and those claims in continuations-in-parts to the extent they are sufficiently described in the application, and any re-examinations or reissues of the foregoing.

As consideration for the rights granted in the license agreement, Aravive Biologics is obligated to pay Stanford University yearly license fees and milestone payments, and a royalty based on net sales of products covered by the patent-related rights set forth above. More specifically, Aravive Biologics is obligated to pay Stanford University (i) annual license payments, (ii) milestone payments of up to an aggregate of $1,000,000 upon achievement of clinical and regulatory milestones, and (iii) royalties equal to a percentage (in the low single digits) of net sales of licensed products; provided that the annual license payments made will offset (and be credited against) any royalties due in such license year. In the event of a sublicense to a third party of any rights based on the patents that are solely owned by Stanford University, Aravive Biologics is obligated to pay royalties to Stanford University equal to a percentage of what Aravive Biologics would have been required to pay to Stanford University had it sold the products under sublicense itself. In addition, in such event Aravive Biologics is required to pay to Stanford University a percent of sublicensing income. The license agreement may be terminated by Stanford University upon 30 days written notice if Aravive Biologics breaches its obligations thereunder, including failing to make any milestone or other required payments or to exercise diligence to bring licensed products to market. In the event of a termination, Aravive Biologics will be obligated to pay all amounts that accrued prior to such termination. The license agreement also contains other customary clauses and terms as are common in similar agreements between industry and academia, including the licensee's agreement to indemnify Stanford University for any liabilities arising out of or related to the licensee's exercise of its rights under, or breach of, the license agreement, the reservation of the licensor of the right to use the licensed intellectual property rights for its internal, non-commercial purposes, limitations/disclaimers of various warranties.

Cancer Prevention and Research Institute of Texas (CPRIT) Grant

In 2016, Aravive Biologics was approved for a $20.0 million grant from CPRIT for development of AVB-S6. The CPRIT Grant is subject to customary CPRIT funding conditions including a matching funds requirement whereby Aravive Biologics was required to match $0.50 for every $1.00 from CPRIT. Consequently, Aravive Biologics was required to raise $10.0 million in matching funds, and it raised $11.4 million since 2016. The grant award, as is customary for all CPRIT awards, contains a requirement that Aravive Biologics pay CPRIT a tiered royalty on sales of commercial products developed using CPRIT funds equal to a low- to mid-single digit percentage of revenue until such time as CPRIT has been paid an aggregate amount equal to 400% of the grant award proceeds. After 400% of the grant award proceeds has been paid, Aravive Biologics will be obligated to pay CPRIT a royalty of less than one percent for as long as Aravive Biologics maintains government exclusivity. The CPRIT Grant contract terminated on November 30, 2019. After the termination date, we are not permitted to retain any unused grant award proceeds without CPRIT's approval, but our royalty and other obligations, including our obligation to repay the disbursed grant proceeds under certain circumstances, to maintain certain records and documentation, to notify CPRIT of certain unexpected adverse events and our obligation to use reasonable efforts to ensure that any new or expanded preclinical testing, clinical trials, commercialization or manufacturing related to any aspect of our CPRIT project take place in Texas, survive the termination of the agreement. We have received all $20 million of the grant award proceeds and have expended all of the grant award proceeds by the agreement termination date.

3D Medicines Inc. Agreement

On November 6, 2020, we entered into the 3D Medicines Agreement, whereby we granted 3D Medicines an exclusive license to develop and commercialize products that contain batiraxcept as the sole drug substance, for the diagnosis, treatment or prevention of human oncological diseases, in the Territory.

In August 2021, 3D Medicines received approval from the Center for Drug Evaluation ("CDE") of the China National Medical Products Administration ("NMPA") of the IND submitted by 3D Medicines to participate in our international batiraxcept Phase 3 PROC clinical trial.

Under the terms of the 3D Medicines Agreement, we received from 3D Medicines cash payments of $27 million (inclusive of $15 million in milestone payments) and are eligible to receive from 3D Medicines cash payments of up to an aggregate of $207 million (inclusive of $15 million in milestone payments) in clinical development, regulatory and commercial milestone payments. There can be no guarantee that any such milestones will in fact be met. We are obligated to make certain payments to Stanford University based on certain amounts received from 3D Medicines under the 3D Medicines Agreement pursuant to the existing license agreement by and between us and Stanford.

We will also be entitled to receive tiered royalties ranging from low double digits to mid-teens on sales in the Territory, if any, of products containing batiraxcept. Royalties are payable with respect to each jurisdiction in the Territory until the latest to occur of: (i) the last-to-expire of specified patent rights in such jurisdiction in the Territory; or (ii) ten (10) years after the first commercial sale of a product in such jurisdiction in the Territory. In addition, royalties payable under the Agreement will be subject to reduction on account of generic competition under certain specified conditions, with any such reductions capped at certain percentages of the amounts otherwise payable during the applicable royalty payment period.

- Under the terms and conditions of the 3D Medicines Agreement, 3D Medicines will be solely responsible for the development and commercialization of licensed products in the Territory.

- If either we or 3D Medicines materially breaches the 3D Medicines Agreement and does not cure such breach, the non-breaching party may terminate the 3D Medicines Agreement in its entirety. Either party may also terminate the 3D Medicines Agreement, upon written notice, if the other party files for bankruptcy, is dissolved or has a receiver appointed for substantially all of its property. We may terminate the 3D Medicines Agreement if 3D Medicines, its affiliates or its sublicensees challenges the validity or enforceability of any of our patents covering any of the licensed compounds or products or ceases substantially all development and commercialization of licensed products in the Territory for a specified period, subject to certain exceptions. 3D Medicines may also terminate the 3D Medicines Agreement for convenience provided certain notice is provided to us.

The Agreement contemplates that we will enter in ancillary arrangements with 3D Medicines, including a clinical supply agreement and a manufacturing technology transfer agreement.

Intellectual Property

We strive to protect and enhance the proprietary technology, inventions and improvements that are commercially important to our business, including seeking, maintaining, and defending patent rights. We also rely on trade secrets relating to our technology and know-how to develop, strengthen and maintain our proprietary position in the field of targeting the GAS6-AXL pathway for the identification and development of therapeutic candidates for cancer therapy and fibrosis. In addition, we rely on regulatory protection afforded through data exclusivity, market exclusivity and patent term extensions where available. We also utilize trademark protection for our company name and expect to do so for products and/or services as they are marketed.

Our commercial success will depend in part on our ability to obtain and maintain patent and other proprietary protection for commercially important technology, inventions and know-how related to our business; defend and enforce our patents; preserve the confidentiality of our trade secrets; and operate without infringing the valid enforceable patents and proprietary rights of third parties. Our ability to stop third parties from making, using, selling, offering to sell or importing our therapeutic candidates may depend on the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities. With respect to both licensed and company-owned intellectual property, we cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any of our existing patents or any patents that may be granted to us in the future will be commercially useful in protecting our commercial products and methods of manufacturing the same.

Our patent position with respect to the GAS6-AXL program is comprised of nine comprehensive patent portfolios containing composition of matter claims relating to novel GAS6-binding fusion proteins, claims to reagents and diagnostic methods for determining susceptibility or likelihood of a tumor to become invasive and/or metastatic, and claims to the use of our novel fusion proteins for the treatment of various oncological conditions, as well as antiviral and antifibrotic disorders. Our license agreement with Stanford University provides us with exclusive rights to intellectual property ("IP"), that is either solely owned by Stanford (Portfolio I below) or co-owned by Stanford and us (Portfolios II, III, and V below). We also have rights to IP that we solely own (Portfolio IV and VI-X below).

As of February 1, 2023, we have exclusive rights to 50 issued patents (including the 36 validated EP countries for Portfolio I), 2 Hong Kong recorded patents, and one pending patent application that are the subject of the license agreement with Stanford University. The expiration date for those patents/patent applications is 2031. We also have exclusive rights to 58 issued patents (including the 36 validated EP countries for Portfolio III and the 7 validated EP countries for Portfolio V) and 2 pending applications that are jointly owned with Stanford University and that are the subject to the license agreement with Stanford. The expiration dates for those patents/patent applications range from 2033-2035. We have 2 issued patent and 30 pending applications that we solely own. The expiration dates for those patents range from 2035-2042. Additional details on our relevant portfolios is provided below:

- **Portfolio I**— "Inhibition of AXL Signaling in Anti-Metastatic Therapy" 14 Granted Patents*--US8618254, US9074192, US9266947, AU2011207381, CA2786149, CN-ZL201180014940, EP2525824 (*Validated in 18 EP countries), EP3241840 (*Validated in 18 EP countries), IN6649/CHENP/2012, JP5965322, KR 127996-6, RU2556822, ZA2012/04866, ZA2013/07676--2 Recorded Patents--HK 1242355 (Recorded), HK 1245806 (Recorded)--1 Pending Application ---- CN201610819620.7

- **Portfolio II**— "Inhibition Of AXL/GAS6 Signaling in the Treatment Of Disease" 1 Granted Patent—US9,879,061

- **Portfolio III**— "Modified AXL Peptides and Their Use in Inhibition of AXL Signaling in Anti- Metastatic Therapy" 10 Granted Patents**--US9822347, US11136563, AU2013359179, AU2019210662, CA2894539, EP2931265 (**Validated in 18 EP countries), EP3326622 (**Validated in 18 EP countries), JP2015-547567, JP2018-154641, HK 1256071--1 Pending Application—US17/465,203

- **Portfolio IV**— "Antiviral Activity of GAS6 Inhibitor" 1 Granted US Patent--US10137173--1 Pending Application--CA2909609

- **Portfolio V**— "Antifibrotic Activity of GAS6 Inhibitor" 4 Granted Patents***--US10,876,176, AU2015364437, EP3233902 (*** Validated in 7 EP Countries), HK1244825--1 Pending Application CA2971406

- **Portfolio VI**— "Methods of Treating Metastatic Cancers Using Axl Decoy Receptors" 1 Granted Patent—RU 2020116224--10 Pending Applications--US20200289613, AU2018359863, CA3080732, CN2018800840462, EP18872866.1, HK 62020020701.2, HK 62020020970.3, JP2020-523776, KR10-2020-7016082, MX/a/2020/007130

- **Portfolio VII**— "Methods of Treating Immunoglobulin A Nephropathy (IgAN) Using Axl Decoy Receptors" PCT/US2020/022860—Abandoned-Business Decision

- **Portfolio VIII**— "Methods of Treating Clear Cell Renal Cell Carcinoma (ccRCC) Using Axl Decoy Receptors" –9 Pending Applications-- US17/790282, AU2021206613, CA3166634, CN2021800193394, EP21738664.8, JP20022-541228, KR10-2022-7027149, MX/a/2022/008289, RU2022119783

- **Portfolio IX**— "Diagnostic Methods For Cancer Using AXL Decoy Receptors" 9 Pending Application— US18/016765, AU-Awaiting Serial Number, CA3185356, CN-Awaiting Serial Number, EP21948702.2, JP2-23-502928, KR-Awaiting Serial Number, MX/a/2023/000810, RU2023100902

- **Portfolio X**— "Methods Of Treating Locally Advanced Or Metastatic Pancreatic Adenocarcinoma Using AXL Decoy Receptors As First-line Therapy" 1 Pending Application—PCT/US2022/043234

In the future, we expect to continue prosecuting broader coverage of certain composition of matter applications. Additionally, we will seek to file new patents related to novel candidates, manufacturing, clinical formulations, dose, and indications, as well as evaluate the acquisition of other innovative IP.

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the date of filing the non-provisional application. In the United States, a patent's term may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the U.S. Patent and Trademark Office ("USPTO") in granting a patent, or may be shortened if a patent is terminally disclaimed over an earlier-filed patent.

The term of a patent that covers an FDA-approved drug may also be eligible for patent term extension, which permits patent term restoration of a U.S. patent as compensation for the patent term lost during the FDA regulatory review process. The Hatch-Waxman Act permits a patent term extension of up to five years beyond the expiration of the patent. The length of the patent term extension is related to the length of time the drug is under regulatory review. A patent term extension cannot extend

the remaining term of a patent beyond a total of 14 years from the date of product approval and only one patent applicable to an approved drug may be extended. Moreover, a patent can only be extended once, and thus, if a single patent is applicable to multiple products, it can only be extended based on one product. Similar provisions are available in Europe and other foreign jurisdictions to extend the term of a patent that covers an approved drug. When possible, depending upon the length of clinical trials and other factors involved in the filing of a BLA, we expect to apply for patent term extensions for patents covering its therapeutics candidates and their methods of use.

We may rely, in some circumstances, on trade secrets to protect our technology. However, trade secrets can be difficult to protect. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with our employees, consultants, scientific advisors and contractors. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these procedures, agreements or security measures may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our consultants, contractors or collaborators use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

Government Regulation

Federal, state and local government authorities in the United States and in other countries extensively regulate, among other things, the research, development, testing, manufacturing, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of biological and pharmaceutical products such as those we are developing. Our product candidates must be approved by the FDA before they may be legally marketed in the United States and by the appropriate foreign regulatory agencies before they may be legally marketed in foreign countries. The process for obtaining regulatory marketing approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources.

U.S. Drug Approval Process

In the United States, the FDA regulates pharmaceutical and biological products under the Federal Food, Drug and Cosmetic Act, Public Health Service Act (the "PHSA"), and implementing regulations. Products are also subject to other federal, state and local statutes and regulations. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant to administrative or judicial sanctions. FDA sanctions could include, among other actions, refusal to approve pending applications, withdrawal of an approval, a clinical hold, warning letters, product recalls or withdrawals from the market, product seizures, total or partial suspension of production or distribution injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us. The process required by the FDA before a drug or biological product may be marketed in the United States generally involves the following:

- completion of nonclinical laboratory tests and animal studies according to good laboratory practices, or GLPs, and applicable requirements for the humane use of laboratory animals or other applicable regulations;

- submission to the FDA of an Investigational New Drug which must become effective before human clinical trials may begin;

- performance of adequate and well-controlled human clinical trials according to the FDA’s regulations commonly referred to as good clinical practices, or GCPs, and any additional requirements for the protection of human research subjects and their health information, to establish the safety and efficacy of the proposed product for its intended use;

- submission to the FDA of a BLA for marketing approval that meets applicable requirements to ensure the continued safety, purity, and potency of the product that is the subject of the BLA based on results of nonclinical testing and clinical trials;

- satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the biological product is produced, to assess compliance with cGMP, to assure that the facilities, methods and controls are adequate to preserve the product’s identity, strength, quality and purity;

- potential FDA audit of the nonclinical trial and clinical study sites that generated the data in support of the BLA; and

- FDA review and approval, or licensure, of the BLA.

Before testing any biological development candidate in humans, the candidate enters the preclinical testing stage. Preclinical tests, also referred to as nonclinical studies, include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies to assess the potential safety and activity of the candidate. The conduct of the preclinical tests must comply with federal regulations and requirements including GLPs. The clinical trial sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. Some preclinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions regarding the proposed clinical trials and places the trial on a clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. The FDA may also impose clinical holds on a biological product candidate at any time before or during clinical trials due to safety concerns or non-compliance. If the FDA imposes a clinical hold, trials may not recommence without FDA authorization and then only under terms authorized by the FDA. Accordingly, we cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin, or that, once begun, issues will not arise that suspend or terminate such trials.

Clinical trials involve the administration of the biological product candidate to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety, including stopping rules that assure a clinical trial will be stopped if certain adverse events should occur. Each protocol and any amendments to the protocol must be submitted to the FDA as part of the IND. Clinical trials must be conducted and monitored in accordance with the FDA's regulations composing the GCP requirements, including the requirement that all research subjects provide informed consent. Further, each clinical trial must be reviewed and approved by an independent institutional review board, or IRB, at or servicing each institution at which the clinical trial will be conducted. An IRB is charged with protecting the welfare and rights of trial participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the form and content of the informed consent that must be signed by each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. Human clinical trials are typically conducted in three sequential phases; these phases may overlap or be combined:

- *Phase 1*. The biological product is initially introduced into healthy human volunteers and tested for safety. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients with the targeted disease.

- *Phase 2*. The biological product is evaluated in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance, optimal dosage and dosing schedule.

- *Phase 3*. Clinical trials are undertaken to further evaluate dosage, clinical efficacy, potency, and safety in an expanded patient population at geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk to benefit ratio of the product and provide an adequate basis for product labeling.

Post-approval clinical trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These clinical trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication, particularly for long-term safety follow-up.

During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data, and clinical trial investigators. Annual progress reports detailing the results of the clinical trials must be submitted to the FDA. Written IND safety reports must be promptly submitted to the FDA and the investigators for serious and unexpected adverse events, any findings from other studies, tests in laboratory animals or in vitro testing that suggest a significant risk for human subjects, or any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must submit an IND safety report within 15 calendar days after the sponsor determines that the information qualifies for reporting. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within seven calendar days after the sponsor's initial receipt of the information. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. The FDA or the sponsor or its data safety monitoring board may suspend or terminate a clinical trial at any time on various

grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the biological product has been associated with unexpected serious harm to subjects.

Concurrently with clinical trials, companies usually complete additional studies and must also develop additional information about the physical characteristics of the biological product as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. To help reduce the risk of the introduction of adventitious agents with use of biological products, the PHSA emphasizes the importance of manufacturing control for products whose attributes cannot be precisely defined. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other criteria, the sponsor must develop methods for testing the identity, strength, quality, potency and purity of the final biological product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the biological product candidate does not undergo unacceptable deterioration over its shelf life.

U.S. Review and Approval Processes

After the completion of clinical trials of a biological product, FDA approval of a BLA must be obtained before commercial marketing of the biological product. The BLA must include results of product development, laboratory and animal studies, human trials, information on the manufacture and composition of the product, proposed labeling and other relevant information. The FDA may grant deferrals for submission of data, or full or partial waivers. The testing and approval processes require substantial time and effort and there can be no assurance that the FDA will accept the BLA for filing and, even if filed, that any approval will be granted on a timely basis, if at all.

Under the Prescription Drug User Fee Act ("PDUFA"), as amended, each BLA must be accompanied by a significant user fee. The FDA adjusts the PDUFA user fees on an annual basis. PDUFA also imposes an annual program fee on approved biological products. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. No user fees are assessed on BLAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

The FDA has a Fast Track program that is intended to expedite or facilitate the process for reviewing new drugs and biological products that meet certain criteria. Specifically, new biological products are eligible for Fast Track designation if they are intended to treat a serious or life-threatening condition and demonstrate the potential to address unmet medical needs for the condition. Fast Track designation applies to the combination of the product and the specific indication for which it is being studied. For a Fast Track biological product, the FDA may consider review of completed sections of a BLA on a rolling basis provided the sponsor provides, and the FDA accepts, a schedule for the submission of the completed sections of the BLA. Under these circumstances, the sponsor pays any required user fees upon submission of the first section of the BLA. A Fast Track designated drug candidate may also qualify for priority review, under which the FDA reviews the BLA in six months rather than ten months after it is accepted for filing.

Within 60 days following submission of the application, the FDA reviews a BLA submitted to determine if it is substantially complete before the agency accepts it for filing. The FDA may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the BLA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review of the BLA. The FDA reviews the BLA to determine, among other things, whether the proposed product is safe, potent, and/or effective for its intended use, and has an acceptable purity profile, and whether the product is being manufactured in accordance with cGMP to assure and preserve the product's identity, safety, strength, quality, potency and purity. The FDA may refer applications for novel biological products or biological products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. During the biological product approval process, the FDA also will determine whether a Risk Evaluation and Mitigation Strategy, or REMS, is necessary to assure the safe use of the biological product. If the FDA concludes a REMS is needed, the sponsor of the BLA must submit a proposed REMS. The FDA will not approve a BLA without a REMS, if required.

Before approving a BLA, the FDA will inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure that the clinical trials were conducted in

compliance with IND trial requirements and GCP requirements. To assure cGMP and GCP compliance, an applicant must incur significant expenditure of time, money and effort in the areas of training, record keeping, production, and quality control.

Notwithstanding the submission of relevant data and information, the FDA may ultimately decide that the BLA does not satisfy its regulatory criteria for approval and deny approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data. If the agency decides not to approve the BLA in its present form, the FDA will issue a complete response letter that describes all of the specific deficiencies in the BLA identified by the FDA. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical trials. Additionally, the complete response letter may include recommended actions that the applicant might take to place the application in a condition for approval. If a complete response letter is issued, the applicant may either resubmit the BLA, addressing all of the deficiencies identified in the letter, or withdraw the application.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product.

Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. The FDA may impose restrictions and conditions on product distribution, prescribing, or dispensing in the form of a risk management plan, or otherwise limit the scope of any approval. In addition, the FDA may require post marketing clinical trials, sometimes referred to as Phase 4 clinical trials, designed to further assess a biological product's safety and effectiveness, and testing and surveillance programs to monitor the safety of approved products that have been commercialized.

In addition, under the Pediatric Research Equity Act, a BLA or supplement to a BLA must contain data to assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of data or full or partial waivers.

Post-Approval Requirements

Any products for which we receive FDA approvals are subject to continuing regulation by the FDA, including, among other things, record-keeping requirements, reporting of adverse experiences with the product, providing the FDA with updated safety and efficacy information, product sampling and distribution requirements, and complying with FDA promotion and advertising requirements, which include, among others, standards for direct-to-consumer advertising, restrictions on promoting products for uses or in patient populations that are not described in the product's approved uses, known as 'off-label' use, limitations on industry-sponsored scientific and educational activities, and requirements for promotional activities involving the internet. Although physicians may prescribe legally available products for off-label uses, if the physicians deem to be appropriate in their professional medical judgment, manufacturers may not market or promote such off-label uses.

In addition, quality control and manufacturing procedures must continue to conform to applicable manufacturing requirements after approval to ensure the long-term stability of the product. cGMP regulations require among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Manufacturers and other entities involved in the manufacture and distribution of approved products are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. Discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved BLA, including, among other things, recall or withdrawal of the product from the market. In addition, changes to the manufacturing process are strictly regulated, and depending on the significance of the change, may require prior FDA approval before being implemented. Other types of changes to the approved product, such as adding new indications and claims, are also subject to further FDA review and approval.

The FDA also may require post-marketing testing, known as Phase 4 testing, and surveillance to monitor the effects of an approved product. Discovery of previously unknown problems with a product or the failure to comply with applicable FDA requirements can have negative consequences, including adverse publicity, judicial or administrative enforcement, warning letters from the FDA, mandated corrective advertising or communications with doctors, and civil or criminal penalties, among others. Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our product candidates under development.

Other U.S. Healthcare Laws and Compliance Requirements

In the United States, our activities are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including but not limited to, the Centers for Medicare and Medicaid Services, or CMS, other divisions of the U.S. Department of Health and Human Services, for instance the Office of Inspector General, the U.S. Department of Justice, or DOJ, and individual U.S. Attorney offices within the DOJ, and state and local governments. For example, sales, marketing and scientific/educational grant programs must comply with the anti-fraud and abuse provisions of the Social Security Act, the false claims laws, the physician payment transparency laws, the privacy and security provisions of HIPAA, as amended by HITECH, and similar state laws, each as amended.

The federal anti-kickback statute prohibits, among other things, any person or entity, from knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any item or service reimbursable under Medicare, Medicaid or other federal healthcare programs. The term remuneration has been interpreted broadly to include anything of value. The anti-kickback statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, and formulary managers on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution. The exceptions and safe harbors are drawn narrowly and practices that involve remuneration that may be alleged to be intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. Our practices may not in all cases meet all of the criteria for protection under a statutory exception or regulatory safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor, however, does not make the conduct per se illegal under the anti-kickback statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. Violations of this law are punishable by imprisonment, criminal fines, administrative civil money penalties and exclusion from participation in federal healthcare programs.

Additionally, the intent standard under the anti-kickback statute was amended by the Affordable Care Act ("ACA") to a stricter standard such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the Patient Protection and ACA, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA, provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act ("FCA"), as discussed below.

The civil monetary penalties statute imposes penalties against any person or entity that, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.

Although we would not submit claims directly to payors, drug manufacturers can be held liable under the federal civil FCA, which imposes civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities (including manufacturers) for, among other things, knowingly presenting, or causing to be presented to federal programs (including Medicare and Medicaid) claims for items or services, including drugs, that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services; making a false statement or record material to payment of a false claim; or avoiding, decreasing or concealing an obligation to pay money to the federal government. Penalties for a FCA violation include three times the actual damages sustained by the government, plus mandatory civil penalties for each separate false claim, the potential for exclusion from participation in federal healthcare programs and, although the federal FCA is a civil statute, conduct that results in a FCA violation may also implicate various federal criminal statutes. The government may deem manufacturers to have "caused" the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label. Claims which include items or services resulting from a violation of the federal Anti-Kickback Statute are false or fraudulent claims for purposes of the FCA. Our future marketing and activities relating to the reporting of wholesaler or estimated retail prices for our products, if approved, the reporting of prices used to calculate Medicaid rebate information and other information affecting federal, state and third-party reimbursement for our products, and the sale and marketing of our product and any future product candidates, are subject to scrutiny under this law. Pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the companies' marketing of the product for unapproved, and thus non-reimbursable, uses.

HIPAA created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations or promises, any money or property owned by, or under the control or custody of, any healthcare benefit program, including private third party payors and knowingly and willfully falsifying, concealing or covering up by trick, scheme or device, a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal anti-kickback statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

We may be subject to data privacy and security regulations by both the federal government and the states in which we conduct business. HIPAA, as amended by the HITECH Act, and their respective implementing regulations, impose requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to business associates, defined as independent contractors or agents of covered entities, which include health care providers, health plans, and healthcare clearinghouse, that create, receive, or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities and business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions. In addition, certain state laws govern the privacy and security of health information in specified circumstances, some of which are more stringent and many of which differ from each other in significant ways, thus complicating compliance efforts. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and criminal penalties.

Additionally, the Federal Physician Payments Sunshine Act under the ACA, and its implementing regulations, require that certain manufacturers of drugs, devices, biological and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, (with certain exceptions), to annually report to the Centers for Medicare and Medicaid, or CMS, information related to certain payments or other transfers of value made or distributed to physicians and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals and to report annually certain ownership and investment interests held by physicians and their immediate family members. Failure to submit timely, accurately, and completely the required information may result in civil monetary penalties. Certain states also mandate implementation of compliance programs, impose restrictions on pharmaceutical manufacturer marketing practices and/or require the tracking and reporting of gifts, compensation and other remuneration to healthcare providers and entities.

In order to distribute products commercially, we must also comply with state laws that require the registration of manufacturers and wholesale distributors of drug and biological products in a state, including, in certain states, manufacturers and distributors who ship products into the state even if such manufacturers or distributors have no place of business within the state. Some states also impose requirements on manufacturers and distributors to establish the pedigree of product in the chain of distribution, including some states that require manufacturers and others to adopt new technology capable of tracking and tracing product as it moves through the distribution chain. Several states have enacted legislation requiring pharmaceutical and biotechnology companies to establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities, and/or register their sales representatives, as well as to prohibit pharmacies and other healthcare entities from providing certain physician prescribing data to pharmaceutical and biotechnology companies for use in sales and marketing, and to prohibit certain other sales and marketing practices. All of our activities are potentially subject to federal and state consumer protection and unfair competition laws.

If our operations are found to be in violation of any of the federal and state healthcare laws described above or any other governmental regulations that apply to it, we may be subject to penalties, including without limitation, significant civil, criminal and/or administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government programs, such as Medicare and Medicaid, injunctions, private "qui tam" actions brought by individual whistleblowers in the name of the government, or refusal to enter into government contracts, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings, and the curtailment or restructuring of operations, any of which could adversely affect our ability to operate our business and our results of 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. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource-consuming and can divert a company's attention from the business.

Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we obtain regulatory approval. In the United States and markets in other countries, sales of any products for which we receive regulatory approval for commercial sale will depend, in part, on the extent to that third-party payors provide coverage, and establish adequate reimbursement levels for such products. In the United States, third-party payors include federal and state healthcare programs, private managed care providers, health insurers and other organizations. The process for determining whether a third-party payor will provide coverage for a product may be separate from the process for setting the price of a product or for establishing the reimbursement rate that such a payor will pay for the product. Third-party payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the FDA-approved products for a particular indication. Third-party payors are increasingly challenging the price, examining the medical necessity and reviewing the cost- effectiveness of medical products, therapies and services, in addition to questioning their safety and efficacy. We may need to conduct expensive pharmaco-economic studies in order to demonstrate the medical necessity and cost-effectiveness of our product candidates, in addition to the costs required to obtain the FDA approvals. Our product candidates may not be considered medically necessary or cost-effective. A payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage for the product. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on investment in product development.

Different pricing and reimbursement schemes exist in other countries. Some 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 countries allow companies to fix their own prices for medicines, but monitor and control company profits. The downward pressure on health care costs has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country.

The marketability of any product candidate for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. In addition, emphasis on managed care in the United States has increased and we expect the pressure on healthcare pricing will continue to increase. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

U.S. Healthcare Reform

In the United States and some foreign jurisdictions, there have been, and likely will continue to be, a number of legislative and regulatory changes and proposed changes regarding the healthcare system directed at broadening the availability of healthcare, improving the quality of healthcare, and containing or lowering the cost of healthcare.

Some of the provisions of the ACA have yet to be fully implemented, while certain provisions have been subject to judicial and Congressional challenges. It is unclear how these challenges and other efforts to repeal and replace the ACA will impact our business in the future.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. Additionally, there have been several recent U.S. Congressional inquiries and proposed bills designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drugs.

We cannot predict what healthcare reform initiatives may be adopted in the future. Further federal, state and foreign legislative and regulatory developments are likely, and we expect ongoing initiatives to increase pressure on drug pricing. Such reforms could have an adverse effect on anticipated revenues from product candidates and may affect our overall financial condition and ability to develop product candidates.

We anticipate that current and future U.S. legislative healthcare reforms may result in additional downward pressure on the price that we receive for any approved product, if covered, and could seriously harm our business. Any reduction in reimbursement from Medicare and other government programs may result in a similar reduction in payments from private payors.

Foreign Regulation

In order to market any product outside of the United States, we would need to comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, it would need to obtain the necessary approvals by the comparable foreign regulatory authorities before it can commence clinical trials or marketing of the product in foreign countries and jurisdictions. Although many of the issues discussed above with respect to the United States apply similarly in the context of the European Union, the approval process varies between countries and jurisdictions and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries and jurisdictions might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others.

European Data Collection

The collection and use of personal health data in the European Economic Area (EEA) is governed by the General Data Protection Regulation 2016/679 ("GDPR"), which became effective May 25, 2018. The GDPR applies to any company established in the EEA and to companies established outside the EEA that process personal data in connection with the offering of goods or services to data subjects in the EU or the monitoring of the behavior of data subjects in the EU. The GDPR enhances data protection obligations for data controllers of personal data (including stringent requirements relating to the consent of data subjects, expanded disclosures about how personal data is used, requirements to conduct privacy impact assessments for “high risk” processing, limitations on retention of personal data, mandatory data breach notification and “privacy by design” requirements) and creates direct obligations on service providers acting as data processors. The GDPR also imposes strict rules on the transfer of personal data outside of the EEA to countries that do not ensure an adequate level of protection, like the U.S. Failure to comply with the requirements of the GDPR and the related national data protection laws of the EEA Member States may result in fines up to 20 million Euros or 4% of a company’s global annual revenues for the preceding financial year, whichever is higher. Moreover, the GDPR grants data subjects the right to claim material and non-material damages resulting from infringement of the GDPR. Given the breadth and depth of changes in data protection obligations, maintaining compliance with the GDPR, will require significant time, resources and expense, and we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules. This may be onerous and adversely affect our business, financial condition, results of operations and prospects**.**

Human Capital

We believe that our success depends upon our ability to attract, develop and retain key personnel. Our management and scientific teams possess considerable experience in drug discovery, research, manufacturing, clinical development and regulatory matters and we believe that we benefit from this experience and industry knowledge. Our research team includes M.D., M.S., and Ph.D.-level scientists with expertise in cancer biology. As of December 31, 2022, we had 23 full-time employees, of which 15 were part of our research team and 8 were part of our general and administrative team. Of the management team, 80% are women or minorities. We have no collective bargaining agreements with our employees and have not experienced any work stoppages. We consider our relations with our employees to be good. Although, management continually seeks to add additional talent to its work force, management believes that it has sufficient human capital to operate its business successfully.

Competitive Pay and Benefits

Our compensation programs are designed to align the compensation of our employees with our performance and to provide the proper incentives to attract, retain and motivate employees to achieve superior results. The structure of our compensation programs balances incentive earnings for both short-term and long-term performance. Specifically:

- We provide employee wages that are competitive and consistent with employee positions, skill levels, experience, knowledge and geographic location.

- We engage nationally recognized outside compensation and benefits consulting firms to independently evaluate the effectiveness of our executive compensation and benefit programs and to provide benchmarking against our peers within the industry.

- We align our executives' long-term equity compensation with our shareholders' interests by linking realizable pay with stock performance.

- Annual increases and incentive compensation are based on merit, which is communicated to employees at the time of hiring and documented through our talent management process as part of our annual review procedures and upon internal transfer and/or promotion.

- All employees are eligible for health insurance, paid and unpaid leaves, a 401K retirement plan with employer matching contributions (maximum of 2% match) and life and disability/accident coverage. We also offer a variety of voluntary benefits that allow employees to select the options that meet their needs, including flexible time-off, telemedicine, and paid parental leave.

Health and Safety

The health and safety of our employees is our highest priority, and this is consistent with our operating philosophy. Accordingly, with the global spread of the ongoing novel COVID-19 pandemic, we have implemented plans designed to address and mitigate the impact of the COVID-19 pandemic on the safety of our employees and our business, which include:

- Adding work from home flexibility;

- Adjusting attendance policies to encourage those who are sick to stay home;

- Increasing cleaning protocols across all locations;

- Initiating regular communication regarding impacts of the COVID-19 pandemic, including health and safety protocols and procedures;

Core Values and Culture

Fostering and maintaining a strong, healthy culture is a key strategic focus. Our core values reflect who we are and the way our employees interact with one another, our customers, partners and shareholders. Our core values include: treating one another with respect, considering the needs of others and providing solutions to meet their needs, being constantly working to improve and willing to try new approaches, making decisions with the long-term view in mind, and acting as a team by listening to one another and working across teams toward a common goal. We collaborate to achieve results and focus on success for our patients and shareholders.

Corporate Information

We were incorporated under the laws of the State of Delaware in December 2008 under the name Versartis, Inc. and completed our initial public offering in March 2014. Aravive Biologics was incorporated under the laws of the State of Delaware in April 2007, originally under the name of Hypoximed, Inc, which name was changed to Ruga Corporation in July 2009 and changed to Aravive Biologics, Inc. in October 2016. On October 12, 2018, we, then known as Versartis, Inc. and Aravive Biologics, completed a merger and reorganization (the "Merger"), pursuant to which Aravive Biologics survived as our wholly owned subsidiary. In connection with the completion of the Merger, on October 15, 2018, we changed our name from Versartis, Inc. to "Aravive, Inc." and on October 16, 2018, we effected a reverse split of our common stock at a ratio of 1-for-6 (the "Reverse Split").

Available Information

Our website address is www.aravive.com. We file Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, proxy statements and other materials with the SEC. We are subject to the informational requirements of the Exchange Act and file or furnish reports, proxy statements and other information with the SEC. Such reports and other information filed by the Company with the SEC are available free of charge on our website at http://ir.aravive.com/investors/financial-information. Information contained on, or that can be accessed through, our website is not incorporated by reference into this Annual Report on Form 10-K, and you should not consider information on our website to be part of this Annual Report on Form 10-K.

The SEC also maintains a website that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC at www.sec.gov.

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. You should consider carefully the following risks, together with all the other information in this Annual Report on Form 10-K, including the section titled "Cautionary Note Regarding Forward-Looking Statements," and Part II, Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operation" and our consolidated financial statements and the accompanying notes included elsewhere in this Annual Report on Form 10-K. The risks described below are not the only ones we face. Any of the following risks could materially and adversely affect our business. If any of the following risks actually materializes, our operating results, financial condition and liquidity could be materially adversely affected. As a result, the trading price of our common stock could decline and you could lose part or all of your investment. Our business, financial condition and results of operations could also be harmed by risks and uncertainties not currently known to us or that we currently do not believe are material.

Risks Related to Our Financial Position And Capital Requirements.

We have a limited operating history and have incurred significant losses since our inception, and we anticipate that we will continue to incur substantial and increasing losses for the foreseeable future. We have only one product candidate, batiraxcept, and no commercial sales, which, together with our limited operating history, makes it difficult to evaluate our business and assess our future viability.

We are a clinical-stage biopharmaceutical company with a limited operating history. We have never generated any product revenue and do not have any products approved for sale.

Our operations to date have been primarily focused on developing our only product candidate, batiraxcept. We have not yet successfully obtained marketing approval, manufactured batiraxcept product at commercial scale, or conducted sales and marketing activities that will be necessary to successfully commercialize batiraxcept. Consequently, predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing product candidates.

Even if we receive regulatory approval for the sale of any of our product candidates, we do not know when we will begin to generate revenue, if at all. Our ability to generate revenue depends on a number of factors, including our ability to:

- set an acceptable price for our products and obtain coverage and adequate reimbursement from third-party payors;
- establish sales, marketing, manufacturing and distribution systems;
- add operational, financial and management information systems and personnel, including personnel to support our clinical, manufacturing and planned future clinical development and commercialization efforts and operations as a public company;
- develop manufacturing capabilities for bulk materials and manufacture commercial quantities of product candidates at acceptable cost levels;
- achieve broad market acceptance of our product candidates in the medical community and with third-party payors and consumers;
- attract and retain an experienced management and advisory team;
- launch commercial sales of our products, whether alone or in collaboration with others; and
- maintain, expand and protect our intellectual property portfolio.

Because of the numerous risks and uncertainties associated with development and manufacturing, we are unable to predict if we will generate revenue. If we cannot successfully execute on any of the factors listed above, our business may not succeed, we may never generate revenue and your investment will be adversely affected.

We have incurred significant losses since inception and expect to continue to incur significant losses for the foreseeable future and may never achieve or maintain profitability.

We have incurred significant operating losses in each year since our inception and expect to incur substantial and increasing losses for the foreseeable future. As of December 31, 2022, we had an accumulated deficit of approximately $616.1 million.

To date, we have financed our operations primarily through private placements of our equity securities, debt financing, CPRIT grant proceeds, at-the-market offerings of our common stock, public offerings of our common stock as well as upfront and milestone payments received from license agreements. We have devoted substantially all of our efforts to research and development, including clinical studies, but have not completed development of any product candidate. We anticipate that our expenses will increase to the extent we:

- continue the research and development of our only product candidate, batiraxcept, and any future product candidates;
- conduct additional clinical studies of batiraxcept in the future, especially later stage trials that involve a larger number of patients;
- seek to discover or in-license additional product candidates;
- seek regulatory approvals for batiraxcept and any future product candidates that successfully complete clinical studies;
- establish a sales, marketing and distribution infrastructure and scale-up manufacturing capabilities to commercialize batiraxcept or other future product candidates if they obtain regulatory approval, including process improvements in order to manufacture batiraxcept at commercial scale; and
- enhance operational, financial and information management systems and hire more personnel, including personnel to support development of batiraxcept and any future product candidates and, if a product candidate is approved, our commercialization efforts.

To be profitable in the future, we must succeed in developing and eventually commercializing batiraxcept as well as other products with significant market potential. This will require us to be successful in a range of activities, including advancing batiraxcept and any future product candidates, completing clinical studies of these product candidates, obtaining regulatory approval for these product candidates and manufacturing, marketing and selling those products for which we may obtain regulatory approval. We may not succeed in these activities and may never generate revenue that is sufficient to be profitable in the future. Even if we are profitable, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to achieve sustained profitability would depress the value of our company and could impair our ability to raise capital, expand our business, diversify our product candidates, market our product candidates, if approved, or continue our operations.

We expect our research and development expenses to increase significantly as our product candidates advance in clinical development. Because of numerous risks and uncertainties involved in our business, the timing or amount of increased development expenses cannot be accurately predicted and, our expenses could increase beyond expectations if we are required by the FDA, or comparable non-U.S. regulatory authorities, to perform studies or clinical trials in addition to those we currently anticipate. Even if our product candidate, batiraxcept, is approved for commercial sale, we anticipate incurring significant costs associated with the commercial launch of and the related commercial-scale manufacturing requirements for batiraxcept. As a result, we expect to continue to incur significant and increasing operating losses and negative cash flows for the foreseeable future. Because of the numerous risks and uncertainties associated with biopharmaceutical product development and commercialization, we are unable to accurately predict the timing or amount of future expenses or when, or if, we will be able to achieve or maintain profitability. These losses have had and will continue to have an adverse effect on our financial position and working capital.

There is uncertainty regarding our ability to maintain liquidity sufficient to operate our business effectively, which raises substantial doubt about our ability to continue as a going concern.

Our consolidated audited financial statements as of and for the year ended December 31, 2022 have been prepared under the assumption that we will continue as a going concern for the next twelve months. Our management concluded that our recurring losses from operations and the fact that we have not generated significant revenue or positive cash flows from

operations raise substantial doubt about our ability to continue as a going concern for the next twelve months after issuance of our financial statements. Our auditors also included an explanatory paragraph in its report on our financial statements as of and for the year ended December 31, 2022 with respect to this uncertainty. Our ability to continue as a going concern is dependent upon our ability to obtain additional equity or debt financing, attain further operating efficiencies, reduce expenditures, and, ultimately, to generate revenue. Since inception, we have incurred net losses and negative cash flows from operations. At December 31, 2022, we had an accumulated deficit of $616.1 million and working capital of $35.9 million. We expect to continue to incur losses from expenses related to the development of batiraxcept and related administrative activities for the foreseeable future. As of December 31, 2022, we had a cash and cash equivalents balance of approximately $53.7 million consisting of cash and investments in highly liquid U.S. money market funds. We believe that our current cash and cash equivalents will be sufficient to fund our current planned operations into the fourth quarter of 2023 but that we will need to seek additional capital to fulfill our operating and capital requirement for the next 12 months to advance our clinical development program to later stages of development and commercialize our clinical product candidate. Although management has been successful in raising capital in the past, there can be no assurance that we will be successful or that any needed financing will be available in the future at terms acceptable to the Company. As such, the Company cannot conclude that such plans will be effectively implemented within one year after the date that the financial statements included in this Annual Report on Form 10-K are filed with the SEC and there is uncertainty regarding our ability to maintain liquidity sufficient to operate our business effectively, which raises substantial doubt about our ability to continue as a going concern.

We will need additional funds to support our operations, and such funding may not be available to us on acceptable terms, or at all, which would force us to delay, reduce or suspend our research and development programs and other operations or commercialization efforts.

The completion of the development and the potential commercialization of batiraxcept and any future product candidates, should they receive approval, will require substantial funds. In addition, we expect our manufacturing costs to significantly increase this year as we prepare for submission of a BLA and potential commercialization. As of December 31, 2022, we had approximately $53.7 million in cash and cash equivalents. We believe that our existing cash and cash equivalents will be sufficient to fund our current planned operations into the fourth quarter of 2023 based on our existing business plan; however, our existing cash and cash equivalents will not be sufficient to enable us to complete the clinical development and commercialization of batiraxcept. Our future financing requirements will depend on many factors, some of which are beyond our control, including the following:

- the rate of progress and cost of our future clinical studies;
- the number of patients in our clinical trials and the length of time of progression of their disease;
- the timing of, and costs involved in, seeking and obtaining approvals from the FDA and other regulatory authorities;
- the cost of preparing to manufacture batiraxcept on a larger scale, should we elect to do so;
- the costs of commercialization activities if batiraxcept or any future product candidate is approved, including product sales, marketing, manufacturing and distribution;
- the degree and rate of market acceptance of any products launched by us or future partners;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- our ability to enter into additional collaboration, licensing, commercialization or other arrangements and the terms and timing of such arrangements;
- the emergence of competing technologies or other adverse market developments; and
- the costs of attracting, hiring and retaining qualified personnel.

We do not have any material committed external source of funds or other support for our development efforts. Although we have entered into an at-the-market facility with Piper Sandler & Co. (“Piper Sandler”), and Cantor Fitzgerald & Co. (“Cantor Fitzgerald”), as sales agents, there can be no assurance that we will meet all of the conditions necessary to continue to use such facility or that we can generate sufficient proceeds from the sale of securities pursuant to such facility to support our operations. Until we can generate a sufficient amount of product revenue to finance our cash requirements, which we may

never do, we expect to finance future cash needs through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing and distribution arrangements. To the extent that we raise additional funds by issuing equity securities, our stockholders may experience significant dilution. Any debt financing, if available, may involve restrictive covenants that may impact our ability to conduct our business and may be negatively impacted by inflation. Additional financing may not be available to us when we need it or it may not be available on favorable terms. In addition, certain SEC limitations due to our non-affiliate float being less than $75 million and certain Nasdaq Stock Market Global limitations with respect to fundraising, including limitations on the use of our shelf registration statement, may make it more difficult to raise additional funds. If we are unable to obtain adequate financing when needed, we may have to delay, reduce the scope of, or suspend one or more of our clinical studies or research and development programs or our commercialization efforts.

Raising additional funds by issuing securities may cause dilution to existing stockholders, and raising funds through lending and licensing arrangements may restrict our operations or require it to relinquish proprietary rights.

We expect that significant additional capital will be needed in the future to continue our planned operations and commercialize batiraxcept. Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, strategic alliances and license and development agreements in connection with any collaborations. We do not currently have any committed external source of funds. To the extent that we raise additional capital by issuing equity securities, existing stockholders' ownership may experience substantial dilution, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of a common stockholder. In addition, the exercise of outstanding warrants and options will also cause dilution. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, declaring dividends, creating liens, redeeming its stock or making investments.

If we raise additional 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 when needed, or through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties on acceptable terms, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise develop and market.

Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or our guidance.

Our quarterly and annual operating results may fluctuate significantly in the future, which makes it difficult for us to predict our future operating results. From time to time, we may enter into collaboration agreements with other companies that include development funding and significant upfront and milestone payments and/or royalties, which may become an important source of our revenue. Accordingly, our revenue may depend on development funding and the achievement of development and clinical milestones under any potential future collaboration and license agreements and sales of our products, if approved. These upfront and milestone payments may vary significantly from period to period and any such variance could cause a significant fluctuation in our operating results from one period to the next. In addition, our manufacturing and clinical trial expenses, which are anticipated to be significant, may fluctuate significantly quarter to quarter based upon whether or not we are engaged in clinical trials or manufacturing our product candidate, batiraxcept, and timing of our process development work. Furthermore, we measure compensation cost for stock-based awards made to employees at the grant date of the award, based on the fair value of the award as determined by our board of directors, and recognize the cost as an expense over the employee's requisite service period. As the variables that we use as a basis for valuing these awards change over time, our underlying stock price and stock price volatility, the magnitude of the expense that we must recognize may vary significantly. Furthermore, our operating results may fluctuate due to a variety of other factors, many of which are outside of our control and may be difficult to predict, including the following:

- the timing and cost of, and level of investment in, research and development activities relating to batiraxcept and any future product candidates, which will change from time to time;

- our ability to enroll patients in clinical trials and the timing of enrollment;

- the timing and cost of manufacturing batiraxcept and any future product candidates, which may vary depending on FDA guidelines and requirements, the quantity of production and the terms of our agreements with manufacturers;
- expenditures that we will or may incur to acquire or develop additional product candidates and technologies;
- the timing and outcomes of clinical studies for batiraxcept and any future product candidates or competing product candidates;
- changes in the competitive landscape of our industry, including consolidation among our competitors or partners;
- any delays in regulatory review or approval of batiraxcept or any of our future product candidates;
- the level of demand for batiraxcept and any future product candidates, should they receive approval, which may fluctuate significantly and be difficult to predict;
- the risk/benefit profile, cost and reimbursement policies with respect to our products candidates, if approved, and existing and potential future drugs that compete with our product candidates;
- competition from existing and potential future drugs that compete with batiraxcept or any of our future product candidates;
- our ability to commercialize batiraxcept or any future product candidate inside and outside of the United States, either independently or working with third parties;
- our ability to establish and maintain collaborations, licensing or other arrangements;
- our ability to adequately support future growth;
- potential unforeseen business disruptions that increase our costs or expenses;
- future accounting pronouncements or changes in our accounting policies; and
- the changing and volatile global economic environment.

The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated revenue and/or earnings guidance we may provide.

Risks Related To Our Business

Changes in general economic conditions, geopolitical conditions, domestic and foreign trade policies, monetary policies and other factors beyond our control may adversely impact our business and operating results.

Our operations and performance depend on global, regional and U.S. economic and geopolitical conditions. General worldwide economic conditions have experienced significant instability in recent years including the recent global economic uncertainty and financial market conditions. Russia's invasion and military attacks on Ukraine have triggered significant sanctions from U.S. and European leaders and financial markets around the world experienced volatility following the invasion of Ukraine by Russia in February 2022. Resulting changes in U.S. trade policy could trigger retaliatory actions by Russia, its allies and other affected countries, including China, resulting in a "trade war." Furthermore, if other countries, including the U.S., become further involved in the conflict, we could face significant adverse effects to our business and financial condition.

As we advance our clinical programs, we are in close contact with our clinical research organizations ("CROs") and clinical sites and are continually assessing the impact of COVID-19 on our planned trials and current timelines and costs as well as the impact of the invasion and military attacks on Ukraine. The uncertain financial markets, disruptions in supply chains, mobility restraints, and changing priorities as well as volatile asset values could impact our business in the future. The COVID-19 outbreak and government measures taken in response to the pandemic have also had a significant impact, both direct and indirect, on businesses and commerce, as worker shortages have occurred; supply chains have been disrupted; facilities and production have been suspended; and demand for certain goods and services, such as medical services and supplies, have spiked, while demand for other goods and services, such as travel, have fallen. The future progression of the pandemic and its effects on our business and operations are uncertain. We may face difficulties recruiting or retaining patients in our ongoing and planned clinical trials if patients are affected by the virus or are fearful of traveling to our clinical trial sites because of the outbreak or the military situation in Ukraine expands into other countries where we have or plan to conduct clinical trials. Any such disruptions or delays would, and any such increased clinical program expenses could, adversely affect our business, financial condition, results of operations and growth prospects. We and our third-party contract manufacturers, contract research organizations, and clinical sites may also face disruptions in procuring items that are essential to our research and development activities, including, for example, medical and laboratory supplies used in our clinical trials or preclinical studies, in each case, that are sourced from abroad or for which there are shortages because of ongoing efforts to address the outbreak. Further, although we have not experienced any material adverse effects on our business due to increasing inflation, it has raised operating costs for many businesses and, in the future, could impact demand or pricing manufacturing of our drug candidates or services providers, foreign exchange rates or employee wages. Inflation rates, particularly in the United States and United Kingdom, have increased recently to levels not seen in years, and increased inflation may result in increases in our operating costs (including our labor costs), reduced liquidity and limits on our ability to access credit or otherwise raise capital. In addition, the Federal Reserve has raised, and may again raise, interest rates in response to concerns about inflation, which coupled with reduced government spending and volatility in financial markets may have the effect of further increasing economic uncertainty and heightening these risks.

Actual events involving reduced or limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds, have in the past and may in the future lead to market-wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank, was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation as receiver. Although we did not have any cash or cash equivalent balances on deposit with Silicon Valley Bank, uncertainty and liquidity concerns in the broader financial services industry remain and the failure of Silicon Valley Bank and its potential near- and long-term effects on the biotechnology industry and its participants such as our vendors, suppliers, and investors, may also adversely affect our operations and stock price.

We are actively monitoring the effects these disruptions and increasing inflation could have on our operations.

These conditions make it extremely difficult for us to accurately forecast and plan future business activities.

The above factors, including a number of other economic and geopolitical factors both in the U.S. and abroad, could ultimately have material adverse effects on our business, financial condition, results of operations or cash flows, including the following:

- inability to enroll patients in clinical sites located in affected countries;
- inability or delays in receiving supplies of batiraxcept manufacturing in China;
- effects of significant changes in economic, monetary and fiscal policies in the U.S. and abroad including currency fluctuations, inflationary pressures and significant income tax changes;
- a global or regional economic slowdown in any of our market segments;
- changes in government policies and regulations affecting the Company or its significant customers;
- industrial policies in various countries that favor domestic industries over multinationals or that restrict foreign companies altogether;

- new or stricter trade policies and tariffs enacted by countries, such as China, in response to changes in U.S. trade policies and tariffs;
- postponement of spending, in response to tighter credit, financial market volatility and other factors;
- rapid material escalation of the cost of regulatory compliance and litigation;
- difficulties protecting intellectual property;
- longer payment cycles;
- credit risks and other challenges in collecting accounts receivable; and
- the impact of each of the foregoing on outsourcing and procurement arrangements.

In addition, the outbreak of a pandemic could disrupt our operations due to absenteeism by infected or ill members of management or other employees, or absenteeism by members of management and other employees who elect not to come to work due to the illness affecting others in our office or laboratory facilities, or due to quarantines. Pandemics could also impact members of our Board of Directors resulting in absenteeism from meetings of the directors or committees of directors, and making it more difficult to convene the quorums of the full Board of Directors or its committees needed to conduct meetings for the management of our affairs.

Business disruptions could seriously harm our future revenue and financial condition and increase costs and expenses.

Our operations and those of our third-party suppliers and collaborators, including our manufacturer, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes or other extreme weather conditions, medical epidemics, labor disputes, war or other business interruptions. Any interruption could seriously harm our ability to timely proceed with any clinical programs or to supply product candidates for use in our clinical programs or during commercialization. For example, the current COVID-19 pandemic has, at points, caused an interruption in our clinical trial activities. Additionally, supply chains disruptions impact and may continue to impact our research activities. Moreover, the invasion of Ukraine and the retaliatory measures that have been taken, or could be taken in the future, by the United States, NATO, and other countries have created global security concerns that could result in a regional conflict and otherwise have a lasting impact on regional and global economies, any or all of which could disrupt our supply chain and adversely affect our ability to conduct ongoing and future clinical trials of our product candidates. This could negatively impact the anticipated timing and completion of our clinical trials and/or analyses of clinical results. In addition, if any sanctions were to be imposed on China that effect the export of our clinical trial materials, our ability to complete current and future clinical trials could be adversely impacted.

Reliance on government funding for our programs may impose requirements that limit our ability to take certain actions, and subject us to potential financial penalties, which could materially and adversely affect our business, financial condition and results of operations.

A significant portion of our funding has been through a grant Aravive Biologics received from CPRIT. The CPRIT Grant (as described below) includes provisions that reflect the government's substantial rights and remedies, many of which are not typically found in commercial contracts, including powers of the government to potentially require repayment of all or a portion of the grant award proceeds, in certain cases with interest, in the event we violate certain covenants pertaining to various matters that include any potential relocation outside of the State of Texas. Although our contract with CPRIT terminated November 30, 2019, our royalty and other obligations, including our obligation to repay the disbursed grant proceeds under certain circumstances, to maintain certain records and documentation, to notify CPRIT of certain unexpected adverse events and our obligation to use reasonable efforts to ensure that any new or expanded preclinical testing, clinical trials, commercialization or manufacturing related to any aspect to our CPRIT project take place in Texas, survive the termination of the agreement. We have received the full $20.0 million of the grant proceeds and have expended all of the grant award proceeds by the agreement termination date.

Our award from CPRIT requires us to pay CPRIT a portion of our revenues from sales of certain products by us, or received from our licensees or sublicensees, at tiered percentages of revenue in the low- to mid-single digits until the aggregate amount of such payments equals 400% of the grant award proceeds, and thereafter at a rate of less than one percent for as long

as we maintain government exclusivity, subject to our right, under certain circumstances, to make a one-time payment in a specified amount to CPRIT to terminate such payment obligations.

In order to meet the requirements that any new or expanded preclinical testing, clinical trials, commercialization or manufacturing related to any aspect of our CPRIT project take place in Texas, we will need to hire additional qualified personnel and vendors with expertise in preclinical testing, clinical research and testing, government regulation, formulation and manufacturing, sales and marketing and accounting and financing located in Texas. We will compete for qualified individuals, vendors, clinical trial sites, manufacturers with numerous biopharmaceutical companies, universities and other research institutions. Competition for such individuals is intense, and there can be no assurance that the search for such personnel will be successful, especially in light of the territorial restrictions imposed by CPRIT.

If we fail to maintain compliance with any such requirements that may apply to us now or in the future, we may be subject to potential liability and to termination of our contracts, including potentially the CPRIT Grant, which could result in significant expense to us.

We rely on licenses to use various technologies that are material to our business and if the agreements underlying the licenses were to be terminated or if other rights that may be necessary for commercializing our intended products cannot be obtained, it would halt our ability to market our products and technology, as well as have an immediate material adverse effect on our business, operating results and financial condition.

Our prospects are significantly dependent upon our license with Stanford University (the "Stanford License"). The Stanford License grants us exclusive, worldwide rights to certain existing patents and related intellectual property that cover batiraxcept, the development candidate selected from the AVB-S6 family of proteins. If we breach the terms of the Stanford License, including any failure to make minimum royalty payments required thereunder or failure to reach certain developmental milestones and by certain deadlines or other factors, including but not limited to, the failure to comply with material terms of the Stanford License, the licensor has the right to terminate the license. If we were to lose or otherwise be unable to maintain the license on acceptable terms, or find that it is necessary or appropriate to secure new licenses from other third parties, we would not be able to market our products and technology, which would likely require us to cease our current operations which would have an immediate material adverse effect on our business, operating results and financial condition.

If we fail to comply with our obligations in our intellectual property licenses, we could lose license rights that are important to our business.

In addition to the Stanford License, we are a party to intellectual property license agreements with third parties, and we expect to enter into additional license agreements in the future. Our existing license agreements impose, and we expect that our future license agreements will impose, various diligence, milestone payment, royalty, insurance and other obligations on us. If we fail to comply with these obligations, our licensors may have the right to terminate these agreements, in which event we may not be able to develop and market any product that is covered by these agreements. The occurrence of such events could materially harm our business and financial condition.

The risks described elsewhere pertaining to our intellectual property rights also apply to the intellectual property rights that we license, and any failure by us or our licensors to obtain, maintain, defend and enforce these rights could have a material adverse effect on our business. In some cases, we do not have control over the prosecution, maintenance or enforcement of the patents that we license, and may not have sufficient ability to provide input into the patent prosecution, maintenance and defense process with respect to such patents, and our licensors may fail to take the steps that we believe are necessary or desirable in order to obtain, maintain, defend and enforce the licensed patents. We are responsible for preparing, filing, and prosecuting broad patent claims (including any interference or reexamination actions) for Stanford University’s benefit and for maintaining all licensed patents.

We expect to depend on collaborations with third parties for the development and commercialization of some of our products and product candidates outside of the United States. Our prospects with respect to those products and product candidates will depend in part on the success of those collaborations.

Although we are commercializing batiraxcept ourselves in the United States, we intend to seek to commercialize batiraxcept outside the United States through collaboration arrangements. For instance, we entered into the 3D Medicines Agreement under which we granted 3D Medicines an exclusive sublicense to develop and commercialize batiraxcept, in the Territory.

We may not be able to derive revenue from research and development fees, license fees, milestone payments and royalties under any collaborative arrangement into which we enter. 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, including obtaining regulatory approval in the sublicensed territory, which may not be obtainable even if we obtain regulatory approval to market products in the United States. In addition, our collaborators may have the right to abandon research or development projects and terminate applicable agreements, including funding obligations, prior to or upon the expiration of the agreed upon terms. As a result, we can expect to relinquish some or all of the control over the future success of a product or product candidate that we license to a third party.

Collaborations involving our products and product candidates, such as our license arrangement with 3D Medicines, may pose a number of risks, including the following:

- 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 or in compliance with applicable regulatory requirements;
- collaborators may not pursue development and commercialization of our products and product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, use different doses that us, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;
- collaborators with marketing and distribution rights to one or more products may not commit sufficient resources to the marketing and distribution of such product or products;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the research, development or commercialization of products and product candidates, might lead to additional responsibilities for us with respect to products and product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- 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 intellectual property or 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; and
- 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 in the applicable territories.

Collaboration agreements may not lead to development or commercialization of products or product candidates in the most efficient manner or at all.

In addition, any negative results from clinical trials conducted by any third-party collaborator, including 3D Medicines, will negatively impact our commercialization efforts despite the fact that we will not have conducted those trials.

We rely extensively on our information technology systems which are vulnerable to damage and interruption.

We rely on our information technology systems and infrastructure to process transactions, summarize results and manage our business, including maintaining client and supplier information. Additionally, we utilize third parties, including cloud providers, to store, transfer and process data. Our information technology systems, as well as the systems of our suppliers and other partners, whose systems we do not control, are vulnerable to outages and an increasing risk of continually evolving deliberate intrusions to gain access to company sensitive information. Likewise, data security incidents and breaches by employees and others with or without permitted access to our systems pose a risk that sensitive data may be exposed to unauthorized persons or to the public. A cyber-attack or other significant disruption involving our information technology systems, or those of our vendors, suppliers and other partners, could also result in disruptions in critical systems, corruption or loss of data and theft of data, funds or intellectual property. We may be unable to prevent outages or security breaches in our systems. Loss of preclinical or clinical trial data could result in delays in regulatory approval efforts and increase costs to recover or reproduce data. We remain potentially vulnerable to additional known or yet unknown threats as, in some instances, we, our suppliers and our other partners may be unaware of an incident or its magnitude and effects. We also face the risk that we expose our vendors or partners to cybersecurity attacks. Any or all of the foregoing could adversely affect our results of operations and our business reputation.

Any failure to maintain the security of information relating to our customers, employees and suppliers, whether as a result of cybersecurity attacks or otherwise, could expose us to litigation, government enforcement actions and costly response measures, and could disrupt our operations and harm our reputation.

In connection with the sales and marketing of our products and services, we may from time to time transmit confidential information. We also have access to, collect or maintain private or confidential information regarding our clinical trials and the patients enrolled therein, employees, and suppliers, as well as our business. Cyberattacks are rapidly evolving and becoming increasingly sophisticated. It is possible that computer hackers and others might compromise our security measures, or security measures of those parties that we do business with now or in the future, and obtain the personal information of patients in our clinical trials, vendors, employees and suppliers or our business information. A security breach of any kind, including physical or electronic break-ins, computer viruses and attacks by hackers, employees or others, could expose us to risks of data loss, litigation, government enforcement actions, regulatory penalties and costly response measures, and could seriously disrupt our operations. Any resulting negative publicity could significantly harm our reputation, which could cause us to lose market share and have an adverse effect on our results of operations.

We may face particular data protection, data security and privacy risks in connection with privacy regulations.

In the United States we are subject to several laws that protect the privacy of protected health information as well as data breach notification laws, the violation of which can result in penalties, criminal and civil penalties. Outside of the United States, the laws, regulations and standards in many jurisdictions apply broadly to the collection, use, and other processing of personal information. For example, in the European Union, the collection and use of personal data are governed by the provisions of the General Data Protection Regulation (the "GDPR"). The GDPR, together with national legislation, regulations and guidelines of the European Union. member states governing the processing of personal data, impose strict obligations on entities, including but not limited to: (i) accountability and transparency requirements, and enhanced requirements for obtaining valid consent from data subjects; (ii) obligations to consider data protection as any new products or services are developed and to limit the amount of personal data processed; (iii) obligations to comply with the data protection rights of data subjects; and (iv) obligations to report certain personal data breaches to governmental authorities and individuals. Data protection authorities from the different E.U. member states and other European countries may enforce the GDPR and national data protection laws differently and introduce additional national regulations and guidelines, which adds to the complexity of processing European personal data. Failure to comply with the requirements of the GDPR and national data protection laws may result in significant monetary fines and other administrative penalties (the GDPR authorizes fines for certain violations of up to 4% of global annual revenue or €20 million, whichever is greater) as well as civil liability claims from individuals whose personal data was processed. Additionally, expenses associated with compliance could reduce our operating margins.

The GDPR also prohibits the transfer of personal data from the E.U. to countries outside of the E.U. unless made to a country deemed by the European Commission to provide adequate protection for personal data or accomplished by means of an approved data transfer mechanism (e.g., standard contractual clauses). Data protection authority guidance and enforcement actions that restrict companies' ability to transfer data may increase risks relating to data transfers or make it more difficult or impossible to transfer E.U. personal data to the U.S.

We currently have only one product candidate, batiraxcept, in clinical development and are dependent on the success of batiraxcept, which requires additional clinical testing before seeking regulatory approval. If batiraxcept does not successfully complete clinical trials and receive regulatory approval or is not successfully commercialized, our business will be harmed.

We are currently developing one clinical product candidate, batiraxcept, as a potential treatment for several types of cancer. Batiraxcept is currently being tested in clinical trials, and, to date, we have not had any product candidate approved for commercial sale. It is possible that we may never be able to develop a marketable product candidate. Our main focus is the development of batiraxcept, for the treatment of platinum-resistant recurrent ovarian cancer, ccRCC and pancreatic cancer. If our Phase 3 trial of batiraxcept for PROC is successful, we expect to submit a BLA to the FDA at the end of 2023. The FDA may refuse to file a BLA or issue a complete response letter rather than approval, including for reasons that it disagrees with our interpretation of the data or that it finds our single pivotal trial insufficient evidence of clinical efficacy. FDA may ask us to conduct another Phase 3 trial.

We expect that a substantial portion of our efforts and expenditures over the next few years will be devoted to batiraxcept. Accordingly, our business currently depends heavily on the successful development, regulatory approval and commercialization of batiraxcept, which may not receive regulatory approval or be successfully commercialized even if regulatory approval is received. The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of product candidates are and will remain subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries that each have differing regulations. We are not permitted to market any product in the United States unless and until we receive approval of a BLA, from the FDA, or in any foreign countries unless and until we receive the requisite approval from regulatory authorities in such countries. We have never submitted a BLA to the FDA or comparable applications to other regulatory authorities and expect to submit one at the end of 2023, if our ongoing Phase 3 PROC trial is successful. Obtaining approval of a BLA is an extensive, lengthy, expensive and inherently uncertain process, and the FDA may delay, limit or deny approval of a product for many reasons.

Our success depends largely upon our ability to advance our clinical product candidate, batiraxcept, which is in early stages of development, through the various stages of drug development. If we are unable to successfully advance or develop batiraxcept, our business will be materially harmed.

Our clinical product candidate, batiraxcept, is in early stages of clinical development, and its commercial viability remains subject to the successful outcome of future preclinical studies, clinical trials, manufacturing processes, regulatory approvals and the risks generally inherent in the development of pharmaceutical product candidates. Failure to advance the development of batiraxcept may have a material adverse effect on our business. The long-term success of our business ultimately depends upon our ability to advance the development of batiraxcept through clinical trials, appropriately formulate and consistently manufacture it in accordance with strict specifications and regulations, obtain approval for sale by the FDA or similar regulatory authorities in other countries, and ultimately successfully commercialize it directly or with a strategic partner or licensee. We cannot assure investors that the results of our ongoing or future research, preclinical studies or clinical trials will support or justify the continued development of batiraxcept or that we will ultimately receive approval from the FDA, or similar regulatory authorities in other countries, to advance the development of batiraxcept.

Batiraxcept must satisfy rigorous regulatory standards of safety, efficacy and manufacturing before we can advance or complete its development and before it can be approved for sale by the FDA or similar regulatory authorities in other countries. To satisfy these standards, we must engage in expensive and lengthy studies and clinical trials, develop acceptable and cost-effective manufacturing processes, and obtain regulatory approval of batiraxcept. Despite these efforts, batiraxcept may not:

- demonstrate clinically meaningful therapeutic or other medical benefits as compared to a patient receiving no treatment or over existing drugs or other product candidates in development to treat the same patient population;
- be shown to be safe and effective in future preclinical studies or clinical trials;
- have the desired therapeutic or medical effects;
- be tolerable or free from undesirable or unexpected side effects;
- meet applicable regulatory standards;

- be capable of being appropriately formulated and manufactured in commercially suitable quantities or scale and at an acceptable cost; or

- be successfully commercialized by us or our licensees or collaborators.

Even if we demonstrate favorable results in preclinical studies and early-stage clinical trials, we cannot assure you that the results of late-stage clinical trials will be sufficient to support the continued development of batiraxcept. Many, if not most, companies in the pharmaceutical and biopharmaceutical industries have experienced significant delays, setbacks and failures in all stages of development, including late-stage clinical trials, even after achieving promising results in preclinical testing or early-stage clinical trials. Accordingly, results from completed preclinical studies and early-stage clinical trials of our batiraxcept may not be predictive of the results we may obtain in future late-stage trials, especially in light of the fact that the results from our clinical trials to date have been from a small number of patients and may not be replicated with a larger number of patients. Furthermore, even if the data collected from preclinical studies and clinical trials involving any of our clinical product candidates demonstrate a satisfactory safety, tolerability and efficacy profile, such results may not be sufficient to obtain regulatory approval from the FDA in the United States, or other similar regulatory agencies in other jurisdictions, which is required to market and sell the product.

Clinical trials are risky, lengthy and expensive. We incur substantial expense for, and devote significant time and resources to, preclinical testing and clinical trials, yet cannot be certain that these tests and trials will demonstrate that a product candidate is effective and well-tolerated, or will ever support its approval and commercial sale. For example, clinical trials require adequate supplies of clinical trial material and sufficient patient enrollment to power the trial. Delays in patient enrollment can result in increased costs and longer development times. Even if we, or a licensee or collaborator, if applicable, successfully complete clinical trials for batiraxcept, we or they might not file the required regulatory submissions in a timely manner and may not receive marketing approval for batiraxcept. We cannot assure you that batiraxcept will successfully progress further through the drug development process, or ultimately will result in an approved and commercially viable product.

We have limited experience conducting clinical trials.

We are an early-stage clinical stage company, and our success is dependent upon our ability to obtain regulatory approval for and commercialization of batiraxcept, and we have not demonstrated an ability to perform the functions necessary for the approval or successful commercialization of any product candidate. The successful commercialization of any product candidate may require us to perform a variety of functions, including:

- continuing to undertake preclinical development and successfully enroll subjects in clinical trials;

- participating in regulatory approval processes;

- formulating and manufacturing products; and

- conducting sales and marketing activities.

We have limited experience conducting and enrolling subjects in clinical trials. While certain members of our management and staff have significant experience in conducting clinical trials, to date, we have only limited experience conducting clinical trials. In part because of this lack of experience, we cannot guarantee that planned clinical trials will be completed on time, if at all, or that we will not require changes to our trial designs. Large-scale trials require significant additional financial and management resources, monitoring and oversight, and reliance on third-party clinical investigators, consultants or contract research organizations, or CROs. Relying on third-party clinical investigators, CROs and manufacturers, which are all also subject to governmental oversight and regulations, may also cause us to encounter delays that are outside of our control.

If the actual or perceived therapeutic benefits, or the safety or tolerability profile of our clinical product candidate, batiraxcept, is not equal to or superior to other competing treatments approved for sale or in clinical development, we may terminate the development of batiraxcept at any time, and our business prospects and potential profitability could be harmed.

We are aware of a number of companies marketing or developing product candidates for the treatment of patients with cancer and fibrosis that are either approved for sale or further advanced in clinical development than ours, such that their time to approval and commercialization may be shorter than that for batiraxcept.

There are currently no FDA approved biological drugs that target the GAS6/AXL pathway. However, if ever approved as a treatment for cancer, batiraxcept would indirectly compete with drugs approved to treat various types of cancer, such as those that regulate T-cell proliferation, including nivolumab, pembrolizumab, atezolizumab and other small molecule chemically manufactured drugs that target this pathway or other classes of drugs that are used for the clinical indications that ours is currently pursuing in clinic.

If at any time we believe that batiraxcept may not provide meaningful or differentiated therapeutic benefits, perceived or real, equal to or better than its competitor's products or product candidates, or we believe that it may not have as favorable a safety or tolerability profile as potentially competitive compounds, we may delay or terminate its development. We cannot provide any assurance that the future development of batiraxcept will demonstrate any meaningful therapeutic benefits over potentially competitive compounds currently approved for sale or in development, or an acceptable safety or tolerability profile sufficient to justify its continued development.

For the Phase 3 clinical trial in patients with platinum-resistant recurrent ovarian cancer and for the Phase 1b/2 clinical trials in patients with ccRCC or pancreatic adenocarcinoma we are administering, or plan to administer, our clinical product candidate, batiraxcept, in combination with approved standard of care drugs. Any problems obtaining the standard of care drugs could result in a delay or interruption in our clinical trials.

For each of our ongoing clinical trials, we are administering batiraxcept in combination with already approved standard of care drugs. Therefore, our success will be dependent upon the continued use of and ability to obtain the standard of care drugs. We expect that in any other clinical trials we conduct for additional indications, our clinical product candidate will also be administered in combination with drugs owned by third parties. If any of the standard of care drugs that are used in our clinical trials are unavailable while the trials are continuing, the timeliness and commercialization costs could be impacted. In addition, if any of these other drugs are determined to have safety or efficacy problems, our clinical trials and commercialization efforts would be adversely affected.

If our product candidate, batiraxcept, requires or would commercially benefit from a companion diagnostic, and if we are unable to successfully validate, develop and obtain regulatory clearance or approval for such a companion diagnostic test, or experience significant delays in doing so, we may not realize the full commercial potential of our product candidates.

In connection with the clinical development of batiraxcept or other product candidates for certain indications, we may work with collaborators to develop or obtain access to in vitro companion diagnostic tests to identify patient subsets within a disease category who may derive selective and meaningful benefit from our drug candidates. Such companion diagnostics may be used during our clinical trials as well as in connection with the commercialization of our product candidates. To be successful, we or our collaborators will need to address a number of scientific, technical, regulatory and logistical challenges. The FDA and comparable foreign regulatory authorities regulate in vitro companion diagnostics as medical devices and, under that regulatory framework, will likely require the conduct of clinical trials to demonstrate the safety and effectiveness of any diagnostics we may develop, which we expect will require separate regulatory clearance or approval prior to commercialization. We may be unable to successfully validate, develop and obtain regulatory clearance or approval for any such companion diagnostic tests or may experience delays in doing so, which could materially harm or limit the commercial potential of our product candidates.

Our clinical product candidate, batiraxcept, may exhibit undesirable side effects when used alone or in combination with other approved pharmaceutical products, which may delay or preclude its development or regulatory approval, or limit its use if ever approved.

Throughout the drug development process, we must continually demonstrate the activity, safety and tolerability of batiraxcept, in order to obtain regulatory approval to further advance our clinical development, or to eventually market it. Even if our clinical product candidate demonstrates adequate biologic activity and clear clinical benefit, any unacceptable side effects or adverse events, when administered alone or in the presence of other pharmaceutical products, may outweigh these potential benefits. We may observe adverse or serious adverse events or drug-drug interactions in preclinical studies or clinical trials of batiraxcept, which could result in the delay or termination of its development, prevent regulatory approval, or limit its market acceptance if it is ultimately approved.

For our clinical product candidate, batiraxcept, we rely upon one third party to manufacture its drug substance. Any problems experienced by either our third-party manufacturer or our vendors could result in a delay or interruption in the supply of batiraxcept to us until the third-party manufacturer or its vendor cures the problem or until we locate and qualify an alternative source of manufacturing and supply.

For our clinical product candidate, batiraxcept, we currently rely on one third-party manufacturer located in China to manufacture batiraxcept for our clinical studies and that manufacturer purchases materials from our third-party vendors and transports the materials necessary to produce batiraxcept, such as the required reagents and containers. If a virus should spread to the districts in which our manufacturer's facilities are located, we could experience delays in manufacturing and shipments of our clinical product, which could result in clinical trial delays. If the third-party manufacturer were to experience any prolonged disruption for our manufacturing, we could be forced to seek additional third-party manufacturing contracts, thereby increasing our development costs and negatively impacting our timelines and any commercialization costs. If we change manufacturers at any point during the development process or after approval of a product candidate, we will be required to demonstrate comparability between the product manufactured by the old manufacturer and the product manufactured by the new manufacturer. If we are unable to do so we may need to conduct additional clinical trials with product manufactured by the new manufacturer.

If our manufacturer is not able to manufacture sufficient quantities of batiraxcept, our development activities would be impaired. In addition, the manufacturing facility where our clinical product candidate, batiraxcept, is manufactured is subject to ongoing, periodic inspection by the FDA or other comparable regulatory agencies to ensure compliance with cGMP. Any failure to follow and document the manufacturer's adherence to such cGMP regulations or other regulatory requirements may lead to significant delays in the availability of clinical bulk drug substance and finished product for clinical trials, which may result in the termination of or a hold on a clinical trial, or may delay or prevent filing or approval of marketing applications for batiraxcept. We also may encounter problems with the following:

- achieving adequate or clinical-grade materials that meet FDA or other comparable regulatory agency standards or specifications with consistent and acceptable production yield and costs;
- Our contract manufacturers failing to develop an acceptable formulation to support late-stage clinical trials for, or the commercialization of, our clinical product candidate, batiraxcept;
- Our contract manufacturer being unable to increase the scale of or the capacity for, or reformulate the form of our clinical product candidate, batiraxcept, which may cause us to experience a shortage in supply, or cause the cost to manufacture batiraxcept to increase. We cannot assure you that our contract manufacturers will be able to manufacture batiraxcept at a suitable commercial scale, or that we will be able to find alternative manufacturers acceptable to us that can do so;
- Our contract manufacturer placing a priority on the manufacture of other customers' or its own products, rather than our products;
- Our contract manufacturer or our vendors failing to perform as agreed, including failing to properly package, transport or store batiraxcept or its reagents, or exiting from the contract manufacturing business;
- Our contract manufacturers' plants being closed as a result of regulatory sanctions or a natural disaster or pandemic;
- Shortages of qualified personnel, raw materials or key contractors;
- Our contract manufacturers failing to obtain FDA approval for commercial scale manufacturing; and
- Ongoing compliance with cGMP regulations and other requirements of the FDA or other comparable regulatory agencies.

If we encounter any of these problems or are otherwise delayed, or if the cost of manufacturing in the China facility is not economically feasible or we cannot find another third-party manufacturer, we may not be able to produce our clinical product candidate, batiraxcept, in a sufficient quantity to meet future demand.

In addition, since we rely on a third-party manufacturer located in China, our business is subject to risks associated with doing business in China, including:

- adverse political and economic conditions, particularly those potentially negatively affecting the trade relationship between the United States and China;
- trade protection measures, such as tariff increases, and import and export licensing and control requirements;
- potentially negative consequences from changes in tax laws;
- difficulties associated with the Chinese legal system, including increased costs and uncertainties associated with enforcing contractual obligations in China;
- historically lower protection of intellectual property rights;
- changes and volatility in currency exchange rates;
- unexpected or unfavorable changes in regulatory requirements;
- possible patient or physician preferences for more established pharmaceutical products and medical devices manufactured in the United States; and
- difficulties in managing foreign relationships and operations generally.

These risks are likely to be exacerbated by our limited experience with our current products and manufacturing processes. If demand for our products materializes, we may have to invest additional resources to purchase materials, hire and train employees, and enhance our manufacturing processes. It may not be possible for us to manufacture our clinical product candidate, batiraxcept, at a cost or in quantities sufficient to make its clinical product candidate commercially viable. Any of these factors may affect our ability to manufacture our products and could reduce gross margins and profitability.

Reliance on third-party manufacturers and suppliers entails risks to which we would not be subject if we manufactured batiraxcept ourself, including:

- reliance on the third parties for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreements by the third parties because of factors beyond our control or the insolvency of any of these third parties or other financial difficulties, labor unrest, natural disasters or other factors adversely affecting their ability to conduct their business; and
- possibility of termination or non-renewal of the agreements by the third parties, at a time that is costly or inconvenient for us, because of our breach of the manufacturing agreement or based on their own business priorities.

If our contract manufacturer or its suppliers fail to deliver the required commercial quantities of our clinical product candidate, batiraxcept, required for our clinical trials and, if approved, for commercial sale, on a timely basis and at commercially reasonable prices, and we are unable to find one or more replacement manufacturers or suppliers capable of production at a substantially equivalent cost, in substantially equivalent volumes and quality, and on a timely basis, we would likely be unable to meet demand for our products and would have to delay or terminate our pre-clinical or clinical trials, and we would lose potential revenue. It may also take a significant period of time to establish an alternative source of supply for batiraxcept and to have any such new source approved by the FDA or any applicable foreign regulatory authorities. Furthermore, any of the above factors could cause the delay or suspension of initiation or completion of clinical trials, regulatory submissions or required approvals of batiraxcept, cause it to incur higher costs and could prevent us from commercializing batiraxcept successfully.

We may not be able to manufacture batiraxcept in sufficient quantities for commercialization.

In order to receive FDA approval of our clinical product candidate, batiraxcept, we will need to manufacture such clinical product candidate in larger quantities. Our third-party manufacturer may not be willing or able to increase successfully the manufacturing capacity for batiraxcept in a timely or economic manner, or at all. In the event FDA approval is received, we

will need to increase production of batiraxcept. Significant scale-up of manufacturing may require additional validation studies, which the FDA must review and approve. If we are unable to successfully increase the manufacturing capacity for batiraxcept, the clinical trials as well as the regulatory approval or commercial launch of batiraxcept may be delayed or there may be a shortage in supply. Batiraxcept requires precise, high quality manufacturing. Failure to achieve and maintain high quality manufacturing, including the incidence of manufacturing errors, could result in patient injury or death, delays or failures in testing or delivery, cost overruns or other problems that could harm our business, financial condition and results of operations.

In the event that we need to change our third-party contract manufacturer, our preclinical studies or our clinical trials, the commercialization of our clinical product candidate, batiraxcept, could be delayed, adversely affected or terminated, or such a change may result in the need for us to incur significantly higher costs, which could materially harm our business.

Due to various regulatory restrictions in the United States and many other countries, as well as potential capacity constraints on manufacturing that occur from time-to-time in our industry, various materials in the manufacturing of batiraxcept are solely-sourced from certain contract manufacturers. In accordance with cGMPs, changing manufacturers may require the re-validation of manufacturing processes and procedures, and may require further preclinical studies or clinical trials to show comparability between the materials produced by different manufacturers. Changing our current or future contract manufacturers may be difficult, if not impossible for us, and could be extremely costly if we do make such a change, which could result in our inability to manufacture batiraxcept for an extended period of time and a delay in the development of batiraxcept. Further, in order to maintain our development timelines in the event of a change in a third-party contract manufacturer, we may incur significantly higher costs to manufacture batiraxcept.

If third-party vendors, upon whom we rely to conduct our preclinical studies or clinical trials, do not perform or fail to comply with strict regulations, these studies or trials may be delayed, terminated, or fail, or we could incur significant additional expenses, which could materially harm our business.

We have limited resources dedicated to designing, conducting and managing our preclinical studies and clinical trials. We have historically relied on, and intend to continue to rely on, third parties, including CROs, consultants and principal investigators, to assist us in designing, managing, conducting, monitoring and analyzing the data from our preclinical studies and clinical trials. We rely on these vendors and individuals to perform many facets of the clinical development process on our behalf, including conducting preclinical studies, the recruitment of sites and subjects for participation in our clinical trials, maintenance of good relations with the clinical sites, and ensuring that these sites are conducting our trials in compliance with the trial protocol and applicable regulations. If these third parties fail to perform satisfactorily, or do not adequately fulfill their obligations under the terms of our agreements with them, we may not be able to enter into alternative arrangements without undue delay or additional expenditures, and therefore the preclinical studies and clinical trials of our clinical product candidate, batiraxcept, may be delayed or prove unsuccessful.

Further, the FDA, the EMA, or similar regulatory authorities in other countries, may inspect some of the clinical sites participating in our clinical trials or our third-party vendors' sites to determine if our clinical trials are being conducted according to good clinical practices, or GCPs, or similar regulations. If we or a regulatory authority determine that our third-party vendors are not in compliance with, or have not conducted our clinical trials according to applicable regulations, we may be forced to exclude certain data from the results of the trial, or delay, repeat or terminate such clinical trials.

We rely on third parties to conduct, supervise and monitor our clinical trials, and if those third parties perform in an unsatisfactory manner, it may harm our business.

We rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials, and we expect to have limited influence over their actual performance.

We also rely upon CROs to monitor and manage data for our clinical programs, as well as the execution of future nonclinical studies. We expect to control only certain aspects of our CROs' activities. Nevertheless, we will be responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards and our reliance on the CROs does not relieve us of our regulatory responsibilities.

We and our CROs will be required to comply with the Good Laboratory Practices and GCPs, which are regulations and guidelines enforced by the FDA and are also required by the Competent Authorities of the Member States of the EEA and comparable foreign regulatory authorities in the form of International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use guidelines for any of our product candidates that are in preclinical and clinical development. The Regulatory authorities enforce GCPs through periodic inspections of trial sponsors, principal investigators and clinical trial sites. If we or our CROs fail to comply with GCPs, the clinical data generated in our clinical trials 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. Accordingly, if our CROs fail to comply with these regulations or fail to recruit a sufficient number of subjects, we may be required to repeat clinical trials, which would delay the regulatory approval process and increase our costs.

Our CROs are not our employees, and we do not control whether or not they devote sufficient time and resources to our future clinical and nonclinical programs. These CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials, or other drug development activities which could harm our competitive position. We face the risk of potential unauthorized disclosure or misappropriation of our intellectual property by CROs, which may reduce our trade secret protection and allow our potential competitors to access and exploit our proprietary technology. If our CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for any 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 any product candidate that we develop. As a result, our financial results and the commercial prospects for any product candidate that it develops would be harmed, its costs could increase, and our ability to generate revenues could be delayed.

If our relationship with these CROs terminate, we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms. Switching or adding additional CROs involves substantial cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we intend to carefully manage our relationships with our CROs, there can be no assurance that it will not encounter challenges or delays in the future or that these delays or challenges will not have an adverse impact on our business, financial condition and prospects.

Our future success depends on our ability to retain executive officers and attract, retain and motivate qualified personnel.

We are highly dependent on our executive officers and the other principal members of our management and scientific teams. The employment of our executive officers is at-will and our executive officers may terminate their employment at any time. The loss of the services of any of our senior executive officers could impede the achievement of our research, development and commercialization objectives. We do not maintain “key person” insurance for any executive officer or employee.

Recruiting and retaining qualified scientific, clinical, manufacturing and sales and marketing personnel is also critical to our success. We may not be able to attract and retain these personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. Our industry has experienced an increasing rate of turnover of management and scientific personnel in recent years. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist it in devising our research and development and commercialization strategy. Our consultants and advisors may be employed by third parties and have commitments under consulting or advisory contracts with other entities that may limit their availability to advance our strategic objectives. If any of these advisors or consultants can no longer dedicate a sufficient amount of time to the company, our business may be harmed.

Many of the other pharmaceutical companies that we compete against for qualified personnel and consultants have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high-quality candidates and consultants than what it has to offer. If we are unable to continue to attract and retain high-quality personnel and consultants, the rate and success at which we can select and develop our clinical product candidate, batiraxcept, and our business will be limited.

Risks Related to Clinical Development, Regulatory Approval and Commercialization

If the results from preclinical studies or clinical trials of batiraxcept are unfavorable, we could be delayed or precluded from its further development or commercialization, which could materially harm our business.

In order to further advance the development of, and ultimately receive marketing approval to sell batiraxcept, we must conduct extensive preclinical studies and clinical trials to demonstrate our safety and efficacy to the satisfaction of the FDA or similar regulatory authorities in other countries, as the case may be. Preclinical studies and clinical trials are expensive, complex, can take many years to complete, and have highly uncertain outcomes. Delays, setbacks, or failures can and do occur at any time, and in any phase of preclinical or clinical testing, and can result from concerns about safety, tolerability, toxicity, a lack of demonstrated biologic activity or improved efficacy over similar products that have been approved for sale or are in more advanced stages of development, poor study or trial design, and issues related to the formulation or manufacturing

process of the materials used to conduct the trials. The results of prior preclinical studies or early-stage clinical trials are not predictive of the results we may observe in late-stage clinical trials, especially since the number of subjects in our completed clinical trials was small. In many cases, product candidates in clinical development may fail to show the desired tolerability, safety and efficacy characteristics, despite having favorably demonstrated such characteristics in preclinical studies or early-stage clinical trials.

In addition, we may experience numerous unforeseen events during, or as a result of, preclinical studies and the clinical trial process, which could delay or impede our ability to advance the development of, receive marketing approval for, or commercialize our clinical product candidate, batiraxcept, including, but not limited to:

- communications with the FDA, or similar regulatory authorities in different countries, regarding the scope or design of a trial or trials, or placing the development of a product candidate on clinical hold or delaying the next phase of development until questions or issues are satisfactorily resolved, including performing additional studies to answer their queries;

- regulatory authorities or institutional review boards ("IRBs") not authorizing us to commence or conduct a clinical trial at a prospective trial site or delays in reaching or fail to reach agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;

- enrollment in our clinical trials being delayed, or proceeding at a slower pace than we expected, because we have difficulty recruiting participants or participants drop out of our clinical trials at a higher rate than we anticipated;

- our third-party contractors, upon whom we rely to conduct preclinical studies, clinical trials and the manufacturing of our clinical trial materials, failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner;

- having to suspend or ultimately terminate a clinical trial if participants are being exposed to unacceptable health or safety risks;

- regulatory authorities or IRBs requiring that we hold, suspend or terminate our preclinical studies and clinical trials for various reasons, including non-compliance with regulatory requirements; and

- the supply or quality of material necessary to conduct our preclinical studies or clinical trials being insufficient, inadequate or unavailable.

Even if the data collected from preclinical studies or clinical trials involving batiraxcept, demonstrate a satisfactory tolerability, safety and efficacy profile, such results may not be sufficient to support the submission of a BLA to obtain regulatory approval from the FDA in the United States, or other similar regulatory authorities in other foreign jurisdictions, which is required for us to market and sell batiraxcept.

Clinical trials are very expensive, time-consuming, difficult to design and implement and involve an uncertain outcome, and if they fail to demonstrate safety and efficacy to the satisfaction of the FDA, or similar regulatory authorities, we will be unable to commercialize our clinical product candidate, batiraxcept.

Batiraxcept is still in clinical development and will require extensive additional clinical testing before we are prepared to submit a BLA for regulatory approval for any indication or for any treatment regime. We cannot predict with any certainty if or when we might submit a BLA for regulatory approval for batiraxcept, or whether any such future BLA would be approved by the FDA. Human clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. For instance, the FDA may not agree with endpoints for any clinical trial we propose, which may delay the commencement of our clinical trials. The clinical trial process is also time-consuming. Furthermore, failure can occur at any stage of the trials, and we could encounter problems that cause us to abandon or repeat clinical trials. A product candidate in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials, and the results of our Phase 1 clinical trial of the clinical product candidate as well as the pre-clinical results may not be predictive of the results of our Phase 2 or Phase 3 trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles.

Moreover, preclinical and clinical data are often susceptible to multiple interpretations and analyses. Many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products. Success in preclinical testing and early clinical trials does not ensure that later

clinical trials, which involve many more subjects and the results of later clinical trials may not replicate the results of prior clinical trials and preclinical testing. For example, during 2022 we revised the statistical analysis plan for our adaptive design Phase 3 trial of batiraxcept in PROC by omitting the interim analysis in the trial. Although we believe we can enroll the number of bevacizumab naïve patients needed to have a potentially successful study, our belief may be incorrect, and we may ultimately have negative trial results or indeterminate trial results that are not able to support BLA approval.

If we are required to conduct additional clinical trials or other testing of batiraxcept beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of batiraxcept or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- be delayed in obtaining marketing approval for batiraxcept;
- require additional funding not budgeted for;
- not obtain marketing approval at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings, including boxed warnings;
- be subject to additional post-marketing testing requirements; or
- have the product removed from the market after obtaining marketing approval.

Product development costs will also increase if we experience delays in testing or in receiving marketing approvals. We do not know whether any clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our clinical product candidate, batiraxcept, could allow our competitors to bring products to market before we do, and could impair our ability to successfully commercialize batiraxcept, any of which may harm our business and results of operations.

Enrollment and retention of subjects 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.

We may encounter delays in enrolling, or be unable to enroll, a sufficient number of participants to complete our ongoing enrolling clinical trials and future clinical trials. Even if we rare able to enroll a sufficient number of patients, once enrolled, we may be unable to retain a sufficient number of participants to complete any of our trials. Late-stage clinical trials of batiraxcept may require the enrollment and retention of large numbers of subjects. Subject enrollment and retention in clinical trials depends on many factors, including the size of the subject population, the nature of the trial protocol, the existing body of safety and efficacy data with respect to the trial drug, the number and nature of competing treatments and ongoing clinical trials of competing drugs for the same indication, the proximity of subjects to clinical sites and the eligibility criteria for the trial.

Furthermore, any negative results we may report in clinical trials of batiraxcept, negative results reported from clinical trials conducted by our collaborators or negative results of similar product candidates may make it difficult or impossible to recruit and retain participants in other clinical trials of that same clinical product candidate. Delays or failures in planned subject enrollment or retention may result in increased costs, program delays or both, which could have a harmful effect on its ability to develop its clinical product candidate, or could render further development impossible. In addition, we expect to rely on CROs and clinical trial sites to ensure proper and timely conduct of our future clinical trials and, while we intend to enter into agreements governing our services, we will be limited in our ability to compel their actual performance in compliance with applicable regulations. Enforcement actions brought against these third parties may cause further delays and expenses related to our clinical development programs.

We intend to seek FDA approval for batiraxcept for ccRCC through the use of the accelerated approval pathway. If we are unable to obtain such approval, we may be required to conduct additional clinical trials beyond those that we contemplate, which could increase the expense of obtaining, and delay the receipt of, necessary marketing approvals. Even if we receive accelerated approval from the FDA, if our confirmatory trials do not verify clinical benefit, or if we do not comply with rigorous post-marketing requirements, the FDA or comparable foreign regulatory authorities may seek to withdraw accelerated approval.

Under the accelerated approval program, the FDA may grant accelerated approval to a product candidate designed to treat a serious or life-threatening condition that provides meaningful therapeutic benefit over available therapies upon a determination that the product candidate has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity or mortality. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit. The accelerated approval pathway may be used in cases in which the advantage of a new drug over available therapy may not be a direct therapeutic advantage, but is a clinically important improvement from a patient and public health perspective. If granted, accelerated approval is usually contingent on the sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the product's clinical benefit. If such post-approval studies fail to confirm the product's clinical benefit, the FDA may withdraw its approval.

Prior to seeking accelerated approval for any of our product candidates, we intend to seek feedback from the FDA or similar foreign regulatory authorities and will otherwise evaluate our ability to seek and receive accelerated approval. There can be no assurance that after our evaluation of the feedback and other factors we will decide to pursue or submit a BLA or similar application for accelerated approval or any other form of expedited development or review. Similarly, there can be no assurance that after subsequent FDA or similar foreign regulatory authorities feedback we will continue to pursue or apply for accelerated approval or any other form of expedited development or review, even if we initially decide to do so. Furthermore, if we decide to submit an application for accelerated approval or other expedited development or review for our product candidates, there can be no assurance that such submission or application will be accepted or that any expedited development or review will be granted on a timely basis, or at all. The FDA or other comparable foreign regulatory authorities could also require us to conduct further studies prior to considering our application or granting approval of any type. A failure to obtain accelerated approval or any other form of expedited development or review for our product candidate would result in a longer time period to commercialization of such product candidate, if any, could increase the cost of development of such product candidate, and could harm our competitive position in the marketplace.

Fast Track designation for our product candidates may not lead to a faster development or regulatory review or approval process, and neither of these designations increases the likelihood that our product candidates will receive marketing approval.

We have obtained Fast Track designation for batiraxcept for PROC. If a drug or biologic candidate is intended for the treatment of a serious or life-threatening condition or disease and the drug demonstrates the potential to address unmet medical needs for the condition, the sponsor may apply for Fast Track designation. The receipt of Fast Track designation for a product candidate may not result in a faster development process, review or approval compared to products considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, the FDA may later decide that the product no longer meets the conditions for Fast Track designation.

It is possible that we may not be able to obtain or maintain orphan drug designation or exclusivity for our drug candidates, which could limit the potential profitability of our product candidates.

Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs for the treatment or prevention of rare diseases or conditions with relatively small patient populations as orphan drugs. Under the Orphan Drug Act of 1983, the ("Orphan Drug Act"), the FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition, which is defined as a patient population of fewer than 200,000 individuals in the United States. We received orphan drug designation from the FDA for batiraxcept for ovarian cancer from the EMA in October 2021. If a product with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a seven-year period of marketing exclusivity, which precludes the FDA from approving another marketing application for the same drug for the same indication during that time period with some exceptions. A similar provision in the European Union allows 10 years of exclusivity in Europe. The European exclusivity period can be reduced to six years if a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently

profitable so that marketing exclusivity is no longer justified. Orphan drug exclusivity may be lost in Europe under certain situations, such as the inability of the holder of the orphan drug designation to produce sufficient quantities of the drug to meet the needs of patients with the rare disease or condition or for certain other reasons.

We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.

Development of cancer treatments is highly competitive and subject to rapid and significant technological advancements. In particular, we face competition from various sources, including larger and better funded pharmaceutical, specialty pharmaceutical and biotechnology companies, as well as academic institutions, governmental agencies and public and private research institutions. These competitors are focused on delivering therapeutics for the treatment of various cancers with products that are available and have gained market acceptance as the standard treatment protocol. Further, it is likely that additional drugs or other treatments will become available in the future for the treatment of certain cancers.

Many of our existing or potential competitors have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of products for the treatment of cancer, as well as in obtaining regulatory approvals of those products in the United States and in foreign countries. Our current and potential future competitors also have significantly more experience commercializing drugs that have been approved for marketing. Mergers and acquisitions in the pharmaceutical and biotechnology industries could result in even more resources being concentrated among a small number of our competitors.

Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may succeed in developing, acquiring or licensing, on an exclusive basis, drugs that are more effective or less costly than any product candidate that we may develop.

We will face competition from other drugs currently approved or that will be approved in the future for the treatment of the other infectious diseases we are currently targeting. Therefore, our ability to compete successfully will depend largely on our ability to:

- develop and commercialize product candidates that are superior to other products in the market;
- demonstrate through our clinical trials that our clinical product candidate, batiraxcept, is differentiated from existing and future therapies;
- attract qualified scientific and commercial personnel;
- obtain patent or other proprietary protection for batiraxcept;
- obtain required regulatory approvals;
- obtain coverage and adequate reimbursement from, and negotiate competitive pricing with, third-party payors; and
- successfully develop and commercialize, independently or with collaborators, new product candidates.

The availability of our competitors' products could limit the demand, and the price we are able to charge, for any product candidate we develop. The inability to compete with existing or subsequently introduced therapies would have an adverse impact on our business, financial condition and prospects.

Established pharmaceutical companies may invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make our product candidate less competitive. In addition, any new products 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. Accordingly, our competitors may succeed in obtaining patent protection, discovering, developing, receiving the FDA's approval for or commercializing medicines before we do, which would have an adverse impact on our business and results of operations.

Our clinical product candidate, batiraxcept, may cause adverse effects or have other properties that could delay or prevent our regulatory approval or limit the scope of any approved label or market acceptance.

Adverse events caused by batiraxcept could cause reviewing entities, clinical trial sites or regulatory authorities to interrupt, delay or halt clinical trials and could result in the denial of regulatory approval. If an unacceptable frequency or severity of adverse events are reported in our clinical trials for batiraxcept, our ability to obtain regulatory approval for such clinical product candidate may be negatively impacted. In addition, adverse events caused by any clinical product candidate administered in combination with our product candidate could cause similar interruptions and delays, even though not caused by batiraxcept.

Furthermore, if any of our products are approved and then cause serious or unexpected side effects, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw their approval of the product candidate or impose restrictions on its distribution or other risk management measures;
- regulatory authorities may require the addition of labeling statements, such as warnings or contraindications;
- we may be required to conduct additional clinical trials;
- we could be sued and held liable for injuries sustained by patients;
- we could elect to discontinue the sale of our product candidate; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product candidate and could substantially increase the costs of commercialization.

Our employees, independent contractors, principal investigators, consultants, commercial collaborators, service providers and other vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have an adverse effect on our results of operations.

We are exposed to the risk that our employees and contractors, including principal investigators, consultants, commercial collaborators, service providers and other vendors may engage in fraudulent or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or other unauthorized activities that violate the laws and regulations of the FDA and other similar regulatory bodies, including those laws that require the reporting of true, complete and accurate information to such regulatory bodies, manufacturing standards, federal and state healthcare fraud and abuse and health regulatory laws and other similar foreign fraudulent misconduct laws, or laws that require the true, complete and accurate reporting of financial information or data. Misconduct by these parties may also involve the improper use or misrepresentation 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 third party misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting it 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 ourselves or asserting our rights, those actions could have a significant impact on our business and financial results, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we will not be able to commercialize, or will be delayed in commercializing, our clinical product candidate, batiraxcept, and our ability to generate revenue will be impaired.

Batiraxcept and the activities associated with our development and commercialization, including our design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries. Failure to obtain marketing approval for a clinical product candidate will prevent us from

commercializing the clinical product candidate. We have not received approval to market batiraxcept from regulatory authorities in any jurisdiction. We only have limited experience in filing and supporting the applications necessary to gain marketing approvals and expect to rely on CROs to assist us in this process. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the clinical product candidate's safety and efficacy. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Batiraxcept may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may prevent it from obtaining marketing approval or prevent or limit commercial use.

The process of obtaining marketing approvals, both in the United States and elsewhere, is expensive, may take many years and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidate involved. We cannot assure you that our product candidate will ever obtain any marketing approvals in any jurisdiction. The fact that the FDA has designated the investigation of batiraxcept for platinum-resistant recurrent ovarian cancer as a Fast Track development program, while potentially favorable, provides no assurance as to the timing or outcome of any FDA regulatory process. Fast Track status may be withdrawn if the conditions for such designation are no longer met. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations or changes in regulatory review for each submitted product application may cause delays in the approval or rejection of an application. The FDA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional preclinical or other studies, and clinical trials. In addition, varying interpretations of the data obtained from preclinical testing and clinical trials could delay, limit or prevent marketing approval of a product candidate. Additionally, any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

Even if we obtain FDA approval in the United States, we may never obtain approval for or commercialize our clinical product candidate, batiraxcept, in any other jurisdiction, which would limit our ability to realize each product's full market potential.

In order to market batiraxcept in a particular jurisdiction, we must establish and comply with numerous and varying regulatory requirements on a country-by-country basis regarding safety and efficacy. Approval by the FDA in the United States does not ensure approval by regulatory authorities in other countries or jurisdictions and approval by regulatory authorities in other countries or jurisdictions does not ensure approval by the FDA. In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country. Approval processes vary among countries and can involve additional product candidate testing and validation and additional administrative review periods. Seeking foreign regulatory approval could result in difficulties and costs for us and require additional preclinical studies or clinical trials which could be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of batiraxcept in those countries. We do not have any product candidates approved for sale in any jurisdiction, including in international markets, and we do not have experience in obtaining regulatory approval in international markets. If we or our collaborators fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of any product candidate we develop will be unrealized.

Even if we obtain regulatory approval, we will still face extensive ongoing regulatory requirements and our clinical product candidate, batiraxcept, may face future development and regulatory difficulties.

Any product candidate for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, packaging, distribution, adverse event reporting, storage, recordkeeping, export, import, advertising and promotional activities for such product candidate, among other things, will be subject to extensive and ongoing requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety, efficacy and other post-marketing information and reports, establishment registration and drug listing requirements, continued compliance with cGMP requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping and current GCP requirements for any clinical trials that we conduct post-approval. 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 candidate may be marketed or to the conditions of approval. If batiraxcept receives marketing approval, the accompanying label may limit the approved use of our product, which could limit sales.

The FDA may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety and/or efficacy of batiraxcept. The FDA closely regulates the post-approval marketing and promotion of drugs to ensure drugs 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 batiraxcept for its approved indications, we may be subject to enforcement action for off-label marketing. Violations of the Federal Food, Drug, and Cosmetic Act relating to the promotion of prescription drugs may lead to FDA enforcement actions and investigations alleging violations of federal and state health care fraud and abuse laws, as well as state consumer protection laws.

In addition, later discovery of previously unknown adverse events or other problems with batiraxcept, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including:

- restrictions on manufacturing such clinical product candidate;
- restrictions on the labeling or marketing of such clinical product candidate;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning letters;
- withdrawal of the clinical product candidate from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of such clinical product candidate;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of such clinical product candidate;
- clinical product candidate seizure; or
- injunctions or the imposition of civil or criminal penalties.

The FDA's policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of batiraxcept. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained.

Even if our clinical product candidate, batiraxcept, receives marketing approval, we may fail to achieve market acceptance by physicians, patients, third-party payors or others in the medical community necessary for commercial success.

If batiraxcept receives marketing approval, we may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. If we do not achieve an adequate level of acceptance, we may not generate significant revenues and become profitable. The degree of market acceptance, if approved for commercial sale, will depend on a number of factors, including but not limited to:

- the efficacy and potential advantages compared to alternative treatments;
- effectiveness of sales and marketing efforts;

- the cost of treatment in relation to alternative treatments;
- our ability to offer batiraxcept for sale at competitive prices;
- the convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the willingness of the medical community to offer customers our product candidate option in addition to or in the place of batiraxcept ;
- the strength of marketing and distribution support;
- the availability of third-party coverage and adequate reimbursement;
- the prevalence and severity of any side effects; and
- any restrictions on the use of our product together with other medications.

Because we expect sales of all of batiraxcept to be based on the same mechanism of action, the failure of our first product candidate to achieve market acceptance would harm our business and could require us to seek additional financing sooner than we otherwise planned.

The insurance coverage and reimbursement status of newly-approved products is uncertain. Our product candidates may become subject to unfavorable pricing regulations, third-party coverage and reimbursement practices, or healthcare reform initiatives, which would harm our business. Failure to obtain or maintain adequate coverage and reimbursement for new or current products could limit our ability to market those products and decrease our ability to generate revenue.

The regulations that govern marketing approvals, pricing, coverage, and reimbursement for new drugs vary widely from country to country. In the United States, recently enacted legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenue we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if any product candidates we may develop obtain marketing approval.

Our ability to successfully commercialize our product candidates also will depend in part on the extent to which coverage and adequate reimbursement for these products and treatments 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. The availability of coverage and extent of reimbursement by governmental and private payors is essential for most patients to be able to afford treatments such as gene therapy products. Sales of these or other product candidates that we may identify will depend substantially, both domestically and abroad, on the extent to which the costs of our product candidates will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payors. If coverage and adequate reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment.

The availability and extent of reimbursement by governmental and private payors is essential for most patients to be able to afford expensive treatments. Sales of batiraxcept that receive marketing approval will depend substantially, both in the United States and internationally, on the extent to which the costs of batiraxcept will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payors. If reimbursement is not available, or is available only on a limited basis, we may not be able to successfully commercialize batiraxcept. Even if coverage is provided, the approved

reimbursement amount may not be high enough to allow us to establish or maintain adequate pricing that will allow it to realize a sufficient return on our investment.

Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe, Canada, China and other countries may cause us to price batiraxcept on less favorable terms that we currently anticipate. In many countries, particularly the countries of the European Union, the prices of medical products are subject to varying price control mechanisms as part of national health systems. 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 batiraxcept to other available therapies. In general, the prices of products under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for products but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that is able to be charged for clinical product candidates. Accordingly, in markets outside the United States, the reimbursement for products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenues and profits.

Moreover, increasing efforts by governmental and third-party payors, in the United States and internationally, to cap or reduce healthcare costs may cause such organizations to limit both coverage and level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for clinical product candidates. We expect to experience pricing pressures in connection with the sale of batiraxcept due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected for new products entering the marketplace.

If we fail to comply with state and federal healthcare regulatory laws, we could face substantial penalties, damages, fines, disgorgement, exclusion from participation in governmental healthcare programs, and the curtailment of operations, any of which could harm our business.

Although we do not provide healthcare services or submit claims for third party reimbursement, we are subject to healthcare fraud and abuse regulation and enforcement by federal and state governments which could significantly impact our business. The laws that may affect our ability to operate include, but are not limited to:

- the federal anti-kickback statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering, or paying remuneration, directly or indirectly, in cash or in kind, in exchange for or to induce either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service for which payment may be made, in whole or in part, under federal healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of this statute or specific intent to violate it;

- the civil FCA, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other third-party payors that are false or fraudulent; knowingly making using, or causing to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the government; or knowingly making, using, or causing to be made or used, a false record or statement to avoid, decrease or conceal an obligation to pay money to the federal government;

- the criminal FCA, which imposes criminal fines or imprisonment against individuals or entities who make or present a claim to the government knowing such claim to be false, fictitious or fraudulent;

- HIPAA, which created federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

- the federal civil monetary penalties statute, which prohibits, among other things, the offering or giving of remuneration to a Medicare or Medicaid beneficiary that the person knows or should know is likely to influence the beneficiary's selection of a particular supplier of items or services reimbursable by a Federal or state governmental program;

- the federal physician sunshine requirements under the ACA, which require certain manufacturers of drugs, devices, biologics, and medical supplies to report annually to the U.S. Department of Health and Human Services information related to payments and other transfers of value to physicians, other healthcare providers, and teaching hospitals, and

ownership and investment interests held by physicians and other healthcare providers and their immediate family members; and

- state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the device industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; and state laws that require device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures.

Further, the ACA, among other things, amended the intent requirements of the federal anti-kickback statute and certain criminal statutes governing healthcare fraud. A person or entity can now be found guilty of violating the statute without actual knowledge of the statute or specific intent to violate it. In addition, the ACA provided that the government may assert that a claim including items or services resulting from a violation of the federal Anti- Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. If a government authority were to conclude that we provide improper advice to our customers or encouraged the submission of false claims for reimbursement, we could face action against us by government authorities. Any violations of these laws, or any action against us for violation of these laws, even if we successfully defend against it, could result in a material adverse effect on our reputation, business, results of operations and financial condition.

We have entered into consulting and scientific advisory board arrangements with physicians and other healthcare providers. Compensation for some of these arrangements includes the provision of stock options. While we have worked to structure our arrangements to comply with applicable laws, because of the complex and far-reaching nature of these laws, regulatory agencies may view these transactions as prohibited arrangements that must be restructured, or discontinued, or for which we could be subject to other significant penalties. We could be adversely affected if regulatory agencies interpret our financial relationships with providers who influence the ordering of and use our products to be in violation of applicable laws.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry.

Responding to investigations can be time- and resource-consuming and can divert management's attention from the business. Additionally, as a result of these investigations, healthcare providers and entities may have to agree to additional onerous compliance and reporting requirements as part of a consent decree or corporate integrity agreement. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business.

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

We face an inherent risk of product liability exposure related to the testing of batiraxcept in human clinical trials and will face an even greater risk if we commercially sell any products that we may develop after approval. Any adverse reactions in our clinical trials could be deemed to be related to batiraxcept and could result in claims from these injuries and we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend any related litigation;
- substantial monetary awards to trial subjects or patients;
- loss of revenue; and
- the inability to commercialize any products we may develop.

Although we maintain product liability insurance coverage in the amount of up to $10 million per claim and in the aggregate $000 million, we may not be adequate to cover all liabilities that we may incur. We anticipate that we will need to increase our insurance coverage as we continue clinical trials and if we successfully commercialize any products. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

If we are unable to establish sales, marketing and distribution capabilities either on our own or in collaboration with third parties, we may not be successful in commercializing our clinical product candidate, batiraxcept, ***if approved.***

We do not have any infrastructure for the sales, marketing or distribution of batiraxcept, and the cost of establishing and maintaining such an organization may exceed the cost-effectiveness of doing so. In order to market any product candidate that may be approved, we must build our sales, distribution, marketing, managerial and other non-technical capabilities or make arrangements with third parties to perform these services. To achieve commercial success for any product candidate for which we have obtained marketing approval, we will need a sales and marketing organization. We expect to build a focused sales, distribution and marketing infrastructure to market any other product candidates in the United States, if approved. There are significant expenses and risks involved with establishing our own sales, marketing and distribution capabilities, including our ability to hire, retain and appropriately incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel, and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities could delay any product candidate launch, which would adversely impact commercialization.

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

- Our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or attain adequate numbers of physicians to administer our products; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

We intend to pursue collaborative arrangements regarding the sale and marketing of batiraxcept, if approved, for certain international markets; however, we may not be able to establish or maintain such collaborative arrangements, if able to do so, that our collaborators may not have effective sales. To the extent that we depend on third parties for marketing and distribution, any revenues we receive will depend upon the efforts of such third parties, and there can be no assurance that such efforts will be successful.

If we are unable to build our own sales force in the United States or negotiate a collaborative relationship for the commercialization of batiraxcept outside the United States we may be forced to delay the potential commercialization or reduce the scope of our sales or marketing activities. We may have to enter into arrangements with third parties or otherwise at an earlier stage than we would otherwise choose and we may be required to relinquish rights to our intellectual property or otherwise agree to terms unfavorable to us, any of which may have an adverse effect on our business, operating results and prospects.

We may be competing with many companies that currently have extensive and well-funded marketing and sales operations. Without an internal team or the support of a third party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies.

If we obtain approval to commercialize our clinical product candidate, batiraxcept outside of the United States, a variety of risks associated with international operations could harm our business.

If our clinical product candidate is approved for commercialization, we intend to enter into agreements with third parties to market them in certain jurisdictions outside the United States such as we have with 3D Medicine. We expect that we will be subject to additional risks related to international operations or entering into international business relationships, including:

- different regulatory requirements for drug approvals and rules governing drug commercialization in foreign countries;
- reduced protection for intellectual property rights;

- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign reimbursement, pricing and insurance regimes;
- foreign taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential noncompliance with the U.S. Foreign Corrupt Practices Act of 1977, as amended, the U.K. Bribery Act 2010 and similar anti-bribery and anticorruption laws in other jurisdictions;
- product shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

We have no prior experience in these areas. In addition, there are complex regulatory, tax, labor and other legal requirements imposed by both the European Union and many of the individual countries in Europe as well as China with which we will need to comply.

Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our clinical product candidate, batiraxcept, 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, among other things, prevent or delay marketing approval of our clinical product candidate, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidate for which we obtain marketing approval. Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements, (ii) additions or modifications to product labeling, (iii) the recall or discontinuation of our products or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect our business, financial condition and results of operations.

Among policy makers in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. In March 2010, the ACA was passed, which substantially changed the way healthcare is financed by both the government and private insurers, and significantly impacts the U.S. pharmaceutical industry. The ACA, among other things, subjects biological products to potential competition by lower-cost biosimilars, addresses a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increases the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extends the rebate program to individuals enrolled in Medicaid managed care organizations, establishes annual fees and taxes on manufacturers of certain branded prescription drugs, and creates a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D.

Some of the provisions of the ACA have yet to be fully implemented, while certain provisions have been subject to judicial and Congressional challenges. Congress has considered legislation that would repeal or repeal and replace all or part of the ACA, and it is unclear how such challenges and other efforts to repeal and replace the ACA will impact the ACA and our business.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. 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. Such reforms could have an adverse effect on anticipated revenue from product candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop product candidates.

We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products, which could result in reduced demand for batiraxcept or additional pricing pressures. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain patent protection for our clinical product candidate, batiraxcept, or if the scope of the patent protection obtained is not sufficiently broad, we may not be able to compete effectively in our markets.

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our drug development programs and clinical product candidate. Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our development programs and clinical product candidate. The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner.

It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our product candidates in the United States or in other countries. There is no assurance that all potentially relevant prior art that could invalidate our patents or that could prevent our pending patent applications from issuing as patents have been found. Even if patents do successfully issue, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed, invalidated, or held unenforceable. Any successful challenge to these patents or any other patents owned by or licensed to us could deprive us of rights necessary for the successful commercialization of our product candidates or companion diagnostic that we may develop. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate and companion diagnostic under patent protection could be reduced.

If the patent applications we hold with respect to our platform technology and clinical product candidate fail to issue, if their breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for batiraxcept, it could dissuade companies from collaborating with us to develop future product candidates and threaten our ability to commercialize future drugs. Any such outcome could harm our business.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. For example, European patent law restricts the patentability of methods of treatment of the human body more than U.S. law does. Publications of discoveries in scientific literature often lag behind 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. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued that protect our technology or product candidates, in whole or in part, or which effectively prevent others from commercializing competitive technologies. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of ours issued patents. In 2011, the Leahy-Smith America Invents Act (the "Leahy-Smith Act"), was signed into law. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The U.S. Patent Office recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, only became effective in 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on

the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have an adverse effect on our business and financial condition.

Moreover, we may be subject to a third party pre-issuance submission of prior art to the USPTO, or become involved in derivation, reexamination, *inter partes* review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. In other countries, we may be subject to or become involved in opposition proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission or proceeding could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or product candidates and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize product candidates without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, 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 of our technology and product candidates. Moreover, patents have a limited lifespan. In the United States and other countries, the natural expiration of a patent is generally 20 years after it is filed. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Without patent protection for our current or future product candidates, we may be open to competition from generic versions of such product candidates. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, we owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing product candidates similar or identical to ours.

We may be involved in lawsuits to protect or enforce our patents, the patents of our licensors or our other intellectual property rights, which could be expensive, time consuming and unsuccessful.

Competitors and other third parties may infringe or otherwise violate our patents, the patents of our licensors, of our licensees or our other intellectual property rights. To counter infringement or unauthorized use, we may be required to file legal claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that such patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing. The initiation of a claim against a third party may also cause the third party to bring counter claims against us such as claims asserting that our patents are invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, nonenablement or lack of statutory subject matter. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant material information from the USPTO, or made a materially misleading statement, during prosecution. Third parties may also raise similar validity claims before the USPTO in post-grant proceedings such as *inter partes* review, or post-grant review, or oppositions or similar proceedings outside the United States, in parallel with litigation or even outside the context of litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. We cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. For the patents and patent applications that we have licensed, we may have limited or no right to participate in the defense of any licensed patents against challenge by a third party. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of any future patent protection on our current or future product candidates. Such a loss of patent protection could harm our business.

We may not be able to prevent, alone or with our licensors or licensees, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. Our business could be harmed if in litigation the prevailing party does not offer us a license on commercially reasonable terms. Any litigation or other proceedings to enforce our intellectual property rights may fail, and even if successful, may result in substantial costs and distract our management and other employees.

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. There could also 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, it could have an adverse effect on the price of our common stock.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our clinical product candidate, batiraxcept.

The United States has recently enacted and implemented wide-ranging patent reform legislation. The United States Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we have licensed or that we might obtain in the future.

If a third party claims we are infringing on their intellectual property rights, we could incur significant expenses, or be prevented from further developing or commercializing our clinical product candidate, batiraxcept, which could materially harm our business.

Our success will also depend on our ability to operate without infringing the patents and other proprietary intellectual property rights of third parties. This is generally referred to as having "freedom to operate." We have not conducted an in-depth freedom to operate search which would be time consuming and costly. The biotechnology and pharmaceutical industries are characterized by extensive litigation regarding patents and other intellectual property rights. The defense and prosecution of intellectual property claims, interference proceedings and related legal and administrative proceedings, both in the United States and internationally, involve complex legal and factual questions. As a result, such proceedings are lengthy, costly and time-consuming, and their outcome is highly uncertain. We may become involved in protracted and expensive litigation in order to determine the enforceability, scope and validity of the proprietary rights of others, or to determine whether we have freedom to operate with respect to the intellectual property rights of others. For example, we are aware of U.S. Patent Nos. 8,168,415 and 8,920,799, which claim AXL fusion proteins and their use in treating cancer. In the event that one of these patents or another patent is successfully asserted against our GAS6-AXL program in the future, we may be unable to market the product, absent a license from the patentee, which may not be available on commercially reasonable terms, if at all.

Patent applications in the United States are, in most cases, maintained in secrecy until approximately 18 months after the patent application is filed. The publication of discoveries in the scientific or patent literature frequently occurs substantially later than the date on which the underlying discoveries were made. Therefore, patent applications relating to product candidates similar to ours may have already been filed by others without our knowledge. In the event that a third party has also filed a patent application covering batiraxcept, we may have to participate in an adversarial proceeding, such as an interference proceeding, in the USPTO, or similar proceedings in other countries, to determine the priority of invention. In the event an infringement claim is brought against us, we may be required to pay substantial legal fees and other expenses to defend such a claim and, if we are unsuccessful in defending the claim, we may be prevented from pursuing the development and commercialization of a product candidate and may be subject to injunctions and/or damage awards.

In the future, the USPTO or a foreign patent office may grant patent rights covering batiraxcept to third parties. Subject to the issuance of these future patents, the claims of which will be unknown until issued, we may need to obtain a license or sublicense to these rights in order to have the appropriate freedom to further develop or commercialize them. Any required licenses may not be available to us on acceptable terms, if at all. If we need to obtain such licenses or sublicenses, but are unable to do so, we could encounter delays in the development of batiraxcept, or be prevented from developing, manufacturing and commercializing batiraxcept at all. If it is determined that we have infringed an issued patent and do not have freedom to operate, we could be subject to injunctions, and/or compelled to pay significant damages, including punitive damages. In cases where we have in-licensed intellectual property, our failure to comply with the terms and conditions of such agreements could harm our business.

It is becoming common for third parties to challenge patent claims on any successfully developed product candidate or approved drug. If we or our licensees or collaborators become involved in any patent litigation, interference or other legal proceedings, we could incur substantial expense, and the efforts and attention of our technical and management personnel could be significantly diverted. A negative outcome of such litigation or proceedings may expose us to the loss of our proprietary position or to significant liabilities, or require us to seek licenses that may not be available from third parties on commercially acceptable terms, if at all. We may be restricted or prevented from developing, manufacturing and selling batiraxcept in the event of an adverse determination in a judicial or administrative proceeding, or if we fail to obtain necessary licenses.

We may not be able to protect our intellectual property rights throughout the world, which could impair our business.

Filing, prosecuting and defending patents covering batiraxcept throughout the world would be prohibitively expensive. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we may obtain patent protection, but where patent enforcement is not as strong as that in the United States. These other products may compete with batiraxcept in jurisdictions where we do not have any issued or licensed patents and any future patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

We seek to protect our proprietary technology in part by entering into confidentiality agreements with third parties and, if applicable, material transfer agreements, consulting agreements or other similar agreements with our advisors, employees, third-party contractors and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have an adverse effect on our business and results of operations.

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors and consultants to publish data potentially relating to our trade secrets, although our agreements may contain certain limited publication rights. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development or publication of information by any of our third-party collaborators. A competitor's discovery of our trade secrets would impair our competitive position and have an adverse impact on our business.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submissions, 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 payments and other similar provisions 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 and our licensors fail to maintain the patents and patent applications covering batiraxcept, our competitive position would be adversely affected.

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. The following examples are illustrative:

- Others may be able to make products that are similar to our product candidates but that are not covered by the claims of the patents that we license;
- Our licensors or collaborators might not have been the first to make the inventions covered by an issued patent or pending patent application;
- Our licensors or collaborators might not have been the first to file patent applications covering an invention;

- Others may independently develop similar or alternative technologies or duplicate any of our or our licensors' technologies without infringing our intellectual property rights;
- Pending patent applications may not lead to issued patents;
- Issued patents may not provide us with any competitive advantages, or 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 or in-license 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.

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

Many of our employees, including our senior management, were previously employed at other biotechnology or pharmaceutical companies. These employees typically executed proprietary rights, non-disclosure and non-competition agreements in connection with their previous employers. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. We are not aware of any threatened or pending claims related to these matters, but in the future litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

Risks Related to the Ownership of Our Common Stock

Our failure to meet the continued listing requirements of The Nasdaq Global Select Market could result in a delisting of our common stock.

Our shares of common stock are currently listed on The Nasdaq Global Select Market ("Nasdaq"). If we fail to satisfy the continued listing requirements of Nasdaq, such as the corporate governance requirements, minimum bid price requirement or the minimum stockholder's equity requirement, The Nasdaq Stock Market LLC may take steps to delist our common stock. Any delisting would likely have a negative effect on the price of our common stock and would impair stockholders' ability to sell or purchase their common stock when they wish to do so.

On August 9, 2022, we received written notice from the Listing Qualifications Department of The Nasdaq Stock Market LLC notifying us that for the preceding 30 consecutive business days (June 27, 2022 through August 8, 2022), our common stock did not maintain a minimum closing bid price of $1.00 per share ("Minimum Bid Price Requirement") as required by Nasdaq Listing Rule 5550(a)(2). In November 2022 we received written notice from the Listing Qualifications Department of The Nasdaq Stock Market LLC that we had regained compliance with Nasdaq's listing requirements. We can provide no assurance that we will be able to continue to meet Nasdaq listing requirements. Any future failure to meet the listing requirements or a delisting of our common stock by Nasdaq could adversely affect our ability to attract new investors, decrease the liquidity of the outstanding shares of our common stock, reduce the price at which such shares trade and increase the transaction costs inherent in trading such shares with overall negative effects for our stockholder. In addition, delisting of our common stock from Nasdaq could deter broker-dealers from making a market in or otherwise seeking or generating interest in our common stock, and might deter certain institutions and persons from investing in our common stock.

Our stock price has fluctuated in the past, has recently been volatile and may be volatile in the future, and as a result, investors in our common stock could incur substantial losses.

Our stock price has fluctuated in the past, has recently been volatile and may be volatile in the future. From January 1, 2022 through December 31, 2022 the reported high and low sales price of our common stock has fluctuated between $0.58 and $2.84 per share. The stock market in general and the market for biotechnology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may experience losses on their investment in our common stock. The market price for our common stock may be influenced by many factors, including the following:

- investor reaction to our business strategy;
- the success of competitive products or technologies;
- results of clinical studies of batiraxcept or future product candidates or those of our competitors;
- regulatory or legal developments in the United States and other countries, especially changes in laws or regulations applicable to our products;
- introductions and announcements of new products by us, results of clinical trials, our commercialization partners, or our competitors, and the timing of these introductions or announcements;
- actions taken by regulatory agencies with respect to our products, clinical studies, manufacturing process or sales and marketing terms;
- variations in our financial results or those of companies that are perceived to be similar to us;
- the success of our efforts to acquire or in-license additional products or product candidates;
- developments concerning our collaborations, including but not limited to those with our sources of manufacturing supply and our commercialization partners;
- developments concerning our ability to bring our manufacturing processes to scale in a cost-effective manner;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- developments or disputes concerning patents or other proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our products;
- our ability or inability to raise additional capital and the terms on which we raise it;
- the recruitment or departure of key personnel;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- declines in the market prices of stocks generally;
- actual or anticipated changes in earnings estimates or changes in stock market analyst recommendations regarding our common stock, other comparable companies or our industry generally;
- trading volume of our common stock;
- sales of our common stock by us or our stockholders;

- general economic, industry and market conditions;

- other events or factors, including those resulting from such events, or the prospect of such events, including war, terrorism and other international conflicts, public health issues including health epidemics or pandemics, such as the ongoing COVID-19 pandemic, and natural disasters such as fire, hurricanes, earthquakes, tornados or other adverse weather and climate conditions, whether occurring in the United States or elsewhere, could disrupt our operations, disrupt the operations of our suppliers or result in political or economic instability; and

- the other risks described in this "Risk factors" section.

These broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance. Since the stock price of our common stock has fluctuated in the past, has been recently volatile and may be volatile in the future, investors in our common stock could incur substantial losses. In the past, following periods of volatility in the market, securities class-action litigation has often been instituted against companies. Such litigation, if instituted against us, could result in substantial costs and diversion of management's attention and resources, which could materially and adversely affect our business, financial condition, results of operations and growth prospects.

Our executive officers, directors, and entities under our control, and principal stockholders will continue to maintain the ability to control or significantly influence all matters submitted to stockholders for approval.

As of March 10, 2023, our current executive officers, directors and entities under their control, and principal stockholders, in the aggregate, owned shares representing approximately 60.2% of our common stock. Dr. Fredric N. Eshelman, our Executive Chairman beneficially owns 55.5% of our common stock. As a result, Dr. Eshelman acting on his own, would be able to control or significantly influence all matters submitted to our stockholders for approval, as well as our management and affairs. For example, Dr. Eshelman will control or significantly influence the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of voting power could delay or prevent an acquisition of our company on terms that other stockholders may desire.

We incur significant costs as a result of operating as a public company, and our management devotes substantial time to new compliance initiatives.

As a public company, we have incurred and will continue to incur significant legal, accounting and other expenses that we did not incur as a private company. We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, the other rules and regulations of the SEC, and the rules and regulations of Nasdaq. Compliance with the various reporting and other requirements applicable to public companies requires considerable time and attention of management. For example, the Sarbanes-Oxley Act and the rules of the SEC and national securities exchanges have imposed various requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls. Our management and other personnel are devoting and will continue to need to devote a substantial amount of time to these compliance initiatives. These rules and regulations will continue to increase our legal and financial compliance costs and will make some activities more time-consuming and costly. The impact of these events could also make it more difficult for us to attract and retain qualified personnel to serve on our board of directors, our board committees, or as executive officers.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal control over financial reporting and disclosure controls and procedures. In particular, we must perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal control over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. In addition, we will be required to have our independent registered public accounting firm attest to the effectiveness of our internal control over financial reporting beginning with our annual report on Form 10-K following the date on which we are once again an accelerated filer and are no longer an emerging growth company. Our compliance with Section 404 of the Sarbanes-Oxley Act will require that we incur substantial accounting expense and expend significant management efforts. If we are not able to comply with the requirements of Section 404 in a timely manner, or if we or our independent registered public accounting firm identify deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities, which would require additional financial and management resources.

Our ability to successfully implement our business plan and comply with Section 404 requires us to be able to prepare timely and accurate consolidated financial statements. We expect that we will need to continue to improve existing, and implement new operational and financial systems, procedures and controls to manage our business effectively. Any delay in the implementation of, or disruption in the transition to, new or enhanced systems, procedures or controls, may cause our operations to suffer and we may be unable to conclude that our internal control over financial reporting is effective and to obtain an unqualified report on internal controls from our auditors as required under Section 404 of the Sarbanes-Oxley Act. This, in turn, could have an adverse impact on trading prices for our common stock, and could adversely affect our ability to access the capital markets.

We are currently a "smaller reporting company," as defined in the Exchange Act and have elected to take advantage of certain of the scaled disclosures available to smaller reporting companies which may make our stock less attractive to investors.

We are currently a "smaller reporting company," as defined in the Exchange Act and have elected to take advantage of certain of the scaled disclosures available to smaller reporting companies. To the extent that we continue to qualify as a "smaller reporting company" as such term is defined in Rule 12b-2 under the Exchange Act, certain exemptions are available to us from certain disclosure requirements that are applicable to other public companies that are not a "smaller reporting company," including exemption from compliance with the auditor attestation requirements pursuant to SOX and reduced disclosure about our executive compensation arrangements.

As a result, the information we provide stockholders will be different than the information that is available with respect to other public companies. In this Annual Report on Form 10-K, we have not included all of the executive compensation related information that would be required if we were not a smaller reporting company, nor have we included all of the quantitative and qualitative disclosures about market risk that would be required if we were not a smaller reporting company. We cannot predict whether investors will find our common stock less attractive if we 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.

An active trading market for our common stock may not be maintained, or we may fail to satisfy applicable Nasdaq listing requirements.

Our common stock is currently traded on Nasdaq, but we can provide no assurance that we will be able to maintain an active trading market for our shares on Nasdaq or any other exchange in the future. The fact that a significant portion of our outstanding shares of common stock is closely held by a few individuals, results in it being more difficult for us to maintain an active trading market. 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, our stock price could decline, and we may be unable to maintain compliance with applicable Nasdaq listing requirements.

If securities or industry analysts do not publish research, or publish inaccurate or unfavorable research, about our business, our stock price and trading volume could decline.

The trading market for our common stock depends, in part, on the research and reports that securities or industry analysts publish about us or our business. The analysts that cover us may cease to publish research on our company at any time in their discretion. If one or more of these analysts cease coverage of our company, or fail to publish reports on us regularly, demand for our common stock could decrease, which might cause our stock price and trading volume to decline. In addition, if one or more of the analysts who cover us downgrade our stock or publish inaccurate or unfavorable research about our business, our stock price would likely decline. If our operating results fail to meet the forecast of analysts, our stock price would likely decline.

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

Provisions in our corporate charter and our 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 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, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Because our board of directors is responsible for appointing the

members of our management team, these provisions could in turn affect any attempt by our stockholders to replace current members of our management team. Among others, these provisions include the following:

- our board of directors is divided into three classes with staggered three-year terms which may delay or prevent a change of our management or a change in control;
- our board of directors has the right to elect directors to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;
- our stockholders are not able to act by written consent or call special stockholders' meetings; as a result, a holder, or holders, controlling a majority of our capital stock are not able to take certain actions other than at annual stockholders' meetings or special stockholders' meetings called by the board of directors, the chairman of the board, the chief executive officer or the president;
- our certificate of incorporation prohibits cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- our stockholders are required to provide advance notice and additional disclosures in order to nominate individuals for election to the board of directors or to propose matters that can be acted upon at a stockholders' meeting, which may discourage or deter a potential acquiror from conducting a solicitation of proxies to elect the acquiror's own slate of directors or otherwise attempting to obtain control of our company; and
- our board of directors are able to issue, without stockholder approval, shares of undesignated preferred stock, which makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to acquire us.

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 us 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.

Certain provisions of certain of our outstanding warrants could make it more difficult or expensive for a third party to acquire us. Certain of the warrants prohibit us from engaging in certain transactions constituting "fundamental transactions" unless, among other things, the surviving entity assumes our obligations under the warrants. Further, such warrants provide that, in the event of certain transactions constituting "fundamental transactions," with some exception, holders of such warrants will have the right, at their option, to require us to repurchase such warrants at a designated price.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for certain disputes between us and 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 amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware shall be the sole and exclusive forum for any derivative action or proceeding brought on behalf of the Company, 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, any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law or any action asserting a claim governed by the internal affairs doctrine. This forum selection provision does not apply to suits brought to enforce a duty or liability created by the Securities Act or the Exchange Act or any claim for which the federal courts have exclusive jurisdiction.

This forum selection provision may limit a stockholder's ability to bring certain claims in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, other employees or stockholders, which may discourage lawsuits with respect to such claims, although our stockholders will not be deemed to have waived our compliance with federal securities laws and the rules and regulations thereunder. If a court were to find this forum selection provision to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business and financial condition.

Our employment arrangements with our executive officers may require us under certain circumstances to pay severance benefits.

Certain of our executive officers are parties to employment or other agreements or participants under plans that contain change in control and severance provisions providing for aggregate cash payments for severance and other benefits and acceleration of vesting of stock options in the event of a termination of employment in connection with a change in control of us. The accelerated vesting of options could result in dilution to our existing stockholders and harm the market price of our common stock. The payment of these severance benefits could harm our financial condition and results. In addition, these potential severance payments may discourage or prevent third parties from seeking a business combination with us.

Because we do not anticipate paying any cash dividends on our common stock in the foreseeable future, capital appreciation, if any, will be our stockholders' sole source of gain.

We have never declared or paid cash dividends on our common stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of existing or any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be our stockholders' sole source of gain for the foreseeable future.

Item 1B. Unresolved Staff Comments.

None

Item 2. Properties.

We do not own any real property and lease facilities in Morrisville, North Carolina, Menlo Park, California and Houston, Texas. Our principal executive offices are located in Houston, Texas where we occupy office space pursuant to the terms of a lease agreement that expires on October 31, 2023, which will automatically renew at the end of the term for a six-month term, unless a three-month notice is given to cancel. Our rent under the lease is approximately $1,800 per month.

In March 2017, we entered into an operating facility lease agreement with Bohannon Associates, a California partnership, dated March 17, 2017 (the "Master Lease") for approximately 34,500 rentable square feet of office space located at 1020 Marsh Road, Menlo Park, California (the "1020 Marsh Facility"). The lease for the 1020 Marsh Facility commenced in August 2017 for a period of 86 months with one renewal option for a five-year term. Future base rent we owe over the lease term as of December 31, 2021 is $8.3 million.

On August 1, 2021, the sublease dated June 8, 2021 (the "Sublease Agreement") by and between us and Grail, Inc., or Grail ("Subtenant") became effective, whereby we agreed to sublease to Subtenant all of the approximately 34,500 rentable square feet of office space at the 1020 Marsh Facility currently leased pursuant to the Master Lease. The sublease commenced on August 1, 2021 and the term of the sublease was through October 31, 2024, unless the Master Lease was terminated earlier due to a breach by Subtenant. Base rent Subtenant was obligated to pay us as of December 31, 2021 was $6.7 million.

In August 2020, we entered into an operating facility lease agreement with Perimeter Center 7 Pack, LLC dated August 14, 2020 for approximately 4,128 square feet of office space at 1800 Perimeter Park Suite 130, Morrisville, North Carolina. Future base rent we owe over the lease term as of December 31, 2022 is $0.5 million.

We believe that our existing facilities are adequate for our current needs.

Item 3. Legal Proceedings.

We are not currently subject to any material legal proceedings. From time to time, we may be subject to various legal proceedings and claims that arise in the ordinary course of its business activities. Litigation, regardless of the outcome, could 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.

Market for Registrant's Common Equity

Since October 16, 2018, our common stock has been listed on Nasdaq under the symbol "ARAV". Prior to that, from March 21, 2014 until October 16, 2018, our common stock traded on Nasdaq under the symbol "VSAR". In connection with the completion of the Merger, on October 15, 2018, our amended and restated certificate of incorporation was amended to effect, on October 16, 2018, a reverse split of our common stock at a ratio of 1-for-6.

Holders

On March 10, 2023, there were 36 stockholders of record of our common stock, one of which was Cede & Co., a nominee for Depository Trust Company, or DTC. All of the shares of our common stock held by brokerage firms, banks and other financial institutions as nominees for beneficial owners are deposited into participant accounts at DTC and are therefore considered to be held of record by Cede & Co. as one stockholder.

Dividend Policy

We have not paid dividends on our common stock. We currently intend to retain any earnings for use in the development and expansion of our business. We, therefore, do not anticipate paying cash dividends on our common stock in the foreseeable future.

Sales of Unregistered Equity Securities

There were no unregistered sales of equity securities by us during the year ended December 31, 2022 that were not previously disclosed in our filings with the SEC.

Issuer Purchases of Equity Securities

There were no issuer purchases of equity securities during the fourth quarter of the year ended December 31, 2022.

Performance Graph

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

Item 6. [Reserved]

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and related notes included elsewhere in this Annual Report on Form 10-K. This discussion and other parts of this Form 10-K contain forward-looking statements that involve risks and uncertainties, such as statements of our plans, objectives, expectations and intentions. Our actual results could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the section of this Form 10-K entitled "*Risk Factors.*"

Important Note

This Management's Discussion and Analysis of Financial Condition and Results of Operations includes a discussion of our operations for the years ended December 31, 2022 and December 31, 2021.

References in this report to "we," "us," "our" and similar first-person expressions refer to Aravive, Inc. (formerly known as Versartis, Inc.) and its subsidiaries, including Private Aravive. References to "Versartis, Inc." or "Private Aravive" refer to those respective companies prior to the completion of their merger in October 2018.

Overview

We are a clinical-stage oncology company developing transformative treatments designed to halt the progression of life-threatening diseases, including cancer and fibrosis.

Batiraxcept (formerly AVB-500), is an ultrahigh-affinity, decoy protein that targets the GAS6-AXL signaling pathway. By capturing serum GAS6, batiraxcept starves the AXL pathway of its signal, potentially halting the biological programming that promotes disease progression. AXL receptor signaling plays an important role in multiple types of malignancies by promoting metastasis, cancer cell survival, resistance to treatments, and immune suppression.

Our current development program benefits from the availability of a proprietary serum-based biomarker that has accelerated batiraxcept drug development by allowing us to select a pharmacologically active dose and may potentially identify the cancer patients that have the best chance of responding to batiraxcept.

In our completed Phase 1 clinical trial in healthy volunteers with batiraxcept, we have demonstrated proof of mechanism for batiraxcept in neutralizing GAS6. Importantly, batiraxcept had a favorable safety profile preclinically and in the first in human trial and Phase 1b clinical trial in cancer patients.

In August 2018, the FDA designated as a Fast Track development program the investigation of batiraxcept for platinum-resistant recurrent ovarian cancer.

In December 2018, we initiated our Phase 1b clinical trial of batiraxcept combined with standard of care therapies in patients with PROC, for which we reported results in July 2020.

In April 2020, we entered into a license and collaboration agreement with WuXi, the objective of which is to identify and develop novel high-affinity bispecific antibodies against CCN2, also known as CTGF, implicated in cancer and fibrosis and identified from a similar target discovery screen that identified the significance of the AXL/GAS6 pathway in cancer. However, in August 2022, the Company temporarily halted work on the CTGF program with WuXi in an effort to focus all resources on the clinical programs.

In November 2020, we entered into the 3D Medicines Agreement, whereby we granted 3D Medicines an exclusive license to develop and commercialize products that contain batiraxcept as the sole drug substance, for the diagnosis, treatment or prevention of human oncological diseases, in the Territory.

During the fourth quarter of 2020, we initiated our Phase 1b portion of the Phase 1b/2 trial of batiraxcept in ccRCC and we dosed our first patient in the trial in March 2021.

During the first quarter 2021, we initiated our registrational Phase 3 trial of batiraxcept in PROC and we dosed our first patient in the trial in April 2021.This global, randomized, double-blind, placebo-controlled trial is designed to evaluate efficacy and safety of batiraxcept at a dose of 15 mg/kg in combination with PAC versus PAC alone.

In May 2021, we announced expansion of batiraxcept development programs into first line pancreatic ductal adenocarcinoma ("PDAC") with the goal of initiating the trial by end of 2021. We dosed our first patient in August 2021.

In June 2021, we announced initial safety, pharmacokinetic, and pharmacodynamic results from the batiraxcept Phase 1b portion of the Phase 1b/2 clinical trial in ccRCC.

In October 2021, the EMA granted orphan drug designation for batiraxcept for the treatment of PROC, following a recommendation from the Committee for Orphan Medicinal Products.

In November 2021, we announced preliminary data from our Phase 1b trial evaluating batiraxcept in combination with cabozantinib for treatment of ccRCC.

In January 2022, we announced that we had dosed the first patient in the Phase 2 portion of the Phase 1b/2 study of batiraxcept in combination with cabozantinib for treatment of ccRCC.

In March 2022, we announced updated data and new biomarker data from our Phase 1b trial of batiraxcept in ccRCC.

In May 2022, we provided updated data and information at our Key Opinion Leader symposium.

In October 2022, we received a $6 million development milestone payment from 3D Medicines based on the initiation of the global Phase 3 platinum resistant ovarian cancer ("PROC") clinical trial in the Territory for the development of batiraxcept.

In November 2022, the FDA designated as a Fast Track development program the investigation of batiraxcept for treatment of patients with advanced or metastatic ccRCC who have progressed after 1 or 2 prior lines of systemic therapy that include both immuno-oncology (IO)-based and vascular endothelial growth factor tyrosine kinase inhibitor (VEGF-TKI)-based therapies (either in combination or sequentially).

In January 2023, the Company announced complete enrollment in the global Phase 3 platinum resistant ovarian cancer ("PROC") clinical trial.

Recent Clinical Developments

The Phase 3 Platinum Resistant Ovarian Cancer (PROC) Trial Remains On Track

The registration-directed Phase 3 program of batiraxcept in combination with paclitaxel in PROC remains on track and enrollment has been completed. We expect to report topline data from the trial by mid-2023. CMC work remains on track with the goal of filing a BLA by year-end 2023. The global, randomized, double-blind, placebo-controlled Phase 3 trial is evaluating efficacy and tolerability of batiraxcept at a dose of 15 mg/kg in combination with paclitaxel versus placebo in combination with paclitaxel. The trial has completed enrollment of over 360 patients with platinum resistant, high-grade serous ovarian cancer who have received 1-4 prior lines of therapy.

Updated Clear Cell Renal Cell Cancer Data (ccRCC) Continues to Be Encouraging

As of August 8, 2022, 26 previously treated (2L+) patients with ccRCC have been treated with batiraxcept in the Phase 1b portion of a Phase 1b/2 trial at doses of 15 mg/kg (n=16) and 20 mg/kg (n=10), plus cabozantinib 60 mg daily. There were no dose limiting toxicities observed at either dose. The best overall response rate (ORR, confirmed) in the ITT population was 42%. One of the objectives of the ongoing Phase 1b/2 ccRCC trial is to evaluate the correlation of baseline serum soluble AXL (sAXL)/GAS6 (biomarker) with radiographic response in patients with ccRCC treated with batiraxcept plus cabozantinib. The best ORR in the biomarker high population was 55%. The 9-month progression-free survival (PFS) rate was 65% in the ITT population and 72% in the biomarker high population. We have discussed a registrational path with the US FDA that includes use of the sAXL/Gas6 ratio as a basis for an accelerated approval.

We expect to report additional data from the Phase 1b portion and preliminary data from the Phase 2 portion of the ccRCC trial mid-2023.

Expansion of Phase 1b Pancreatic Adenocarcinoma Study

As of September 20, 2022, 18 patients with pancreatic adenocarcinoma ("PDAC") had been treated with 15 mg/kg (Days 1 & 15) + nab-paclitaxel (125 mg/m2 on Days 1, 8, & 15) and gemcitabine (1000 mg/m2 on Days 1, 8, & 15) and have pharmacokinetic data. As has been seen for other Phase 1b cancer studies with batiraxcept, there is a relationship between batiraxcept exposures and clinical activity such that 5 out of the 9 patients in the PDAC study whose batiraxcept levels exceeded the minimum efficacious concentration (MEC) of batiraxcept had a response vs 1 out of 9 patients in the low MEC group. Similarly, the mPFS in the high MEC group was 5.6 months (95% CI 2.1, not evaluable) vs 2.7 months (95% CI 1.1, 5.4) in the low MEC group. In May 2022, we had reported that batiraxcept in combination with gemcitabine and nab-paclitaxel was generally well-tolerated with no unexpected safety signals. Based on these data, we intend to dose an additional 6-18 patients at higher doses (20mg/kg and potentially 25mg/kg) to see if higher doses will increase the proportion of patients who will achieve high MEC of batiraxcept and increase the clinical activity of batiraxcept in combination with gemcitabine + nab-paclitaxel.

Recent Financial Developments

In January 2022, we entered into an investment agreement (the "Investment Agreement") with Eshelman Ventures, LLC and, solely for purposes of Article IV and Article V of the Investment Agreement, Dr. Eshelman, Eshelman Ventures, agreed to purchase pre-funded warrants of up to 4,545,455 shares of our common stock, par value $0.0001 per share ("Warrant Shares"), at a price of $2.20 per share, which was the consolidated closing bid price of our common stock on Nasdaq on December 31, 2021, for an aggregate purchase price of $10 million. The closing of the transaction occurred on January 5, 2022. Pursuant to the terms of the Investment Agreement, we were required to file a registration statement registering the shares of common stock underlying the pre-funded warrant. The registration statement was filed on January 5, 2022 and declared effective by the SEC on January 18, 2022. The pre-funded warrants issued to Eshelman Ventures, LLC were exercisable upon the approval by our stockholders of the exercise, which approval was obtained on April 1, 2022, at which time the pre-funded warrants were exercised in full.

On March 31, 2022, we closed a registered direct offering of our common stock with a single healthcare-focused institutional investor and Eshelman Ventures, LLC, pursuant to which we issued 3,185,216 shares of common stock, 1,665,025 pre-funded warrants (the "March Pre-Funded Warrants") and common stock warrants (the "Common Stock Warrants") to purchase up to 4,850,241 shares of common stock in a registered direct offering priced at-the-market under Nasdaq rules. The purchase price per share and accompanying common stock warrant was $2.005 for the institutional investor and $2.325 for Eshelman Ventures, LLC. The purchase price per March Pre-Funded Warrant and accompanying Common Stock Warrant was $2.004 for the institutional investor. The net proceeds from the offering were $9.3 million, after deducting underwriting discounts, commission and offering expenses. The Common Stock Warrants issued to the institutional investor are exercisable immediately, will expire five years from the exercisable date and will have an exercise price of $1.88 per share. The Common Stock Warrants issued to Eshelman Ventures, LLC were exercisable upon the approval by our stockholders of the exercise of previously issued securities, which approval was obtained on April 1, 2022, will expire five years following the exercise date and will have an exercise price of $2.20 per share. We could receive additional gross proceeds of $9.4 million, if the Common Stock Warrants are fully exercised. The 1,665,025 Pre-Funded Warrants were exercised on June 6, 2022.

On October 27, 2022, we closed a private placement offering with new biotechnology investors, existing investors, our management and certain of our directors for the issuance and sale of an aggregate of 45,178,811 shares of our common stock, or pre-funded warrants in lieu thereof (the "October Pre-Funded Warrants" and together with the March Pre-Funded Warrants, the "Pre-Funded Warrants") and warrants (the "October Warrants" and together with the March Common Warrant, the "Warrants") to purchase up to an aggregate of 45,178,811 shares of common stock or pre-funded warrants (the "Private Placement") priced at-the-market under Nasdaq rules. The purchase price per share and accompanying warrant was $0.9199 for all investors who participated in the deal (or $0.9198 per pre-funded warrant and accompanying October Warrant). Fifty percent of the October Warrants have an exercise price of $0.7949 per share and will expire on the date that is the later of: (i) 15 months from the date an increase in the number of authorized shares of common stock is effected, or (ii) one month after the public announcement of the topline Phase 3 PROC data. The remaining 50% of the October Warrants have an exercise price of $0.7949 per share and will expire 30 months from the date an increase in the number of authorized shares of common stock is effected. All of the October Warrants other than the October Pre-funded warrants are exercisable for exchange of cash from the warrant holder. The net proceeds were approximately $40 million and will be used to fund our clinical development programs. Pursuant to the terms of the registration rights agreements that we entered into, we were required to file a registration statement registering the shares of common stock issued and the shares of common stock underlying the October Warrants and October Pre-funded Warrants, underlying the pre-funded warrant. The registration statement was filed on November 18, 2022 and declared effective by the SEC on November 28, 2022.

Financial overview

Revenue

To date, we have not generated any revenue from commercial sales of any of our product candidates. However, for the years ended December 31, 2022 and 2021, we generated approximately $9.1 million and $7.4 million from the 3D Medicine Agreement, which represents a portion of initial signing and milestone payments received from 3D Medicines that is recognized at the time of the receipt and a portion of the payments that is deferred and recognized over the PROC trial period.

In the future, we may generate revenue from a variety of sources, including product sales if we develop products which are approved for sale, license fees, milestones, research and development and royalty payments in connection with strategic collaborations or government contracts, or licenses of our intellectual property.

Research and development expenses

We recognize both internal and external research and development expenses as incurred. Our external research and development expenses consist primarily of:

- the cost of acquiring and manufacturing clinical trial and other materials, including expenses incurred under agreements with contract manufacturing organizations;
- expenses incurred under agreements with contract research organizations, investigative sites, and consultants that conduct our clinical trials;
- other costs associated with development activities, including additional studies; and

Internal research and development costs consist primarily of salaries and related fringe benefit costs for our employees (such as workers' compensation and health insurance premiums), stock-based compensation charges and travel costs.

General and administrative expenses

General and administrative expenses consist principally of personnel-related costs, professional fees for legal, consulting, audit and tax services, rent and other general operating expenses not included in research and development.

Other income (expense), net

Other income (expense), net is primarily comprised of sublease income for our 1020 Marsh Facility lease, gains and losses on foreign currency transactions related to third party contracts with foreign-based contract manufacturing organizations and change in fair value of the warrant liability.

Results of operations

Comparison of the years ended December 31, 2022 and 2021

The following table summarizes our net loss during the periods indicated (in thousands, except percentages):

	Year Ended December 31,		Increase/ (Decrease)	
	2022	2021		
Revenue:				
Collaboration revenue	$ 9,137	$ 7,442	$ 1,695	23%
Operating expenses:				
Research and development	66,938	37,541	29,397	78%
General and administrative	13,036	10,550	2,486	24%
Total operating expenses	79,974	48,091	31,883	66%
Loss from operations	(70,837)	(40,649)	30,188	74%
Total other income (expense), net	(5,485)	1,498	(6,983)	-466%
Net loss	$ (76,322)	$ (39,151)	$ 37,171	95%

Collaboration revenue

Collaboration revenue was approximately $9.1 million and $7.4 million for the years ended December 31, 2022 and 2021, respectively. The increase in revenue in 2022 compared to the same period in 2021 was driven primarily by increased expenditures related to the Phase 3 PROC trial, which drives the recognition of deferred revenue over the trial period.

Research and development expense

Research and development expense increased by $29.4 million, or 78%, to $66.9 million in 2022 from $37.5 million in 2021. The increase was primarily due to the continued progress of our clinical programs, including our Phase 3 trial of batiraxcept in PROC, our Phase 1b/2 trial of batiraxcept in ccRCC, and our Phase 1 trial of batiraxcept in pancreatic cancer. The continued advancement of our Phase 3 trial of batiraxcept in PROC is the most significant driver to the increase in expense in 2022 when compared to the same period in 2021. There were also significant increased CMC manufacturing activities during 2022 in order to prepare for our BLA filing at the end of 2023.

General and administrative expense

General and administrative expense increased by approximately $2.5 million, or 24%, to approximately $13.0 million in 2022 from approximately $10.6 million for the same period in 2021. The increase was primarily driven by higher salary expense, higher stock-based compensation expense, higher severance expense, and increased consulting fees.

Total other income (expense), net

Total other income (expense), net fluctuated by approximately $7.0 million, to approximately $5.5 million of total other expense, net in 2022 from approximately $1.5 million of total other income, net in 2021. The change relates to sublease income received from our subtenant for a full year in 2022, compared to only a part of the year in 2021, offset by an increase in the fair value of our warrant liability totaling approximately $9.0 million for 2022.

Liquidity and Capital Resources

Since our inception and through December 31, 2022, we have financed our operations through private placements of our equity securities, public offerings of our equity securities, debt financing, CPRIT grant proceeds, sales of common stock through our at-the-market facility as well as payments received from license agreements. As of December 31, 2022, we had an accumulated deficit of approximately $616.1 million, primarily as a result of research and development and general and administrative expenses, and working capital of $35.9 million. As of December 31, 2022, we had cash and cash equivalents of approximately $53.7 million, a majority of which is invested in money market funds at several highly rated financial institutions.

During 2021 and 2022, our primary sources of funding have been milestone payments from 3D Medicines and proceeds from the sale of our common stock and other securities. In November 2020, June 2021 and August 2021, we received $12 million, $6 million and $3 million, respectively, in upfront and milestone payments from 3D Medicines pursuant to the 3D Medicines Agreement with them. In October 2022, we received a $6 million milestone payment from 3D Medicines. On February 18, 2021, we received approximately $21 million from the purchase by Eshelman Ventures of 2,875,000 shares of our common stock. On September 4, 2020, we entered into an equity distribution agreement (the "Equity Distribution Agreement") with Piper Sandler and Cantor Fitzgerald to sell shares of our common stock, from time to time, through an “at the market offering” program having an aggregate offering price of up to $60,000,000 through which Piper Sandler and Cantor Fitzgerald will act as sales agents. During the year ended December 31, 2021, we sold 1,432,627 shares of common stock for net proceeds of $9.8 million under the Equity Distribution Agreement. On January 5, 2022, we received approximately $9.9 million in net proceeds from the purchase by Eshelman Ventures, LLC of pre-funded warrants to purchase up to 4,545,455 shares of our common stock. In March 2022, we received approximately $9.3 million in net proceeds, in the aggregate, from the purchase by Eshelman Ventures, LLC and a single healthcare-focused institutional investor of 3,185,216 shares of our common stock, 1,665,025 March Pre-Funded Warrants and March Common Stock Warrants to purchase up to 4,850,241 shares of our common stock in a registered direct offering. In October 2022, we received approximately $40 million in net proceeds from a private placement offering from new biotechnology investors, existing investors, our management and certain of our Directors for the issuance and sale of an aggregate of 45,178,811 shares of our common stock (or October Pre-Funded Warrants in lieu thereof) and October Common Warrants to purchase up to an aggregate of 45,178,811 shares of common stock in a private placement offering priced at-the-market under Nasdaq rules. The purchase price per share and accompanying October Common Warrant was $0.9199 for all investors who participated in the deal (or $0.9198 per October Pre-Funded Warrant and accompanying October Common Warrant). During the year ended December 31, 2022, we sold 54,763 shares of common stock for net proceeds of $0.1 million under the Equity Distribution Agreement.

As of December 31, 2022, we had cash and cash equivalents of approximately $53.7 million. We believe that our existing cash and cash equivalents will be sufficient to sustain operations beyond our PROC Phase 3 top line results and into the fourth quarter of 2023 and that we will need to obtain additional financing in order to advance our clinical development program to later stages of development, build out our pipeline and fund operations beyond the fourth quarter of 2023. We intend to provide financing for the foregoing by seeking funds through equity or debt financings, collaborative or other arrangements with corporate sources, or through other sources of financing. These factors raised substantial doubt about our ability to continue as a going concern. The consolidated financial statements included in this Annual Report on Form 10-K do not include any adjustments relating to the recoverability of the recorded assets or the classification of liabilities that may be necessary should we be unable to continue as a going concern. Although management has been successful in raising capital in the past, there can be no assurance that we will be successful or that any needed financing will be available in the future at terms acceptable to us. Our failure to raise capital as and when needed could have a negative impact on our financial condition and our ability to complete clinical trials and pursue our business strategies. We anticipate that we will need to raise substantial additional capital, the requirements of which will depend on many factors, including:

- the rate of progress, cost of our clinical studies and results of our clinical studies, including the need to conduct additional trials if requested by the FDA;
- the timing of, and costs involved in, seeking and obtaining approvals from the FDA and other regulatory authorities;
- the cost of preparing to manufacture on a larger scale;
- the costs of commercialization activities if any future product candidate is approved, including product sales, marketing, manufacturing and distribution;
- the degree and rate of market acceptance of any products launched by us or future partners;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- our ability to enter into additional collaboration, licensing, commercialization or other arrangements and the terms and timing of such arrangements; and
- the emergence of competing technologies or other adverse market developments.

If we are unable to raise additional funds when needed, or if funds are raised on terms that are not favorable to us, we may be required to delay, reduce, or terminate some or all of our development programs and clinical trials. We may also be required to sell or license our technologies or clinical product candidates or programs that we would prefer to develop and commercialize ourselves.

Cash flows

The following table sets forth the primary sources and uses of cash and cash equivalents for each of the periods presented below:

	Year Ended December 31,	
	2022	2021
	(In thousands)	
Net cash (used in) provided by:		
Operating activities	$ (65,079)	$ (32,177)
Investing activities	(11)	—
Financing activities	59,369	31,061
Net decrease in cash and cash equivalents	$ (5,721)	$ (1,116)

Cash used in operating activities

Net cash used in operating activities was $65.1 million and $32.2 million during the years ended December 31, 2022 and 2021, respectively, which was primarily due to the use of funds in our operations related to the development of batiraxcept, our product candidate. Cash used in operating activities in 2022 increased compared to the year ended December 31, 2021

due primarily to the ramp up in our Phase 3 trial of batiraxcept in PROC along with continuing costs related to our trial of our second oncology indication, ccRCC and our third oncology indication, pancreatic adenocarcinoma. There were also significant increased CMC manufacturing activities during 2022 in order to prepare for our BLA filing at the end of 2023.

Cash used in investing activities

Net cash used in investing activities during the years ended December 31, 2022 and 2021 was $11 thousand and $0, respectively.

Cash provided by financing activities

Net cash provided by financing activities was $59.4 million and $31.1 million during the years ended December 31, 2022 and 2021, respectively. Financing activities related to the year ended December 31, 2022 included a registered direct offering of our securities with proceeds of $9.3 million, issuance of Pre-Funded Warrants with proceeds of $9.9 million, at the market offering proceeds of $0.1 million, and a private placement financing with net proceeds of approximately $40.0 million. Financing activities related to the year ended December 31, 2021 included a registered direct offering with proceeds of $20.9 million along with at the market offering proceeds of $9.8 million.

Critical Accounting Estimates

Our discussion and analysis of our financial condition and results of operations is based upon financial statements that we have prepared in accordance with accounting principles generally accepted in the United States of America, or GAAP. The preparation of these financial statements requires management to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses, and related disclosures. On an on-going basis, we evaluate these estimates, including those related to revenue recognition and estimated future research and development expenses, warrant liabilities and share-based compensation. Estimates are based on historical experience, information received from third parties and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. Historically, revisions to our estimates have not resulted in a material change to the financial statements.

Collaboration Revenue

We enter into out-license and collaboration agreements under which we license certain rights to our product candidate to third parties and which to date are within the scope of ASC 606. The terms of these arrangements typically include payment to us of one or more of the following: non-refundable, up-front license fees; development, regulatory, and commercial milestone payments; payments for manufacturing supply services we provide through our contract manufacturers; and royalties on net sales of licensed products. Each of these payments may result in license, collaboration and other revenue, except for revenues from royalties on net sales of licensed products, which are classified as royalty revenues.

For elements of our collaboration agreements that are accounted for pursuant to ASC 606, we must develop assumptions that require judgment to determine whether the individual promises should be accounted for as separate performance obligations or as a combined performance obligation, and to determine the stand-alone selling price for each performance obligation identified in the contract. We use key assumptions to determine the stand-alone selling price, which may include forecasted revenues, development timelines, reimbursement rates for personnel costs, discount rates, and probabilities of technical and regulatory success. If the license to our intellectual property is determined to be distinct from the other performance obligations identified in an out-license and collaboration arrangement, we recognize revenue from non-refundable, up-front fees allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. For licenses that are bundled with other promises, we utilize judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, up-front fees. With regard to the 3D Medicines collaboration agreements, we recognize revenue related to amounts allocated to the identified performance obligation on a proportional performance basis as the underlying services are performed.

The preceding estimates and judgments materially affect our recognition of collaboration revenues. Changes in our estimates of forecasted development costs could impact proportional performance percentages and could have a material effect on collaboration revenue recorded in the period in which we determine that change occurs.

Clinical Trial Accruals

Our clinical trial accruals are based on estimates of patient enrollment and related costs at clinical investigator sites as well as estimates for the services received and efforts expended pursuant to contracts with multiple research institutions and CROs that conduct and manage clinical trials on the Company's behalf.

Our estimates of preclinical and clinical trial expenses are based on the services performed, pursuant to contracts with research institutions and CROs that conduct and manage preclinical studies and clinical trials on our behalf. In accruing service fees, we estimate the time period over which services will be performed and the level of patient enrollment and activity expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, we will adjust the accrual accordingly. Payments made to third parties under these arrangements in advance of the receipt of the related services are recorded as prepaid expenses until the services are rendered.

The preceding estimates and judgment materially affect our research and development expenses. Changes in our estimates of patient enrollment and related costs could have a material effect on our research and development expenses.

Stock-based Compensation Expense

For purposes of calculating stock-based compensation, we estimate the fair value of share-based compensation awards using a Black-Scholes option-pricing model. The determination of the fair value of stock-based compensation awards utilizing the Black-Scholes model is affected by our stock price and a number of assumptions, including but not limited to expected stock price volatility over the term of the awards and the expected term of stock options.

If factors change and we employ different assumptions, share-based compensation expense may differ significantly from what we have recorded in the past. If there is a difference between the assumptions used in determining stock-based compensation expense and the actual factors which become known over time, we may change the input factors used in determining stock-based compensation expense for future grants. These changes, if any, may materially impact our results of operations in the period such changes are made. For actual forfeitures, we recognize the adjustment to compensation expense in the period the forfeitures occur.

Warrant Liability

The Company estimates the fair value of these liabilities using assumptions that are based on the individual characteristics of the warrants on the valuation date and reporting date. The Company uses the Black-Scholes option-pricing model and the fair value of the underlying stock adjusted for discount for lack of marketability, when applicable, to determine the fair value of these liabilities. The valuation model is based on inputs as of the valuation dates, including the estimated volatility of our stock, the remaining contractual term of the warrants and the risk-free interest rates and various other factors.

If factors change and we employ different assumptions, the warrant liability and other income/expense may differ significantly from what we have recorded in the past. If there is a difference between the assumptions used in determining the warrant liability and the actual factors which become known over time, we might change our inputs used in the valuation model. These changes, if any, may materially impact our results of operations in the period such changes are made.

Additional Information

Refer to Note 2 to the condensed consolidated financial statements for more information on accounting pronouncements that have impacted or are expected to materially impact our consolidated financial condition, results of operations, or cash flows.

Recent Accounting Pronouncements

Recently issued accounting pronouncements that we have adopted or are currently evaluating are described in detail within "Note 2—Summary of Significant Accounting Policies" to the accompanying consolidated financial statements included elsewhere in this Annual Report on Form 10K.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

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

Item 8. Financial Statements and Supplementary Data.

The following consolidated financial statements of the registrant, related notes and reports of independent registered public accounting firms are set forth beginning on page F-1 of this report.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None

Item 9A. Controls and Procedures.

(a) Evaluation of Disclosure Controls and Procedures

An evaluation as of December 31, 2022 was carried out under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of our "disclosure controls and procedures," which are defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act), as controls and other procedures of a company that are designed to ensure that the information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of December 31, 2022.

(b) Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) of the Exchange Act. Our internal control system is designed to provide reasonable assurance regarding the preparation and fair presentation of financial statements for external purposes in accordance with generally accepted accounting principles. All internal control systems, no matter how well designed, have inherent limitations and can provide only reasonable assurance that the objectives of the internal control system are met.

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting, based on criteria established by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in its 2013 Internal Control-Integrated Framework. Based on our evaluation, we concluded that our internal control over financial reporting was effective as of December 31, 2022.

As of December 31, 2022, we are a non-accelerated filer, our independent registered accounting firm is not required to issue an attestation report on our internal control over financial reporting**.**

(c) Changes in Internal Control over Financial Reporting

Our management, including our Chief Executive Officer and Chief Financial Officer, has evaluated any changes in our internal control over financial reporting that occurred during the quarter ended December 31, 2022, and has concluded that there was no change during such period that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

None

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspection

Not Applicable

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

BOARD OF DIRECTORS AND EXECUTIVE OFFICERS OF THE COMPANY

The following table sets forth information concerning our directors and executive officers, including their ages as of March 10, 2023. There are no family relationships among any of our directors or executive officers.

Name	Age	Position(s)
Fredric N. Eshelman, Pharm. D.[1]	74	Executive Chairman of the Board of Directors
Gail McIntyre, Ph.D.[2]	60	President, Chief Executive Officer and Director
Rudy Howard [3]	65	Chief Financial Officer
Robert B. Geller, M.D. [4]	69	Chief Medical Officer
Leonard Scott Dove, Ph.D. [5]	50	Chief Operating Officer
Amato Giaccia, Ph.D.	64	Director
Eric Zhang	41	Director
John A. Hohnecker, M.D.	63	Director
Michael W. Rogers	63	Director
Peter T.C. Ho, M.D., Ph.D.	61	Director
Sigurd C. Kirk	56	Director

(1) Dr. Eshelman was appointed as our company's Executive Chairman on January 3, 2022 and has served as the non-executive Chairman of our Board since April 8, 2020 until his appointment as Executive Chairman of our company.

(2) Dr. McIntyre was appointed President and Chief Executive Officer and director effective April 8, 2020. Dr. McIntyre served as our Chief Scientific Officer from February 12, 2019 until her appointment as Chief Executive Officer.

(3) Mr. Howard has served as our Chief Financial Officer since June 3, 2022.

(4) Dr. Geller has served as our Chief Medical Officer since July 1, 2022.

(5) Dr. Dove has served as our Chief Operating Officer since March 21, 2022.

Fredric N. Eshelman, Pharm. D, Executive Chairman of the Board of Directors

Dr. Eshelman was appointed the Executive Chairman of our company on January 3, 2022 and has served as the non-executive Chairman of the Board of Directors from April 8, 2020 until his appointment as Executive Chairman of our company. Dr. Eshelman is the Founder of Eshelman Ventures, LLC, an investment company primarily interested in healthcare companies. Previously, he founded and served as Chairman and Chief Executive Officer of Pharmaceutical Product Development, Inc. (PPDI) prior to the sale of the company to private equity interests. After PPD, he served as founding chairman and was the largest shareholder of Furiex Pharmaceuticals, Inc. (FURX), a company which in-licensed and rapidly developed new medicines. Furiex was sold to Forest Laboratories Inc. (which was later acquired by Actavis) in 2014. His career has also included positions as SVP development and board member of the former Glaxo, Inc., as well as management positions with Beecham Laboratories and Boehringer Mannheim Pharmaceuticals. Dr. Eshelman is also a member of the Board of Directors of, Amplitude Healthcare Acquisition Corp. (Nasdaq: AMHC) and Eyenovia Inc. (Nasdaq:EYEN). He is currently chairman of several biotech companies and previously was chairman of The Medicines Company (MDCO) and was on the board of Bausch Health (BHC) G1 Therapeutics, Inc. (Nasdaq: GTHX). Dr. Eshelman has served on the executive committee of the Medical Foundation of North Carolina and was appointed by the North Carolina General Assembly to serve on the Board of Governors for the state's multi-campus university system (chair of audit committee), as well as the North Carolina Biotechnology Center. In addition, he chairs the board of visitors for the School of Pharmacy at University of North Carolina at Charlotte (UNC-CH). The school was named the UNC Eshelman School of Pharmacy in recognition of his many contributions to the school and the profession.

He has received many awards including the Davie and Distinguished Service Awards from UNC, outstanding alumnus from both the UNC and University of Cincinnati schools of pharmacy, Life Science Leadership Award (CED) and the North Carolina Biotech Hall of Fame. Dr. Eshelman received the doctor of pharmacy from the University of Cincinnati, completed a residency at Cincinnati General Hospital, and received a BS Pharm from UNC-CH. He completed the OPM program at Harvard Business School. Dr. Eshelman also received an honorary doctor of science from UNC-CH.

We believe Dr. Eshelman is qualified to serve as a member of our Board of Directors based on his experience in the life sciences, biotechnology and pharmaceutical industries and for his knowledge of corporate development matters.

Gail McIntyre, Ph.D., Chief Executive Officer and Director

Dr. McIntyre has served as a member of the Board of Directors and as our President and Chief Executive Officer since April 8, 2020 and from February 2019 until her appointment as our Chief Executive Officer, as our Chief Scientific Officer. Dr. McIntyre also served as our Senior Vice President of Research and Development from the Merger, on October 12, 2018, until February 2019 and served as Aravive Biologics' Senior Vice President of Research and Development from January 2017 to October 2018 and a consultant to Aravive Biologics from August 2016 until January 2017. Having brought multiple drugs to market, Dr. McIntyre has more than 20 years of experience in drug development, strategic business development, licensing and M&A activities. Dr. McIntyre has served as a principal at IntelliDev Consulting, LLC providing consulting services to several biotechnology companies for three years, while also serving as VP of Development for Meryx, Inc. from January 2014 until January 2016. Prior to that, Dr. McIntyre held the position of senior vice president of research at Furiex Pharmaceuticals, Inc. and previously served as head of Pharmaceutical Product Development LLC's (PPD) compound partnering business. At both Furiex and PPD, she strategized and managed all preclinical and clinical activities for drug development programs and was responsible for identification of new partnering opportunities and technical due diligence for both in-licensing opportunities and new business acquisitions. At PPD, she led the partnering and the in-licensing of Alogliptin from Syrrx, Inc. at preIND stage and the licensing to Takeda at Phase 2. She was instrumental to the licensing of Dapoxetine to what is currently Johnson & Johnson and then The Menarini Group. She played a pivotal role in the $1.1 billion acquisition of Allergan in 2014 and successfully negotiated with CSS on scheduling for Viberzi, in addition to driving all aspects of development. Dr. McIntyre has authored more than 30 regulatory submissions and is a board-certified toxicologist. Her experience covers multiple therapeutic areas including oncology (including immune-oncology), infectious diseases, central nervous system, gastrointestinal, and metabolic/endocrine as well as various therapies including small drugs, treatment vaccines, antibodies, immunoconjugates and peptide mimetics. Dr. McIntyre is also board certified in Clinical Pathology (hematology and clinical chemistry) by the American Society of Clinical Pathology. Dr. McIntyre received her B.A. in Biology from Merrimack College. She earned M.S. and Ph.D. degrees in Biochemistry and Biophysics from the University of North Carolina at Chapel Hill.

We believe that Dr. McIntyre is able to make valuable contributions to the Board of Directors due to her clinical and leadership experience in the healthcare and pharmaceutical industries.

Rudy Howard, Chief Financial Officer

Mr. Howard has served as our Chief Financial Officer since June 3, 2022. From June 2015 through December 2021, Mr. Howard, served as the Chief Financial Officer of vTv Therapeutics Inc., a clinical-stage pharmaceutical company listed on the Nasdaq Capital Market (Nasdaq: VTVT). Prior to joining vTv Therapeutics Inc., from January 2010 through May 2015, Mr. Howard served as the Chief Financial Officer of SciQuest, Inc., an international spend-management software company. From November 2008 until joining SciQuest, Mr. Howard served as Senior Vice President and Chief Financial Officer of MDS Pharma Services, a pharmaceutical services company. From 2003 until joining MDS Pharma Services, Mr. Howard operated his own financial consulting company, Rudy C. Howard, CPA Consulting, in Wilmington, North Carolina, where his services included advising on merger and acquisition transactions, equity and debt issuances and other general management matters. From 2001 through 2003, Mr. Howard served as Chief Financial Officer for Peopleclick, Inc., an international human capital management software company. From 2000 until joining Peopleclick, Mr. Howard served as Chief Financial Officer for Marketing Services Group, Inc., a marketing and internet technology company. From 1995 until 2000, Mr. Howard served as Chief Financial Officer for PPD, Inc., a clinical research organization. Prior to joining PPD, Mr. Howard was a partner with PricewaterhouseCoopers. Mr. Howard holds a B.A. in Accounting from North Carolina State University, and he is a Certified Public Accountant.

Robert B. Geller, M.D., Chief Medical Officer

Dr. Geller has served as our Chief Medical Officer since July 1, 2022. Dr. Geller started his academic career as the Director of the Stem Cell Transplant program at the University of Chicago and as the Director of the Leukemia Service and Director of the Unrelated Transplant Program, Emory University. He then transitioned to community practice where he focused on the development of clinical pathways for patients with hematologic malignancies and solid tumors, and the expansion of community-based clinical research programs. After over two decades in clinical practice, he then transitioned to the biopharmaceutical industry, where he held positions in medical affairs and clinical development at Alexion Therapeutics, Heron Therapeutics and Coherus Biosciences. Specifically, from 2019 until June 2022, Dr. Geller served as Senior Vice President (Medical Affairs) at Coherus Biosciences where he was involved in the clinical development and successful commercialization of both their biosimilar franchise and their immune-oncology pipeline. From 2015-2019, Dr. Geller served as Vice President at Heron Therapeutics where he developed and recruited the medical affairs team in anticipation of the

launch of Heron's products and development of its pipeline. Dr. Geller has authored over 200 publications and abstracts and has served as reviewer for numerous medical journals. Dr. Geller earned a Bachelor and Master of Science degrees in Physics at the Massachusetts Institute of Technology (MIT) and Medical Doctor degree from Harvard Medical School. Dr. Geller completed a medical residency at the Hospital of the University of Pennsylvania and Medical Oncology Fellowship at the Johns Hopkins Oncology Center. Dr Geller is a Diplomat in Internal Medicine and Medical Oncology with the American Board of Internal Medicine.

Leonard Scott Dove, Ph.D., Chief Operating Officer

Dr. Dove has served as our Chief Operating Officer since March 21, 2022. Previously, from November 2017 until March 2022, Dr. Dove served as Senior Vice President and General Manager of PPD, Inc. ("PPD"), a Thermo Fisher Scientific company (NYSE: TMO), where he provided strategic direction and oversight of PPD's Early Development Services business unit. In this role, Dr. Dove was responsible for the organizational design and executive management of early phase CRO operations. PPD is a leading global provider of clinical research services to the biopharma and biotech industry. Prior to joining PPD, from August 2015 to November 2017, Dr. Dove was an Executive Director of Clinical Development with Allergan, Inc. ("Allergan") in a contract capacity serving as global clinical development leader for Viberzi®/Truberzi® (eluxadoline). At Allergan, he negotiated marketing approvals, labeling, and post-marketing requirements for eluxadoline as a treatment for irritable bowel syndrome, while overseeing the development and operational execution of its label expansion and lifecycle management clinical strategy. Dr. Dove previously oversaw the development of eluxadoline as program leader at Furiex Pharmaceuticals, Inc., managing the program through successful NDA submission until the acquisition of Furiex by Actavis plc (now Allergan). Dr. Dove received his B.S. in biochemistry and a doctorate in pharmacology from Texas A&M University.

Amato Giaccia, Ph.D., Director

Dr. Giaccia has served as a member of the board of directors since the Merger was completed on October 12, 2018. Prior to the closing date of the Merger, he also served as a member of the board of directors of Private Aravive from August 2010 to October 2018 and as Acting Chief Scientific Officer of Private Aravive from January 2017 until the Merger was completed on October 12, 2018. Dr. Giaccia also served as Professor of Radiation Oncology, Associate Chair for Research & Director of the Division of Radiation & Cancer Biology in the Department of Radiation Oncology at Stanford University School of Medicine, a position he has held since 2011 and has been a Director of Oxford Institute of Radiation Oncology since January 2019. He is also the Associate Director for Basic Science and leader of the Radiation Biology Program in Stanford Cancer Institute. He has also served as the Director of the Cancer Biology Interdisciplinary Graduate Program and is currently the "Jack, Lulu and Sam Willson Professor in Cancer Biology" in the Stanford University School of Medicine. He received his Ph.D. from the University of Pennsylvania.

We believe that Dr. Giaccia is able to make valuable contributions to the board of directors due to his extensive scientific and medical knowledge and experience and his familiarity with Aravive's technology as the leader of the laboratory in which it originated.

Eric Zhang, Director

Mr. Zhang has served as a member of the board of directors since the Merger was completed on October 12, 2018. Prior to the closing date of the Merger, he also served as a member of the board of directors of Aravive Biologics from June 2016 to October 2018. Mr. Zhang is the Managing Partner of New Era Technologies Management Ltd., a company he founded in 2016, which is a multi-strategy investor in biotechnology and applied physical sciences companies. From 2013 until 2016, when he founded New Era Technologies Management Ltd, Mr. Zhang was the manager of his family office investments. Mr. Zhang joined J.P. Morgan's China Investment Banking team in Hong Kong in 2006. In the subsequent seven years, Mr. Zhang worked for Macquarie Capital and Barclays Capital in Hong Kong, responsible for covering clients in the healthcare and technology sectors in the Greater China region. Mr. Zhang received a Bachelor of Commerce and BA in Economics from Queen's University in Kingston, Canada.

We believe that Mr. Zhang is able to make valuable contributions to the board of directors due to his extensive experience as an investor in and director of our company and other biotechnology companies.

John A. Hohneker, M.D., Director

Dr. Hohneker has served as a member of the Board of Directors since May 12, 2021. Dr. Hohneker has 30 years of drug development and leadership experience within the biotech and pharmaceutical industry. Dr. Hohneker served as President and Chief Executive Officer of Anokion SA, a biotechnology company, from January 2018 to January 2021. Prior to joining Anokion SA, Dr. Hohneker was President of Research and Development at FORMA Therapeutics Inc., a biotechnology company, from

August 2015 to January 2018. From 2001 to 2015, Dr. Hohneker held roles of increasing responsibility at Novartis AG, most recently as Senior Vice President and Global Head of Development, Immunology and Dermatology. Prior to joining Novartis, he held positions of increasing responsibility at Glaxo Wellcome and its legacy company, Burroughs Wellcome.

Dr. Hohneker serves on the Board of Directors of the following publicly traded companies: Curis, Inc., Evelo Biosciences, Inc., and Humanigen, Inc. From January to November 2017, he served on the Board of Directors of Dimension Therapeutics Inc., a biotechnology company, until it was acquired by Ultragenyx Pharmaceutical Inc. Dr. Hohneker received a bachelor's degree in chemistry from Gettysburg College and an M.D. from the University of Medicine and Dentistry of New Jersey at Rutgers Medical School. He completed his internship and residency in internal medicine and his fellowship in medical oncology, all at the University of North Carolina at Chapel Hill.

We believe Dr. Hohneker is qualified to serve as a member of our Board of Directors based on his experience in the pharmaceutical and biotech industries.

Michael Rogers, Director

Mr. Rogers has served as a member of the Board of Directors since September 15, 2020. Mr. Rogers has served as Chief Financial Officer of Apnimed, Inc. since November 2020. Prior to Apnimed, Inc., he served as Chief Financial Officer at Aerpio Pharmaceuticals, Inc. (Nasdaq: ARPO) from November 2017 to October 15, 2019. Prior to Aerpio Pharmaceuticals, Inc., he served as Chief Financial Officer at Acorda Therapeutics, Inc. (Nasdaq: ACOR) from 2013 to 2016 and held executive and leadership positions at BG Medicine, Indevus Pharmaceuticals (acquired by Endo Pharmaceuticals), Advanced Health Corporation and Autoimmune. Mr. Rogers currently serves as a member of the Board of Directors for Akebia Therapeutics (Nasdaq Global Market: AKBA), with previous advisory experience at Keryx Biopharmaceuticals, Eyepoint Pharmaceuticals and Coronado Biosciences. Earlier in his career, Mr. Rogers was an investment banker at Lehman Brothers and PaineWebber, where he focused on life sciences companies. He earned his M.B.A. from the Darden School of Business at the University of Virginia and received his bachelor's degree from Union College.

We believe that Mr. Rogers is able to make valuable contributions to the board of directors due to his extensive public company experience as an officer and director of biotechnology companies.

Peter T. C. Ho, M.D., Ph.D., Director

Dr. Ho has served as a member of the Board of Directors since May 12, 2021. Dr. Ho has more than 25 years of biotechnology and pharmaceutical industry experience in numerous operational roles. Dr. Ho served as the Chief Medical Officer of Boston Pharmaceuticals, Inc. from 2018 until 2020. From September 2014 until 2017, Dr. Ho served in various roles at Epizyme, Inc., a commercial stage biopharmaceutical company, including as Executive Vice President and Chief Medical Officer from September 2015 until December 31, 2017 and Chief Development Officer from September 2014 to September 2015. Dr. Ho served as Chief Executive Officer of Metastagen Inc., a pharmaceutical preparation company that he co-founded, from February 2013 until September 2014, as President of BeiGene Ltd., a biopharmaceutical company based in Beijing, China that he co-founded, from October 2010 to December 2012, as Vice President of Oncology Development at Johnson & Johnson from September 2008 to September 2010 and, prior to that, as Senior Vice President of the Oncology Center of Excellence for Drug Development at GlaxoSmithKline. Dr. Ho currently serves on the Board of Directors for Celeris Therapeutics, Inc., the Scientific Advisory Board of Accent Therapeutics, Inc. and Tavotek Biotherapeutics, and is a Senior Scientific and Medical Advisor to Overland Pharmaceuticals (US) Inc. and D3 Bio, Inc., based in Hong Kong. Over his career, Dr. Ho has been directly responsible for the first-in-human dosing of 19 anticancer agents and has overseen the development of over 60 hematology and oncology compounds in all phases of clinical trials. His work has contributed to eleven NCE or biologics approvals to date: Gleevec®; Arranon®; Tykerb®; Promacta®; Votrient®; Synribo®; Tafinlar®; Mekinist®; Sylvant®; Rydap®, and Tazverik®.

Dr. Ho is currently Principal at Phase One Advisors LLC, Adjunct Associate Professor in the Division of Chemical Biology and Medicinal Chemistry at the Eshelman School of Pharmacy, University of North Carolina and Adjunct Lecturer at the John Hopkins University. Dr. Ho received his M.D. and Ph.D. (pharmacology) degrees from Yale University and then completed a pediatrics residency at The Children's Hospital of Boston followed by clinical fellowships in pediatric hematology/oncology at the Dana-Farber Cancer Institute and in clinical oncology and regulatory sciences jointly through the U.S. FDA and the National Cancer Institute. He received his bachelor's degree in Biology at Johns Hopkins University.

We believe Dr. Ho is qualified to serve as a member of our Board of Directors based on his experience in the pharmaceutical and biopharmaceutical industries.

Sigurd C. Kirk, Director

Mr. Kirk has served as a member of the Board of Directors since May 12, 2021. Mr. Kirk is a senior corporate business development executive with more than 15 years of pharmaceutical experience in the areas of branded biopharmaceutical, medical device and generic products. From 2009 until its acquisition by AbbVie Inc. in May 2020, Mr. Kirk held various positions at Allergan plc. (formerly Actavis). From May 2012 until May 2020, Mr. Kirk was Executive Vice President, Corporate Business Development at Allergan plc., where he was a member of the 12-person Executive Leadership Team. He was an integral member assessing development and commercial opportunities, leading due diligence, as well as negotiating and transacting key legal and financial terms. Mr. Kirk also served as Senior Vice President, Global Controller and Chief Accounting Officer for Barr Pharmaceuticals, Inc. from 2003 until 2009. Mr. Kirk started his career at Deloitte & Touche as an Audit Manager, earning his CPA certification. Mr. Kirk received his Bachelor of Business Administration degree from Pace University.

We believe Mr. Kirk is qualified to serve as a member of our Board of Directors based on his experience in the pharmaceutical and biopharmaceutical industries.

TERM AND NUMBER OF DIRECTORS

The board of directors currently consists of eight (8) directors and is divided into three classes. Each class serves for a term of three years, with the terms of office of the respective classes expiring in successive years. Directors in Class I (Dr. Eshelman and Mr. Kirk) will stand for election at the 2024 meeting of stockholders, directors in Class II (Dr. Giaccia, Dr. Hohneker and Mr. Rogers) will stand for election at the 2025 Annual Meeting and directors in Class III (Dr. McIntyre, Dr. Ho and Mr. Zhang) will stand for election at the 2023 annual meeting of stockholders.

Vacancies on the board of directors may be filled only by persons elected by a majority of the remaining directors. A director elected by the board of directors to fill a vacancy in a class, including vacancies created by an increase in the number of directors, shall serve for the remainder of the full term of that class and until the director's successor is duly elected and qualified.

Information Regarding the Board of Directors and Corporate Governance

Independence of the Board of Directors

Our common stock is listed on Nasdaq. Under Nasdaq listing standards, independent directors must comprise a majority of a listed company's board of directors and all members of the Audit Committee, Compensation Committee and Nominating and Corporate Governance Committee must be independent. Audit Committee members must also satisfy the independence criteria set forth in Rule 10A-3 under the Exchange Act and Compensation Committee members must also satisfy the independence criteria set forth in Rule 10C-1 under the Exchange Act. Under Nasdaq listing standards, 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.

In order to be considered to be 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 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.

The board of directors undertook a review of the independence of the members of the board of directors and considered whether any director has a material relationship with our company that could compromise his or her ability to exercise independent judgment in carrying out his or her responsibilities. Based upon information requested from and provided by each director concerning their background, employment and affiliations, including family relationships, the board of directors has determined that all of our current directors, except Dr. Eshelman due to his position as Executive Chairman and Dr. McIntyre, due to her current position as President and Chief Executive Officer of our company, is "independent" as that term is defined under the rules of Nasdaq. As a result, Dr. Giaccia, Dr. Hohneker, Dr. Ho, Mr. Kirk, Mr. Rogers, and Mr. Zhang are deemed to be "independent" as that term is defined under the rules of Nasdaq.

In making these determinations, the board of directors considered the current and prior relationships that each non-employee director has with our company and all other facts and circumstances the board of directors deemed relevant in determining their independence, including the beneficial ownership of capital stock by each non-employee director, and the transactions involving them described in Item 13 of this Amendment "Certain Relationships and Related-Party Transactions, Director Independence."

INFORMATION REGARDING COMMITTEES OF THE BOARD OF DIRECTORS

The board of directors has the authority to appoint committees to perform certain management and administration functions. As disclosed above, the board of directors has established an Audit Committee, a Compensation Committee and Nominating and Corporate Governance Committee. The board of directors may establish other committees to facilitate the management of our company's business. The composition and functions of each committee are described below. Members serve on these committees until their resignation or until otherwise determined by the board of directors.

All of the committees comply with all applicable requirements of the Sarbanes-Oxley Act of 2002, Nasdaq, and SEC, rules and regulations as further described below. The charters for each of these committees are available on our website at www.aravive.com. Information contained on or accessible through our website is not a part of this Annual Report on Form 10-K and the inclusion of such website address in this Annual Report on Form 10-K is an inactive textual reference only.

Committees of the Board of Directors

The table set forth below shows the directors who are currently members or Chairman of each of the Audit Committee, Compensation Committee and Nominating and Corporate Governance Committee. From time to time, the board of directors may also establish *ad hoc* committees to address particular matters.

Name	Audit	Compensation	Nominating and Corporate Governance	Related Party Transactions Committee
Gail McIntyre*				
Fredric N. Eshelman, Pharm. D.***				
Amato Giaccia, Ph.D.	X	X	X**	
Michael W. Rogers	X**	X**		X
Eric Zhang	X			
John A. Hohneker, M.D.		X		X
Peter T. C. Ho, M.D., Ph.D.			X	
Sigurd C. Kirk	X			X**

* Dr. McIntyre joined the board of directors effective April 8, 2020 as a Class III member. She is not a member of any of the committees of the board of directors.

** Committee Chairman

*** Dr. Eshelman serves as the Executive Chairman of the board of directors and is not a member of any committees.

Below is a description of each committee of the board of directors.

Audit Committee

Messrs. Rogers, Kirk, Zhang and Dr. Giaccia currently serve as members of the Audit Committee. The board of directors has determined that Messrs. Rogers, Kirk, Zhang and Dr. Giaccia are each "independent" in accordance with the Nasdaq Stock Market definition of independence. The board of directors has determined that each of Messrs. Rogers, Kirk, Zhang and Dr. Giaccia has the related financial management expertise within the meaning of the Nasdaq Stock Market rules, and that each of Messrs. Rogers, Kirk and Zhang are "financial experts" under the applicable rules and regulations of the SEC and Nasdaq.

The primary purpose of the Audit Committee is to act on behalf of the board of directors in fulfilling the board of directors' oversight responsibilities with respect to our corporate accounting and financial reporting processes, systems of internal control over financial reporting and audits of financial statements, as well as the quality and integrity of our financial statements and reports and the qualifications, independence and performance of the registered public accounting firm or firms engaged as our independent outside auditors for the purpose of preparing or issuing an audit report or performing audit services. Specific responsibilities of the Audit Committee include:

- evaluating the performance of and assessing the qualifications of the independent auditors;
- determining and approving the engagement of the independent auditors;

- determining whether to retain or terminate the existing independent auditors or to appoint and engage new independent auditors;
- reviewing and approving the retention of the independent auditors to perform any proposed permissible non-audit services;
- monitoring the rotation of partners of the independent auditors on our audit engagement team as required by law;
- reviewing and approving or rejecting transactions between us and any related persons;
- conferring with management and the independent auditors regarding the effectiveness of internal controls over financial reporting;
- establishing procedures, as required under applicable law, for the receipt, retention and treatment of complaints received by us regarding accounting, internal accounting controls or auditing matters and the confidential and anonymous submission by employees of concerns regarding questionable accounting or auditing matters; and
- meeting to review our annual audited financial statements and quarterly financial statements with management and the independent auditor.

The Audit Committee operates pursuant to a written charter adopted by the board of directors, which is available on our website at *www.aravive.com*. The charter describes in more detail the nature and scope of responsibilities of the Audit Committee.

Compensation Committee

Dr. Giaccia, Dr. Hohneker and Mr. Rogers currently serve as members of the Compensation Committee, each of whom the board of directors has determined is independent in accordance Rule 10C-1 under the Exchange Act and the Nasdaq definition of independence and that each is a "non-employee director" as defined in Rule 16b-3 promulgated under the Exchange Act.

The primary purpose of the Compensation Committee is to discharge the responsibilities of the board of directors to oversee compensation policies, plans and programs and to review and determine the compensation to be paid to the executive officers, directors and other senior management, as appropriate. Specific responsibilities of the Compensation Committee include:

- reviewing and approving, or recommending that the independent members of the board of directors approve, goals and objectives relevant to the compensation of executive officers, and evaluating performance in light of such goals and objectives, including reviewing and approving employment, severance, change in control provisions and other compensatory arrangements;
- reviewing and approving the compensation of the directors;
- overseeing the administration of equity incentive plans and approve grants and awards;
- reviewing and making recommendations to the board of directors regarding the adoption, amendment and termination of our equity incentive plans;
- assessing the independence of independent compensation consultants, legal counsel or other advisors to the committee, before retaining them;
- reviewing and discussing with management our disclosures regarding compensation for use in any annual reports on Form 10-K, registration statements or proxy statements, to the extent required by law or Nasdaq listing requirements;
- preparing and reviewing the Compensation Committee report on executive compensation included in our annual proxy statement, to the extent required by law and Nasdaq listing requirements;
- investigating any matter brought to the attention of the Compensation Committee within the scope of its duties, if in the judgment of the Compensation Committee, such investigation is appropriate; and

- reviewing and evaluating the performance of the Compensation Committee and the adequacy of its charter.

The Compensation Committee operates pursuant to a written charter adopted by the board of directors, which is available on our website at *www.aravive.com*. The charter describes in more detail the nature and scope of responsibilities of the Compensation Committee.

Nominating and Corporate Governance Committee

Dr. Giaccia and Dr. Ho currently serve as members of the Nominating and Corporate Governance Committee, each of whom, the board of directors has determined is independent in accordance with the Nasdaq definition of independence. Specific responsibilities of the Nominating and Corporate Governance Committee include:

- identifying, evaluating and recommending to the board of directors, candidates for election to the board, and making recommendations regarding re-election of incumbent directors;

- considering recommendations and proposals submitted by stockholders in respect of board nominees, establishing policies in respect of such recommendations and proposals (including stockholder communications with the board of directors), and recommending any action to the board in respect of such stockholder recommendations and proposals;

- identifying, evaluating and recommending to the board of directors, candidates to serve on committees of the board of directors,

- assessing the performance of the board of directors; and

- developing, recommending to the board of directors and reviewing corporate governance principles, and periodically reviewing such principles, our code of business conduct and other governance principles and making recommendations to the board of directors in respect thereof.

The Nominating and Corporate Governance Committee operates pursuant to a written charter adopted by the board of directors, which is available on our website at *www.aravive.com*. The charter describes in more detail the nature and scope of responsibilities of the Nominating and Corporate Governance Committee.

Related Party Transactions Committee

Dr. Hohneker, Mr. Kirk and Mr. Rogers currently serve as members of the Related Party Transactions Committee. The responsibilities of the Related Party Transactions Committee are to review any transaction or series of transactions between our company and our directors or any entity controlled by a director or under common control with a director (an "Affiliate") in which we pay or receive in excess of $1 million (a "Transaction"). The Related Party Transactions Committee is comprised solely of directors who are neither participating in the Transaction nor having an Affiliate participate in the Transaction.

Ad Hoc Committee

In July 2022, we formed a Special Committee that was delegated authority to negotiate terms of a financing transaction and to recommend to the full Board any financing transaction approved by the Special Committee.

Changes to Procedures for Recommending Nominees to the Board of Directors.

None.

Code of Business Conduct and Ethics

We have adopted a code of conduct that applies to all officers, directors and employees, including those officers responsible for financial reporting. The full text of the code of conduct is posted on our website at *www.aravive.com*. If we make any substantive amendments to the code of conduct or grant any waiver from a provision of the code of conduct to any executive officer or director, we will promptly disclose the nature of the amendment or waiver on our website.

Item 11. Executive Compensation.

EXECUTIVE COMPENSATION

We are a "smaller reporting company" under Item 10 of Regulation S-K promulgated under the Exchange Act and the following compensation disclosure is intended to comply with the requirements applicable to smaller reporting companies. Although the rules allow us to provide less detail about our executive compensation program, the Compensation Committee is committed to providing the information necessary to help stockholders understand its executive compensation-related decisions. Accordingly, this section includes supplemental narratives that describe the 2022 executive compensation program for our named executive officers.

The following individuals are our "named executive officers" for the year ended December 31, 2022:

- Gail McIntyre, our Chief Executive Officer
- Rudy Howard, our Chief Financial Officer
- Leonard Scott Dove, our Chief Operating Officer
- Vinay Shah, our Former Chief Financial Officer (Mr. Shah resigned as our Chief Financial Officer effective June 2, 2022)

Oversight of Executive Compensation

The compensation of our named executive officers is determined and approved by our Compensation Committee, in discussion with the Chief Executive Officer with respect to the other named executive officers. The Chief Executive Officer does not participate in discussions or decisions regarding her own compensation.

We believe that in order to create value for our stockholders, it is critical to attract, motivate and retain key executive talent by providing competitive compensation packages. Accordingly, we design our executive compensation programs to:

- attract, motivate and retain executives with the skills and expertise to execute our business plans;
- reward those executives fairly over time for actions consistent with creating long-term stockholder value;
- align the interests of our executive officers with those of our stockholders;
- provide compensation packages that are competitive, reasonable and fair within the highly competitive life sciences market for talented individuals.

The Compensation Committee uses the services of an independent compensation consultant who is retained by, and reports directly to, the Compensation Committee to provide the Compensation Committee with an additional external perspective with respect to its evaluation of relevant market and industry practices. At the end of 2021, the Compensation Committee retained Korn Ferry, as a third-party compensation consultant to assist the Compensation Committee in establishing overall compensation levels for 2022. Korn Ferry conducted analyses and provided advice on, among other things, the appropriate peer group, executive compensation for our executive officers and compensation trends in the life sciences industry. The peer group was recommended by Korn Ferry and chosen by the Compensation Committee in late 2021 based on the following parameters: biopharmaceutical companies that were developing oncology products, with a lead product in a similar phase of development (Phase 1 or 2 clinical trials) as well as other appropriate financial and organizational metrics.

SUMMARY COMPENSATION TABLE

The following table shows compensation awarded to or earned by our named executive officers, for the fiscal years ended December 31, 2022 and 2021.

Name and Principal Position	Year	Salary ($)	Option Awards ($) (1)	Non-Equity Incentive Plan Compensation ($) (2)	All Other Compensation ($) (3)	Total ($)
Gail McIntyre [4]						
Chief Executive Officer	2022	510,000	776,645	267,750	26,244	1,580,639
	2021	500,000	824,291	187,500	12,202	1,523,993
Rudy Howard [5]						
Chief Financial Officer	2022	227,624	298,613	96,358	9,889	632,484
	2021	—	—	—	—	—
Leonard Scott Dove [6]						
Chief Operating Officer	2022	300,781	321,580	126,702	6,947	756,010
	2021	—	—	—	—	—
Vinay Shah [7]						
Former Chief Financial Officer	2022	308,922	455,966	—	217,226	982,114
	2021	370,800	299,742	111,240	14,464	796,246

(1) In accordance with SEC rules, this column reflects the aggregate fair value of the stock and option awards granted or modified during the respective fiscal year computed as of their respective grant dates in accordance with Financial Accounting Standard Board Accounting Standards Codification Topic 718 for stock-based compensation transactions (ASC 718). The valuation assumptions used in determining such amounts are described in Note 2 and Note 9 to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

(2) Amounts reported in the non-equity incentive compensation plan column represent awards earned based on the achievement of company goals for the fiscal year presented as determined by the Compensation Committee of the Board and was paid in the first quarter of 2023 and 2022.

(3) All other compensation is primarily comprised of life insurance payments made by us and employer matching contributions for contributions to our 401(k) plan.

(4) Dr. McIntyre became our Chief Scientific Officer on February 12, 2019 and served in such role until she became our Chief Executive Officer on April 8, 2020.

(5) Mr. Howard became our Chief Financial Officer on June 3, 2022.

(6) Dr. Dove became our Chief Operating Officer on March 21, 2022.

(7) Mr. Shah resigned as our Chief Financial Officer effective June 2, 2022. Other compensation for Mr. Shah consisted of consulting fees, COBRA reimbursement and life insurance payments during 2022.

NARRATIVE TO SUMMARY COMPENSATION TABLE

The three principal components of our executive compensation program for our named executive officers in 2022 were base salary, annual performance-based bonus and long-term equity compensation. Base salary provides financial stability and security through a fixed amount of cash for performing job responsibilities. Annual performance-based bonus and long-term equity incentive compensation are designed to reward achievement of the specific strategic goals that we believe will advance our business strategy and create long-term value for our stockholders.

Consistent with our goal of attracting, motivating and retaining a high-caliber executive team, our executive compensation program is designed to pay for performance. We utilize compensation elements that meaningfully align our named executive officer's interests with those of our stockholders to create long-term value. As such, a significant portion of our Chief Executive Officer's and other executive officers' compensation is "at risk", performance-based compensation, in the form of long-term equity awards and annual cash incentives that are only earned if we achieve measurable corporate metrics, as set forth in the table below.

Name	Fixed	"At Risk"	Annual Target Cash Incentive Awards	Equity Incentives
Gail McIntyre	33%	67%	17%	50%
Rudy Howard	46%	54%	19%	35%
Leonard Scott Dove	45%	55%	18%	37%
Vinay Shah [(1)]	39%	61%	15%	46%

(1) Mr. Shah resigned as our Chief Financial Officer effective June 2, 2022.

We do not have any formal policies for allocating compensation among salary, annual target cash incentive awards and equity grants, short-term and long-term compensation or among cash and non-cash compensation. Instead, the Compensation Committee uses its judgment in determining a total compensation program for each named executive officer to recommend to the Board for its approval that is a mix of current, short-term and long-term incentive compensation, that it believes appropriate to achieve the goals of our executive compensation program and our corporate objectives.

Annual Base Salary

In January 2022, the Compensation Committee reviewed the base salaries for our named executive officers, the market data from Korn Ferry, the scope of each executive's responsibilities, each executive's prior experience and internal pay equity. After such review, Dr. McIntyre's annual base salary was raised from $500,000 to $510,000, and Mr. Shah's annual base salary was raised from $370,800 to $381,924. In February 2022, we entered into an offer letter with Dr. Dove to serve as our Chief Operating Officer commencing March 25, 2022 at an annual base salary of $385,000. In June 2022, Mr. Shah resigned as our Chief Financial Officer, and we entered into an offer letter with Mr. Howard to serve as our Chief Financial Officer at an annual base salary of $395,000. In February 2023, Dr. McIntyre's annual base salary was raised to $560,000, Mr. Howard's annual base salary was raised to $412,775, Dr. Dove's annual base salary was raised to $405,000. The named executive officers' 2022 annual base salaries approved by the Compensation Committee were as follows:

Name	2022 Base Salary ($)
Gail McIntyre	510,000
Rudy Howard	395,000
Leonard Scott Dove	385,000
Vinay Shah [(1)]	381,924

(1) Mr. Shah resigned as our Chief Financial Officer effective June 2, 2022.

Annual Cash Incentive (Performance-Based Award) Opportunity

In addition to base salaries, our named executive officers are eligible to earn an annual performance-based cash incentive award, which is designed to provide an appropriate incentive to our named executives to achieve defined annual corporate performance goals and to reward our executives for individual achievement towards these goals. The annual performance-based incentive award each executive officer is eligible to receive is based on the individual's target incentive award, as a

percentage of base salary. The amount of the performance-based bonus, if any, an executive earns may vary from year to year based on the achievement of certain corporate performance goals recommended by the Compensation Committee and communicated to our named executive officers each year, prior to or shortly following the beginning of the year to which they relate.

The corporate goals typically relate to our annual company goals and various business accomplishments which vary from time to time depending on our overall strategic objectives. The proportional emphasis on each goal may vary from time to time depending on our overall strategic objectives and the Compensation Committee's and Board's subjective determination of which goals have more impact on our performance.

Pursuant to their employment agreements or offer letters, each named executive officer was eligible to earn a 2022 target incentive award represented as a percentage of base salary as set forth below.

Name	Target Incentive Award Percent
Gail McIntyre	50%
Rudy Howard	40%
Leonard Scott Dove	40%
Vinay Shah [(1)]	40%

(1) Mr. Shah resigned as our Chief Financial Officer effective June 2, 2022.

For 2022, the corporate goals primarily included clinical milestones and financing milestones. After careful review, our Compensation Committee and Board, concluded that we had achieved 105% of our corporate performance goals and therefore performance-based incentive awards were paid based upon 105% of target opportunities.

2022 Performance-Based Awards

After the end of the year, the Compensation Committee approves the extent to which the corporate goals have been achieved, based on management's review and recommendation, however, our executives do not make recommendations with respect to their own achievement. Accordingly, whether or not any incentive award is awarded is determined in the Compensation Committee's discretion. Bonuses are not earned or vested until they are awarded and paid. The Compensation Committee also considers any significant corporate events or other significant accomplishments that were not contemplated at the beginning of the performance period in determining the extent to which the strategic goals were satisfied, such as the circumstances surrounding the feasibility of a goal being achieved.

In February 2023, our Compensation Committee and Board approved the 2022 performance-based incentive awards set forth below related to 2022 performance based on the level of attainment of the 2022 specified goals.

Name	Base Salary	Target % of Base Salary	% of Target Achieved	Performance-Based Incentive Payout
Gail McIntyre	$510,000	50%	105%	$267,750
Rudy Howard	$395,000	40%	105%	$96,358
Leonard Scott Dove	$385,000	40%	105%	$126,702
Vinay Shah	$381,924	40%	0% [(1)]	$0 [(1)]

(1) Incentive awards are not earned or vested until they are awarded and paid. As the employee resigned prior to 2022 incentive awards being awarded and paid, no incentive award was earned, awarded, or paid related to the employee's employment by Aravive, Inc. during 2022.

Long-Term Incentive Compensation

Equity incentives are a key component of our executive compensation program that the Compensation Committee believes motivate executive officers to achieve our business objectives by tying incentives to the appreciation of our common stock. During 2022, we granted equity awards in the form of stock options that vest over a four-year period. Our long-term, equity-based incentive awards are designed to align the interests of our named executive officers and our other employees, non-

employee directors and consultants with the interests of our shareholders. Because vesting is based on continued service, our equity-based incentives also encourage the retention of our named executive officers through the vesting period of the awards.

We use stock options as the primary incentive vehicle for long-term compensation to our named executive officers because they are able to profit from stock options only if our stock price increases relative to the stock option's exercise price. We generally provide initial grants in connection with the commencement of employment of our named executive officers as our Compensation Committee, determines appropriate. We also provide annual grants shortly following the end of each year.

In January 2022, the Compensation Committee awarded stock option grants to our named executive officers in conjunction with the Board's review of the 2021 corporate goals. Dr. McIntyre was granted stock options to purchase 425,000 shares at an exercise price of $2.18 per share. Mr. Shah was granted stock options to purchase 175,000 shares at an exercise price of $2.18 per share.

In March 2022, Dr. Dove was granted stock options to purchase 200,000 shares at an exercise price of $1.89 per share upon his appointment as our Chief Operating Officer.

In June 2022, Mr. Howard was granted stock options to purchase 290,000 shares at an exercise price of $1.21 per share upon his appointment as our Chief Financial Officer. Upon resigning as Chief Financial Officer in June 2022 and per the terms of the separation agreement between Aravive, Inc. and Mr. Shah entered into on June 2, 2022, the vesting of Mr. Shah's outstanding options to purchase a total of 403,207 shares was accelerated such that all such awards were fully vested on June 2, 2022.

In January 2023, the Compensation Committee approved and in February 2023, the Board awarded stock option grants to our named executive officers in conjunction with the Board's review of the 2022 corporate goals. Dr. McIntyre was granted stock options to purchase 700,000 shares at an exercise price of $1.67 per share. Mr. Howard and Dr. Dove were each granted stock options to purchase 400,000 shares at an exercise price of $1.67 per share.

Other Compensation

Employee Benefit Plans

Our named executive officers are eligible to participate in our employee benefit plans, including our medical, dental, vision, group life and accidental death and dismemberment insurance plans, in each case, on the same basis as all of our other employees. We maintain a 401(k) plan for the benefit of our eligible employees, including our named executive officers, as discussed in the section below entitled "401(k) plan."

401(k) Plan

All of our employees, including our named executive officers, are eligible to participate in our 401(k) Plan, which is a retirement savings defined contribution plan established in accordance with Section 401(a) of the Internal Revenue Code of 1986, as amended ("Code"). Pursuant to our 401(k) Plan, employees may elect to defer their eligible compensation into the plan on a pre-tax basis, up to the statutorily prescribed annual limit of $19,500 in 2022 (additional salary deferrals not to exceed $6,500 are available to those employees 50 years of age or older) and to have the amount of this reduction contributed to our 401(k) Plan. In general, eligible compensation for purposes of the 401(k) plan includes an employee's wages, salaries, fees for professional services and other amounts received for personal services actually rendered in the course of employment with us, to the extent the amounts are included in gross income, and subject to certain adjustments and exclusions required under the Code. The 401(k) Plan currently does not offer the ability to invest in our securities.

None of our named executive officers participate in or have account balances in qualified or non-qualified defined benefit plans, non-qualified defined contribution plans or pension plans sponsored by us.

Pension Benefits

We do not maintain any pension benefit plans.

Nonqualified Deferred Compensation

We do not maintain any nonqualified deferred compensation plans.

Employment Offer Letters, Severance and Change in Control Arrangements

We have entered into employment offer letters with each of our named executive officers. The offer letters set forth the terms and conditions of employment, including the initial annual base salary, target bonus opportunity, equity compensation, severance benefits and eligibility to participate in our employee benefit plans and programs. There are no ongoing guarantees of increases to future compensation such as base salary increases. The offer letters are for an indefinite period of time and may be terminated by either party with or without cause and without advance notice. Our named executive officers were each required to execute our standard proprietary information and inventions agreement. The material terms of these employment offer letters are summarized below. These summaries are qualified in their entirety by reference to the actual text of the offer letters, which are filed as exhibits.

Gail McIntyre

Effective as of April 8, 2020, upon her appointment as our Chief Executive Officer, we entered into an amendment (the "2020 Amendment") to the employment offer letter with Dr. McIntyre ("the McIntyre Offer Letter") that superseded the offer letter with Aravive Biologics that had been entered into in 2017 and amended in 2019 and 2020. The 2020 Amendment provided among other things that Dr. McIntyre will serve as our President and Chief Executive Officer. The 2020 Amendment, which was amended again in January 2021, January 2022 and February 2023 provided, among other things, (i) for an annual base salary of $415,000 for such service, which was increased to $$500,000 in January 2021, $510,000 in January 2022 and $560,000 in February 2023; (iii) a target bonus equal to 45% of Dr. McIntyre's annual base salary, which was increased to 50% in January 2021; (iv) up to 12 months of salary continuation and reimbursement of COBRA coverage and a pro-rated portion of her year-end target bonus contingent upon corporate goals being met, if terminated for any reason other than Cause or Permanent Disability (as such terms are defined in the Offer Letter) and not in connection with a Change in Control (as such term is defined in the Offer Letter). Dr. McIntyre was also granted an option to purchase 80,000 shares of common stock vesting pro rata on a monthly basis over a four-year period.

On January 24, 2022, Dr. McIntyre was also granted an option to purchase 425,000 shares of our common stock with an exercise price of $2.18 per share and vesting pro rata on a monthly basis over a four- year period. In February 2023, Dr. McIntyre was also granted an option to purchase 700,000 shares of our common stock with an exercise price of $1.67 per share and vesting over a three year period with 50% with 50% vesting on the one-year anniversary of the date of grant and the remaining 50% vesting on a pro rata basis on a monthly basis over a two-year period commencing on the month following the one-year anniversary of the grant date.

Rudy Howard

Pursuant to the terms of an Offer Letter, dated June 2, 2022, that we entered into with Mr. Howard (the "Howard Offer Letter"), Mr. Howard's compensation for serving as our Chief Financial Officer includes: (i) an annual base salary of $395,000, which was increased to $412,775 in February 2023; (ii) an annual discretionary bonus targeted at 40% of his base salary, dependent on our achievement of objective and subjective criteria established by the Company's Executive Chairman and approved by our Board; (iii) an option to purchase 290,000 shares of our common stock; and (iv) eligibility to participate in a number of Company-sponsored benefits, including its medical, dental and 401(k) plans, under the terms and conditions of the benefit plans that may be in effect from time to time. The stock options will have an exercise price equal to the fair market value of the Common Stock on the date of the grant, expire ten years after the date of the grant and will vest as follows: 25% of the shares subject to the options will vest twelve months after the date of the grant, and the remaining 75% of the shares subject to the options will vest in equal monthly installments over the next 36 months following the one-year anniversary of the date of grant, subject to Mr. Howard's continued service to the Company. All compensation offered to Mr. Howard is subject to applicable tax withholdings. In February 2023, Mr. Howard was also granted an option to purchase 400,000 shares of our common stock with an exercise price of $1.67 per share and vesting over a three year period with 50% with 50% vesting on the one-year anniversary of the date of grant and the remaining 50% vesting on a pro rata basis on a monthly basis over a two-year period commencing on the month following the one-year anniversary of the grant date.

If terminated for any reason other than Cause or Permanent Disability and not in connection with a Change in Control (each as defined in the Offer Letter), Mr. Howard will be eligible for certain severance benefits, including the following: (i) up to 12 months of base salary continuation; (ii) reimbursement of COBRA coverage; (iii) 12 months accelerated vesting of the stock options award to Mr. Howard and (iv) up to 12 months post-termination to exercise any vested shares subject to such stock options.

If terminated in connection with a Change in Control, severance benefits will be those specified under our 2019 Equity Incentive Plan and the Company's Change in Control Severance Plan), which provides specified severance benefits to certain eligible officers and employees of the Company. In addition, if during the twelve-month period commencing on the closing

date of a Change in Control we terminate his employment for any reason other than Cause or Permanent Disability, all unvested equity awards will immediately vest, subject to certain restrictions. In addition, under the 2019 Equity Incentive Plan, if Mr. Howard is voluntarily terminated in connection with certain corporate transactions, including a Change in Control, Mr. Howard will be eligible for full accelerated vesting of his outstanding stock options.

Scott Dove

Pursuant to the terms of an offer letter that we entered with Dr. Dove, which was effective as of March 21, 2022 (the "Dove Offer Letter"), Dr. Dove's compensation for services provided as our Chief Operating Officer includes: (i) an annual base salary of $385,000, which was increased in February 2023 to $405,000; (ii) eligibility to be considered for an annual discretionary incentive and retention bonus targeted at 40% of his annual base salary (pro-rated for the number of days worked in 2022), dependent on performance with respect to both corporate and individual goals, as determined by the Company's Board of Directors; and (iii) an option to purchase 200,000 shares of our common stock. The stock options granted have an exercise price equal to the fair market value of the Common Stock on the date of the grant, expire ten years after the date of the grant and will vest as follows: 25% of the shares subject to the options will vest twelve months after the date of the grant, and the remaining 75% of the shares subject to the options will vest in equal monthly installments over the next 36 months following the one-year anniversary of the date of grant, subject to Dr. Dove's continued service to us. All compensation offered to Dr. Dove is subject to applicable tax withholdings. The Dove Offer Letter also contains an Employee Confidential Information and Inventions Assignment Agreement. In February 2023, Mr. Howard was also granted an option to purchase 400,000 shares of our common stock with an exercise price of $1.67 per share and vesting over a three year period with 50% with 50% vesting on the one-year anniversary of the date of grant and the remaining 50% vesting on a pro rata basis on a monthly basis over a two-year period commencing on the month following the one-year anniversary of the grant date.

If terminated in connection with a Change in Control, severance benefits will be those specified under our 2019 Equity Incentive Plan and the Company's Change in Control Severance Plan, which provides specified severance benefits to certain eligible officers and employees of the Company. In addition, if during the twelve-month period commencing on the closing date of a Change in Control we terminate his employment for any reason other than Cause or Permanent Disability, all unvested equity awards will immediately vest, subject to certain restrictions. In addition, under the 2019 Equity Incentive Plan, if Mr. Howard is voluntarily terminated in connection with certain corporate transactions, including a Change in Control, Mr. Howard will be eligible for full accelerated vesting of his outstanding stock options.

Vinay Shah

During the years ended December 31, 2018 and 2019, Mr. Shah's employment was at-will per the terms of an offer letter with Aravive Biologics dated February 1, 2017 as later amended on May 30, 2018 and February 6, 2019 pursuant to which he was entitled to receive an annual base salary of $335,000 for 2019, an annual target bonus of 40% of his base salary and six months' salary as severance in the event of certain terminations.

On March 26, 2020, we entered into an employment offer letter with Mr. Shah or the Shah Offer Letter that superseded the offer letter with Aravive Biologics and provides that Mr. Shah will serve as our Chief Financial Officer basis with compensation that included a base salary of $360,000, which was increased to $370,800 in January 2021 and further increased to $381,924 in January 2022 and a target bonus equal to 40% of Mr. Shah's annual base salary. In addition, the Shah Offer Letter provides for severance payments upon certain conditions if we terminate his employment for any reason other than cause or permanent disability, and not in connection with a change in control and that upon a qualifying termination of employment in connection with a change of control, he would be entitled to certain severance payments and benefits, which are described below under "—Potential payments upon termination or change in control."

Mr. Shah resigned as our Chief financial Officer effective June 2, 2022. On June 2, 2022, we entered into a consulting agreement (the "Consulting Agreement") with Mr. Shah pursuant to which he has agreed to provide consulting services to us from time to time. The Consulting Agreement has a term of four months unless sooner terminated. Mr. Shah may terminate the Consulting Agreement without cause at any time upon thirty (30) days' prior written notice to Company. Either party may terminate the Consulting Agreement immediately in the event that the other party has materially breached the Consulting Agreement.

As compensation, the Company agreed to (i) make a cash payment of $44,557 payable on a monthly basis during the four-month consulting period; and (ii) reimburse all COBRA payments made by Mr. Shah for the benefits continuation during the consulting period.

Mr. Shah also entered into a separation agreement and release with the Company (the "Separation Agreement") providing for (i) the payment to him of a total of $286,443 at the rate of $31,827 per month, less applicable withholding, for nine

(9) months from the Company's first regular payroll date following the date that is four months following the Effective Date (as defined in the Separation Agreement); (ii) reimbursement of COBRA payments for the lesser of (A) twelve (12) months commencing on the later of June 2, 2022 (the "Separation Date") and four months from the date of the Consulting Agreement, or (B) until Mr. Shah commences new employment or substantial self-employment; (iii) the acceleration of the vesting of all shares subject to option awards such that all shares subject to the option awards will be vested; (iv) the extension of the period of time for which Mr. Shah has the right to exercise any vested shares until the earlier of (A) the expiration date of the options, (B) the tenth anniversary of the date of grant of the option, (C) thirty-six (36) months from the Separation Date; or (D) the occurrence of a Change in Control (as defined in the Company's 2019 Equity Incentive Plan) unless assumed in a Change of Control transaction. The Separation Agreement also contains a non-disparagement obligation on both parties and a standard release of claims on the part of Mr. Shah.

POTENTIAL PAYMENTS UPON TERMINATION OR CHANGE IN CONTROL

Severance Benefits Other Than in Connection With a Change in Control

The McIntyre Offer Letter provide that if we terminate any of their employment for any reason other than Cause or Permanent Disability (as defined in the Offer Letters), and not in connection with a change in control, if they (i) execute and do not revoke a release of claims within 60 days following the date of termination of employment with us and (ii) returns all of our property in his or her possession he or she will be entitled to (a) twelve months for Dr. McIntyre of salary continuation payments (b) if he or she timely elects to continue her health insurance coverage under COBRA, we will pay a portion of him or her monthly COBRA premiums (at the same rate that we pay for active employees) for up to twelve months following the date he or she terminates employment with us (c) 12 months accelerated vesting of stock options and RSUs awarded to him or her and (d) up to 9 months post-termination to exercise any vested shares subject to such option. Mr. Howard's Offer Letter provides that if he is terminated for any reason other than Cause or Permanent Disability and not in connection with a Change in Control (each as defined in the Howard Offer Letter), Mr. Howard will be eligible for certain severance benefits, including the following: (i) up to 12 months of base salary continuation; (ii) reimbursement of COBRA coverage; (iii) 12 months accelerated vesting of the stock options award to Mr. Howard and (iv) up to 12 months post-termination to exercise any vested shares subject to such stock options.

In addition, if terminated in connection with a change of control, severance benefits will be those specified under our 2019 Equity Incentive Plan and our Change in Control Severance Plan, which provides for specified severance benefits to certain eligible officers and employees of our company set forth below. In addition, if during the twelve-month period commencing on the closing date of a Change in Control we terminate his or her employment for any reason other than Cause or death or disability or he or she resigns for Good Reason, all unvested equity awards will immediately vest, subject to certain restriction. In addition, under the 2019 Equity Incentive Plan, if involuntarily terminated in connection with certain corporate transactions, including a change in control, Dr. McIntyre, Mr. Howard and Dr. Dove would be eligible for full accelerated vesting of her outstanding stock options and RSUs.

Change in Control Severance Benefit Plan

We have adopted a change in control severance benefit plan (the "severance plan"). The severance plan provides certain of our employees, including our currently employed Named Executive Officers, with severance payments and benefits upon certain qualifying terminations of employment within a one-year period following the closing of a change in control, as defined in the severance plan. The summary below is qualified by reference to the actual text of the severance plan, which is filed as an exhibit to the Form S-1, as amended, filed with the SEC on March 10, 2014.

Under the severance plan, in the event of a participant's involuntary termination without cause (and not due to death or disability) or if a participant resigns for good reason (as each terms is defined in the severance plan), if the participant in the severance plan (i) executes and does not revoke a release of claims within 60 days following the date he terminates employment with us and (ii) returns all of our property in his possession, he will be entitled to cash severance equal to the sum of his or her monthly base salary and monthly annual bonus target, multiplied by a severance multiplier, which is 15 in the case of the Chief Executive Officer and 12 in the case of the other C-Suite employees (which includes our named executive officers). In addition, following a qualifying termination, if a participant timely elects to continue his health insurance coverage under COBRA, we will pay a portion of his monthly COBRA premiums for a period of specified months following the date of termination.

All stock awards which are vested and exercisable as of the date of a qualifying termination under the severance plan (including by virtue of the provisions of the applicable equity plan) will remain outstanding and exercisable until the earliest to occur of (i) the last day of the applicable severance period, which is 15 months in the case of the Chief Executive Officer and 12 months in the case of the other C-Suite employees (ii) the expiration of the original term of such stock awards.

If one of our named executive officers is entitled to severance benefits under the severance plan by virtue of a qualifying termination of employment within 12 months following a change in control, he would not be entitled to severance benefits under the terms of his or her offer letter.

In addition, the severance plan provides that, except as otherwise expressly provided in an agreement between us and a participant, if any payment or benefit a participant would receive in connection with a change in control would constitute a "parachute payment" within the meaning of Section 280G of the Internal Revenue Code and such payment or benefit would be subject to the excise tax imposed by Section 4999 of the Internal Revenue Code, then such payment or benefit will be equal to either (i) the largest portion of the change in control payment that would result in no portion of the payment or benefit being subject to the excise tax, or (ii) the largest portion, up to and including the total payment or benefit, whichever amount, after taking into account all applicable taxes, including the excise tax (all computed at the highest applicable marginal rate), would result in the participant's receipt, on an after-tax basis, of the greatest economic benefit to the participant, notwithstanding that all or some portion of the payment or benefit may be subject to the excise tax. If a reduction is so required, the reduction will occur in the order specified in the severance plan.

OUTSTANDING EQUITY AWARDS AT FISCAL YEAR END

The following table shows for the fiscal year ended December 31, 2022, certain information regarding outstanding equity awards at fiscal year-end for the Named Executive Officers. Each award issued to Dr. McIntyre, Mr. Howard, Dr. Dove, and Mr. Shah, set forth below is subject to accelerated vesting upon a qualifying termination of his employment, as described under "—Potential Payments Upon Termination or Change in Control." Mr. Shah resigned from his position as our Chief Financial Officer, effective June 2, 2022.

OUTSTANDING EQUITY AWARDS AT DECEMBER 31, 2022

		Option Awards [1]			
Name	Grant Date	Number of Securities Underlying Unexercised options (#) exercisable	Number of Securities Underlying Unexercised options (#) unexercisable	Option Exercise Price ($)	Option Expiration Date
Gail McIntyre	6/15/2017 (3)	29,641	—	$ 0.66	6/14/2027
	12/14/2017 (3)	14,820	—	$ 0.90	12/13/2027
	3/20/2018 (3)	14,820	—	$ 0.90	3/19/2028
	2/28/2019 (2)	50,791	2,209	$ 5.83	2/27/2029
	1/22/2020 (2)	35,425	13,158	$ 10.84	1/21/2030
	4/8/2020 (2)	53,333	26,667	$ 6.16	4/7/2030
	1/25/2021 (2)	79,062	85,938	$ 5.95	1/24/2031
	1/24/2022 (2)	97,395	327,605	$ 2.18	1/23/2032
Rudy Howard	6/3/2022 (4)	—	290,000	$ 1.21	6/2/2032
Leonard Scott Dove	3/21/2022 (4)	—	200,000	$ 1.89	3/20/2032
Vinay Shah	10/01/2014 (5)	19,380		$ 0.24	9/30/2024
	6/15/2017 (5)	38,001		$ 0.66	6/1/2025
	12/14/2017 (5)	19,000		$ 0.90	6/1/2025
	3/20/2018 (5)	19,000		$ 0.90	6/1/2025
	2/28/2019 (5)	38,000		$ 5.83	6/1/2025
	1/22/2020 (5)	34,826		$ 10.84	6/1/2025
	1/25/2021 (5)	60,000		$ 5.95	6/1/2025
	1/24/2022 (5)	175,000		$ 2.18	6/1/2025

(1) Except as otherwise indicated, vesting of all options is subject to continued service on the applicable vesting date.
(2) 1/48th of the shares subject to the option become exercisable monthly measured from the date of the grant.
(3) The shares subject to these options vested in full upon the closing of the Merger and were assumed by us in the Merger.
(4) The shares subject to the stock options vest over a four-year period as follows: 25% of the shares underlying the options vest on the one-year anniversary of the vesting start date, and thereafter 1/48th of the shares vest each month.
(5) All options are fully vested. Options unvested on June 2, 2022 were modified on 6/2/2022 to immediately vest on the Separation date and for these options the right to exercise the options was extended until the earlier of (a) the expiration of the options, (b) the tenth anniversary of the date of grant of the option (c) thirty-six months from the Separation date; or (d) the occurrence of a Change in Control (as defined in the Company' 2019 Equity Incentive Plan) unless assumed in a Change of Control transaction.

Treatment of stock awards under the 2019 Plan

The 2019 Plan, provides that in the event of certain corporate transactions, as defined in the 2019 Plan, the following provisions will apply to outstanding stock awards, unless otherwise provided in a stock award agreement or any other written agreement between us and a participant, or unless otherwise expressly provided by the board of directors at the time of grant of a stock award:

The surviving or acquiring corporation (or its parent) may assume, continue or substitute similar stock awards for outstanding stock awards under the 2019 Plan and any reacquisition or repurchase rights held by us may be assigned to the surviving or acquiring corporation (or its parent);

To the extent that outstanding stock awards are not so assumed, continued or substituted, the vesting and, if applicable, exercisability of any such stock awards held by participants whose continuous service has not terminated prior to the effective time of the corporate transaction will be accelerated in full to a date prior to the effective time of such corporate transaction (contingent upon the effectiveness of the corporate transaction), and such stock awards will terminate if not exercised (if applicable) at or prior to the effective time of such corporation transaction, and any reacquisition or repurchase rights held by us will lapse, contingent upon the effectiveness of such corporate transaction;

To the extent that outstanding stock awards are not so assumed, continued or substituted, the vesting and, if applicable, exercisability of any such stock awards held by participants whose continuous service has terminated prior to the effective time of the corporate transaction will not be accelerated and all unvested stock awards held by such participants will terminate if not exercised (if applicable) prior to the effective time of the corporate transaction, but any reacquisition or repurchase rights held by us may continue to be exercised notwithstanding such corporate transaction; or

To the extent a stock award will terminate if not exercised prior to the effective time of a corporate transaction, the board of directors may provide that the holder of the stock award may not exercise the stock award, but instead will receive a payment, in such form as may be determined by the board of directors, equal in value to the excess, if any, of the value of the property the participant would have received upon exercise of the stock award over any exercise price payable by such holder in connection with such exercise. In addition, any escrow, holdback, earn out or similar provisions in the definitive agreement for the corporate transaction may apply to such payment to the same extent and in the same manner as such provisions apply to the holders of common stock.

A stock award may be subject to additional acceleration of vesting and exercisability upon or after a change in control, as defined in the 2019 Plan, as may be provided in the stock award agreement for such stock award or in any other written agreement between us and a participant, but in the absence of such a provision, no such acceleration will occur.

For purposes of the 2019 Plan, a corporate transaction is generally the consummation of: (1) a sale of all or substantially all of our assets, (2) the sale or disposition of more than 50% of our outstanding securities, (3) a merger or consolidation where we do not survive the transaction, or (4) a merger or consolidation where we do survive the transaction but the shares of our common stock outstanding immediately before such transaction are converted or exchanged into other property by virtue of the transaction.

Treatment of stock awards under the 2014 Plan

The 2014 Plan, provides that in the event of certain corporate transactions, as defined in the 2014 Plan, the following provisions will apply to outstanding stock awards, unless otherwise provided in a stock award agreement or any other written agreement between us and a participant, or unless otherwise expressly provided by the board of directors at the time of grant of a stock award:

The surviving or acquiring corporation (or its parent) may assume, continue or substitute similar stock awards for outstanding stock awards under the 2014 Plan and any reacquisition or repurchase rights held by us may be assigned to the surviving or acquiring corporation (or its parent); provided, that if any such stock awards are so assumed, continued or substituted, if a participant incurs an involuntary termination on or within 12 months following the date of such corporate transaction, any unvested shares subject to such assumed, continued or substituted stock awards will vest in full as of the date of such termination;

To the extent that outstanding stock awards are not so assumed, continued or substituted, the vesting and, if applicable, exercisability of any such stock awards held by participants whose continuous service has not terminated prior to the effective time of the corporate transaction will be accelerated in full to a date prior to the effective time of such corporate transaction, and such stock awards will terminate if not exercised (if applicable) at or prior to the effective time of such corporation transaction, and any reacquisition or repurchase rights held by us will lapse, contingent upon the effectiveness of such corporate transaction;

To the extent that outstanding stock awards are not so assumed, continued or substituted, the vesting and, if applicable, exercisability of any such stock awards held by participants whose continuous service has terminated prior to the effective time of the corporate transaction will not be accelerated and all unvested stock awards held by such participants will terminate if not exercised (if applicable) prior to the effective time of the corporate transaction, but any reacquisition or repurchase rights held by us may continue to be exercised notwithstanding such corporate transaction; or

To the extent a stock award will terminate if not exercised prior to the effective time of a corporate transaction, the board of directors may provide that the holder of the stock award may not exercise the stock award, but instead will receive a payment, in such form as may be determined by the board of directors, equal in value to the excess, if any, of the value of the property the participant would have received upon exercise of the stock award over any exercise price payable by such holder in connection with such exercise.

A stock award may be subject to additional acceleration of vesting and exercisability upon or after a change in control, as defined in the 2014 Plan, as may be provided in the stock award agreement for such stock award or in any other written agreement between us and a participant, but in the absence of such a provision, no such acceleration will occur.

For purposes of the 2014 Plan, an involuntary termination generally means, during the 12 months following the closing of a corporate transaction or change in control, either (i) a termination of service other than for cause (as defined in the 2014 Plan) or (ii) a voluntary resignation following: a material diminution in the participant's base salary; a material diminution in the participant's authority, duties, position or responsibilities; a material diminution in the authority, duties, position or responsibilities of the participant's supervisor (including a requirement that a participant report to a corporate officer or employee instead of directly to the board of directors); a material diminution in the budget over which the participant retains authority; a relocation of the participant's principal place of work to a location more than 50 miles away from the principal place of work prior to the consummation of a corporate transaction or a change in control; or any other act or omission that constitutes a material breach by us of the 2014 Plan.

Treatment of stock options under the Aravive Biologics, Inc 2010 and 2017 Equity Incentive Plans

In connection with the Merger, we assumed the Aravive Biologics, Inc. 2010 and 2017 Equity Incentive Plans. The Aravive Biologics, Inc. 2010 and 2017 Equity Incentive Plans provide that in the event of certain corporate transactions, as defined in the plans, the board of directors may take one or more of the following actions with respect to outstanding stock awards, unless otherwise provided in a stock award agreement or any other written agreement between us and a participant, or unless otherwise expressly provided by the board of directors at the time of grant of a stock award: each outstanding stock award may be assumed or continued or an equivalent stock award may be substituted by a successor corporation and any reacquisition or repurchase rights held by us in respect of common stock issued pursuant to prior stock awards may be assigned to the successor corporation. The plans also provide that in the event of a specified corporate transaction the board of directors may determine to accelerate the vesting, in whole or in part of a stock award, with such stock award becoming fully vested and exercisable prior to the corporate transaction arrange for the lapse of any reacquisition or repurchase rights held by us with respect to the stock award or cancel or arrange for the cancellation of a stock award in exchange for cash consideration. Any awards that have not been assumed, continued, substituted, or exercised prior to the corporate transaction will terminate at the closing of the transaction. All options issued under the Aravive Biologics, Inc 2010 and 2017 Equity Plans that were outstanding on the closing of the Merger vested upon the closing of the Merger.

DIRECTOR COMPENSATION

The board of directors reviews the compensation of our non-employee directors from time to time to ensure that the amount and form of such compensation reflects the practices of the competitive market. In January 2020, the board of directors evaluated a competitive market analysis prepared by the Compensation Committee's compensation consultant, Korn Ferry, which assessed our then-current director compensation policy. This analysis examined how our director compensation levels, practices, and design features compared to the constituent members of our compensation peer group, which was the same peer group that the Compensation Committee used as a reference when setting executive compensation. Based on this analysis, as well as its consideration of our financial performance, general market conditions, and the interests of our stockholders, the board of directors determined at that time to maintain our non-employee director compensation policy at its then-current cash and equity compensation levels. These compensation levels were maintained until September 2020 when the board of directors evaluated a competitive market analysis prepared by the Compensation Committee's compensation consultant, Korn Ferry, which assessed our then-current director compensation policy. In September 2020, the committee annual fees remained the same, the non-executive annual cash compensation was increased from $40,000 to $65,000, the cap for total compensation to be received by the chairperson was increased from $70,000 to $95,000, and the annual equity awards and new director awards were revised from a grant of an option to purchase 7,500 shares of common stock to a grant of an option to purchase shares of common stock having a grant date fair market value of $75,000. The fees remained the same for 2021 and 2022.

The following table shows for the fiscal year ended December 31, 2022 certain information with respect to the compensation of all of our current and former non-employee directors:

DIRECTOR COMPENSATION FOR FISCAL YEAR 2022

Name	Fees Earned or Paid in Cash ($)	Option Awards ($) (1)	Restricted Stock Awards ($)	Total ($)
Fredric N. Eshelman, Pharm. D. [2]	$ 95,000	$ 75,000	—	$ 170,000
Amato Giaccia, Ph.D.	$ 87,500	$ 75,000	—	$ 162,500
Michael W. Rogers [3]	$ 92,500	$ 75,000	—	$ 167,500
Eric Zhang	$ 72,500	$ 75,000	—	$ 147,500
John A. Hohneker, M.D. (4)	$ 70,000	$ 75,000	—	$ 145,000
Peter T.C. Ho, M.D., Ph.D. (4)	$ 68,500	$ 75,000	—	$ 143,500
Sigurd C. Kirk [4]	$ 72,500	$ 75,000	—	$ 147,500

(1) In accordance with SEC rules, this column reflects the aggregate fair value of the option awards granted during the respective fiscal year computed as of their respective grant dates in accordance with Financial Accounting Standard Board Accounting Standards Codification Topic 718 for stock-based compensation transactions (ASC 718). The valuation assumptions used in determining such amounts are described in Note 2 and Note 9 to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K.
(2) Dr. Eshelman was appointed Chairman of the Board on April 8, 2020 until his appointment as Executive Chairman of the Board on January 3, 2022.
(3) Mr. Rogers was appointed as a director on September 15, 2020.
(4) Dr. Hohneker, Dr Ho and Mr. Kirk were appointed directors on May 12, 2021.

The table below shows the aggregate number of option awards outstanding at fiscal year-end for each of our current and former non-employee directors.

Name	Number of Shares Subject to Outstanding Options as of December 31, 2022
Fredric Eshelman, Pharm. D. [1]	146,630
Amato Giaccia, Ph.D. (2)	312,626
Michael Rogers [3]	149,886
Eric Zhang	155,592
John A. Hohneker, M.D. (4)	140,555
Peter T.C. Ho, M.D., Ph.D. (4)	140,555
Sigurd C. Kirk [4]	140,555

(1) Dr. Eshelman was appointed Chairman of the Board on April 8, 2020 until his appointment as Executive Chairman of the Board on January 3, 2022.
(2) Amounts in the director compensation table above for Dr. Giaccia include options assumed by us in the Merger that were issued by Aravive Biologics prior to the Merger.
(3) Mr. Rogers was appointed as a director on September 15, 2020.
(4) Dr. Hohneker, Dr. Ho and Mr. Kirk were appointed directors on May 12, 2021.

NON-EMPLOYEE DIRECTOR COMPENSATION POLICY

Under our non-employee director compensation policy in effect during the year ended December 31, 2022, we paid each of our non-employee directors a cash retainer for service on the board of directors and for service on each committee on which the director is a member. The chairman of each committee receives an additional retainer for such service. These retainers are payable in arrears in four equal quarterly installments on the last day of each quarter, provided that the amount of such payment will be prorated for any portion of such quarter that the director is not serving on the board of directors.

The retainers paid to non-employee directors for service on the board of directors and for service on each committee of the board of directors on which the director was a member for the year ended December 31, 2022 are as follows:

	Member Annual Service Retainer	Chairman Annual Service Retainer
Board	$ 65,000	$ 30,000
Audit Committee	$ 7,500	$ 15,000
Compensation Committee	$ 5,000	$ 12,500
Nominating and Corporate Governance Committee	$ 3,500	$ 10,000

The board of directors reviews the compensation of our non-employee directors from time to time to ensure that the amount and form of such compensation reflects the practices of the competitive market. In September 2020, the board of directors evaluated a competitive market analysis prepared by the Compensation Committee's compensation consultant, Korn Ferry, which assessed our then-current director compensation policy. This analysis examined how our director compensation levels, practices, and design features compared to the constituent members of our compensation peer group, which is the same peer group that we use as a reference when setting executive compensation. Based on this analysis, as well as its consideration of our financial performance, general market conditions, and the interests of our stockholders, the board of directors determined to to provide the cash compensation set forth above and the equity compensation described below.

On the date of each annual meeting of stockholders held, each non-employee director that continues to serve as a non-employee member on the board of directors will receive options to acquire shares of common stock having a fair value on the grant date of $75,000, vesting 1/12th per month with full vesting, if not fully vested at such time, on the date of our next annual meeting of stockholder. The exercise price of such options will equal the fair market value of our common stock on the date of grant. All new non-employee directors are also awarded a new non-employee director award of options to acquire shares of common stock having a fair value on the grant date of $75,000, vesting monthly over 36 months. For any new non-employee director who joins the board of director at a time other than at the annual stockholder meeting, then, in addition to the new non-employee director grants, such directors will receive an option to purchase shares of common stock, such number of shares of common stock equity equal to the product of the (i) number of shares of common stock having a grant date fair value of $75,000 and (ii) a fraction with (x) a numerator equal to the number of days between the date of the director's initial election or appointment to the board of directors and the date which is the first anniversary of the date of the most recent annual stockholder meeting occurring before the director is elected or appointed to the board of directors, and (y) a denominator equal to 365. In each case, vesting of the award is subject to the director's continuous service on each vesting date. This policy is intended to provide a total compensation package that enables us to attract and retain qualified and experienced individuals to serve as directors and to align our directors' interests with those of our stockholders in accordance with the terms of the policy. On September 23, 2022 we issued an option to each of Dr. Eshelman, Dr. Giaccia, Mr. Rogers, Mr. Zhang, Dr. Ho, Dr. Hohneker and Mr. Kirk to purchase 97,063 shares of our common stock.

Directors have been and will continue to be reimbursed for expenses directly related to their activities as directors, including attendance at board and committee meetings. Directors are also entitled to the protection provided by their indemnification agreements and the indemnification provisions in our certificate of incorporation and bylaws.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth certain information regarding the beneficial ownership of our common stock as of March 10, 2023 by: (i) each director; (ii) each of the executive officers named in the Summary Compensation Table; (iii) all executive officers and directors of the Company as a group; and (iv) all those known by us to be beneficial owners of more than five percent of its common stock.

	Beneficial Ownership (1)	
Beneficial Owner	**Number of Shares**	**Percent of Total**
Greater than 5% stockholders other than executive officers and directors:		
Eshelman Ventures, LLC (2)	42,684,225	55.43%
Invus Public Equities, L.P and its affiliated entities (3)	6,132,553	9.99%
Entities affiliated with BVF Partners (4)	3,908,320	6.4%
Entities affiliated with Baker Bros. Advisors, L.P. (5)	4,586,404	7.5%
Named Executive officers and directors:		
Fredric N. Eshelman, Pharm. D. (6)	42,790,412	55.49%
Amato Giaccia, Ph.D. (7)	1,757,599	2.9%
Michael W. Rogers (8)	107,361	*
Eric Zhang (9)	2,061,989	3.4%
Rudy Howard (10)	21,740	*
Gail McIntyre (11)	558,887	*
Robert B. Geller (12)	—	*
Leonard Scott Dove (13)	54,166	*
Peter T.C. Ho, M.D., Ph.D. (14)	204,673	*
John A. Hohneker, M.D. (15)	94,967	*
Sigurd C. Kirk (16)	94,967	*
Vinay Shah (17)	594,049	1.0%
All current executive officers and directors as a group (11 persons) (18)	47,746,761	60.2%

* Represents beneficial ownership of less than one percent (1%) of the outstanding common stock.

(1) This table is based upon information supplied by officers, directors and principal stockholders and Schedules 13D and 13G filed with the SEC. Unless otherwise indicated in the footnotes to this table and subject to community property laws where applicable, we believe that each of the stockholders named in this table has sole voting and investment power with respect to the shares indicated as beneficially owned. Applicable percentages are based on 59,844,850 shares outstanding on March 10, 2023, adjusted as required by rules promulgated by the SEC. Beneficial ownership of shares is determined in accordance with the rules of the SEC and includes voting and investment power with respect to the shares. Shares of common stock subject to outstanding options that are exercisable within 60 days of March 10, 2023 are deemed outstanding for computing the percentage of ownership of the person holding such options. Shares of Common Stock issuable upon exercise of the Warrants issued in the Private Placement and other financing are deemed outstanding for computing the percentage of ownership of the person holding such Warrants. Unless otherwise indicated, the address of each beneficial owner listed in the table below is c/o Aravive, Inc., River Oaks Tower, 3730 Kirby Drive, Suite 1200, Houston, Texas 77098.

(2) Information for Eshelman Ventures, LLC is based upon a Schedule 13D/A filed with the SEC on November 3, 2022. Consists of: (i) 25,517,889 shares of Common Stock directly held by Eshelman Ventures, LLC, an entity wholly owned by Dr. Eshelman; (ii) 860,216 shares of Common Stock issuable upon exercise of the March Warrants 2; and (iii) 16,306,120 shares of Common Stock issuable upon exercise of the October Warrants. The address for Eshelman Ventures, LLC is 319 North 3rd Street, Suite 301, Wilmington, North Carolina 28401.

(3) Information is based upon a Schedule 13G/A filed with the SEC on February 13, 2023 by Invus Public Equities, L.P ("Invus Public Equities"), Invus Public Equities Advisors, LLC ("Invus PE Advisors"), Artal International S.C.A ("Artal International"), Artal International Management S.A. ("Artal International Management"), Artal Group S.A. ("Artal Group"), Westend S.A.("Westend"), Stichting Administratiekabntoor Westland ("Stichting")and Mr. Amaury Wittouck ("Wittouck"). Invus Public Equities directly holds 4,572,515 shares of Common Stock and October Warrants to purchase an additional 7,609,522 shares of common stock, subject to a 9.99% beneficial ownership limitation in the warrants. As a result, as of December 31, 2022, Invus Public Equities and its affiliated entities listed above beneficially owned an aggregate of 6,132,553 shares of Common Stock, consisting of (i) 4,572,515 shares of Common Stock and (ii) 1,560,038 shares of Common Stock issuable upon exercise of certain of the October Warrants. Invus PE Advisors, as the general partner of Invus Public Equities, controls Invus Public Equities and accordingly may be deemed to beneficially own the shares of Common Stock held by Invus Public Equities. The Geneva branch of Artal International, as the managing partner of Invus PE Advisors, controls Invus PE Advisors and, accordingly, may be deemed to beneficially own the shares of Common Stock that Invus PE Advisors Artal International Management, as the managing partner of Artal International, controls Artal International and, accordingly, may be deemed to beneficially own the shares of Common Stock that Artal International may be deemed to beneficially own. Artal Group, as the sole stockholder of Artal International Management, controls Artal International Management and, accordingly, may be deemed to beneficially own the shares of Common Stock that Artal International Management may be deemed to beneficially own. Westend, as the parent company of Artal Group, controls Artal Group and, accordingly, may be deemed to beneficially own the shares of Common Stock that Artal Group may be deemed to beneficially own. The Stichting, as majority shareholder of Westend, controls Westend and, accordingly, may be deemed to beneficially own the shares of common stock that Westend may be deemed to beneficially own. Mr. Wittouck, as the sole member of the board of the Stichting, controls the Stichting and, accordingly, may be deemed to beneficially own the shares of common stock that the Stichting may be deemed to beneficially own. The address for Invus Public Equities and Invus PE Advisors is 750 Lexington Avenue, 30th Floor, New York, New York 10022. The address for Artal International, Artal International Management and Artal Group, Westend is Valley Park, 44, Rue de la Vallée, L-2661, Luxembourg. The address for Stichting is Claude Debussylaan, 46, 1082 MD Amsterdam, The Netherlands. The address for Wittouck is Valley Park, 44, Rue de la Vallée, L-2661, Luxembourg.

(4) Information is based on a Schedule 13G filed with the SEC on November 7, 2023 by Biotechnology Value Fund, L.P. ("BVF"), BVF I GP LLC ("BVF GP"), Biotechnology Value Fund II, L.P.(BVF 2"), BVF II GP LLC ("BVF 2 GP"), Biotechnology Value Trading Fund OS LP ("Trading Fund OS"), BVF Partners OS Ltd. ('Partners OS") , BVF GP Holdings LLC ("BVF GPH"), BVF Partners L.P. ('Partners"), BVF Inc., and Mark N. Lampert ("Lampert") (BVF, BVF GP, BVF 2, BVF 2 GP, Trading Fund OS, Partners OS, BVF GPH, Partners, BVF Inc. and Lampert collectively, the "BVF Affiliates"). As of the close of business on November 7, 2022 (i) BVF beneficially owned 3,908,320 shares of Common Stock including 1,324,744 shares of Common Stock underlying certain October Pre-Funded Warrants held by it and excluding 1,961,882 shares of common stock underlying certain October Pre-Funded Warrants held by it; (ii) BVF2 beneficially owned 1,961,528 shares of Common Stock, excluding 2,495,477 shares of Common Stock underlying the October Pre-Funded Warrants held by it; and (iii) Trading Fund OS beneficially owned 191,368 shares of Common Stock, excluding 243,461 shares of Common Stock underlying the October Pre-Funded Warrants held by it. BVF GP, as the general partner of BVF, may be deemed to beneficially own the 3,908,320 shares of Common Stock beneficially owned by BVF. BVF2 GP, as the general partner of BVF2, may be deemed to beneficially own the 1,961,528 shares of Common Stock beneficially owned by BVF2. Partners OS, as the general partner of Trading Fund OS, may be deemed to beneficially own the 191,368 shares of Common Stock beneficially owned by Trading Fund OS. BVF GPH, as the sole member of each of BVF GP and BVF2 GP, may be deemed to beneficially own the 5,869,848 shares of Common Stock beneficially owned in the aggregate by BVF and BVF2. Partners, as the investment manager of BVF, BVF2 and Trading Fund OS, and the sole member of Partners OS, may be deemed to beneficially own the 6,109,058 shares of Common Stock beneficially owned in the aggregate by BVF, BVF2 and Trading Fund OS and held in a certain Partners managed account (the "Partners Managed Account"), including 47,842 shares of Common Stock held in the Partners Managed Account, which excludes 60,865 shares of Common Stock underlying the October Pre-Funded Warrants held in the Partners Managed Account. BVF Inc., as the general partner of Partners, may be deemed to beneficially own the 6,109,058 shares of Common Stock beneficially owned by Partners. Mr. Lampert, as a director and officer of BVF Inc., may be deemed to beneficially own the 6,109,058 shares of Common Stock beneficially owned by BVF Inc. The October Pre-Funded Warrants and the October Warrants are subject to a 9.99% beneficial ownership limitation in the October Warrants The address for Biotechnology Value Fund, L.P., BVF I GP LLC, Biotechnology Value Fund II, L.P., BVF II GP LLC, BVF GP Holdings LLC, BVF Partners L.P., BVF Inc., and Mark N. Lampert is 44 Montgomery St., 40Th Floor, San Francisco, California 94104. The address for Biotechnology Value Trading Fund OS LP and BVF Partners OS Ltd.is PO Box 309 Ugland House, Grand Cayman, KY1-1104.

(5) Information is based on a Schedule 13G filed with the SEC on February 14, 2023 by Baker Bros. Advisors LP (the "Adviser"), Baker Bros. Advisors (GP) LLC (the "Adviser GP"), Felix J. Baker and Julian C. Baker (collectively, the "Baker Brothers Reporting Persons"). 667, L.P. and Baker Brothers Life Sciences, L.P. (collectively, the "Funds") own 447,661 and 4,138,743, shares of our Common Stock, respectively. The Funds also hold October Warrants to purchase an aggregate of 4,586,404 shares of Common Stock, subject to a 4.99% beneficial ownership limitation in the October Common Stock Warrants and a 7.5% beneficial ownership limitation in the October Pre-Funded Warrants. Pursuant to the management agreements, as amended, among the Adviser, the Funds and their respective general partners, the Funds' respective general partners relinquished to the Adviser all discretion and authority with respect to the investment and voting power of the securities held by the Funds, and thus the Adviser has complete and unlimited discretion and authority with respect to the Funds' investments and voting power. The Adviser GP is the sole general partner of the Adviser. The Adviser GP, Felix J. Baker and Julian C. Baker as managing members of the Adviser GP, and the Adviser may be deemed to be beneficial owners of securities of the Issuer directly held by the Funds. The business address for Baker Brothers Reporting Persons is 860 Washington Street, 3rd Floor, New York, New York 10014.

(6) Includes 106,187 shares of Common Stock issuable pursuant to stock options exercisable within 60 days of March 10, 2023, 860,216 shares of Common Stock issuable upon exercise of the March Warrants, and 16,306,120 shares of Common Stock issuable upon exercise of the October Warrants.

(7) Includes an aggregate of 272,183 shares of Common Stock issuable pursuant to stock options exercisable within 60 days of March 10, 2023 and 271,768 shares of Common Stock issuable upon exercise of the October Warrants.

(8) Includes an aggregate of 107,361 shares of Common Stock issuable pursuant to stock options exercisable within 60 days of March 10, 2023.

(9) Includes an aggregate of 115,149 shares of Common Stock issuable pursuant to stock options exercisable within 60 days of March 10, 2023 and 543,537 shares of Common Stock issuable upon exercise of the October Warrants.

(10) Includes an aggregate of 0 shares of Common Stock issuable pursuant to stock options exercisable within 60 days of March 10, 2023 and 10,870 shares of Common Stock issuable upon exercise of the October Warrants.

(11) Includes an aggregate of 439,044 shares of Common Stock issuable pursuant to stock options exercisable within 60 days of March 10, 2023 and 54,353 shares of Common Stock issuable upon exercise of the October Warrants.

(12) Includes an aggregate of 0 shares of Common Stock issuable pursuant to stock options exercisable within 60 days of March 10, 2023.

(13) Includes an aggregate of 54,166 shares of Common Stock issuable pursuant to stock options exercisable within 60 days of March 10, 2023.

(14) Includes an aggregate of 94,967 shares of Common Stock issuable pursuant to stock options exercisable within 60 days of March 10, 2023 and 54,353 shares of Common Stock issuable upon exercise of the October Warrants.

(15) Includes an aggregate of 94,967 shares of Common Stock issuable pursuant to stock options exercisable within 60 days of March 10, 2023.

(16) Includes an aggregate of 94,967 shares of Common Stock issuable pursuant to stock options exercisable within 60 days of March 10, 2023.

(17) Includes an aggregate of 403,207 shares of Common Stock issuable pursuant to stock options exercisable within 60 days of March 10, 2023.

(18) Consists of 28,266,553 shares held by the directors and current executive officers, an aggregate of 1,378,991 shares issuable pursuant to stock options exercisable within 60 days of March 10, 2023 and 18,101,217 shares of Common Stock issuable upon exercise of the March and October Warrants.

The following table presents information as of December 31, 2022 with respect to shares of our common stock that may be issued under our existing equity compensation plans, including the 2014 Plan, the 2019 Plan and the 2014 Employee Stock Purchase Plan. We do not maintain any equity incentive plans that have not been approved by shareholders.

Equity Compensation Plan Information

Plan Category	Number of securities to be issued upon exercise of outstanding options (a)	Weighted-average exercise price of outstanding options (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity Compensation Plan approved by security holders [1]			
2014 Equity Incentive Plan	120,091	$ 5.26	—
2014 Employee Stock Purchase Plan	—	—	327,496
2019 Equity Incentive Plan	3,621,973	$ 2.89	673,591
Total	3,742,064	$ 2.97	1,001,087

(1) This table does not present information regarding equity awards under the Aravive Biologics, Inc. 2010 Equity Incentive Plan and the Aravive Biologics, Inc. 2017 Equity Incentive Plan that were assumed by us in connection with the Merger. As of December 31, 2022, an additional 828,368 shares of our common stock were subject to options outstanding that were assumed in the Merger.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

TRANSACTIONS WITH RELATED PERSONS

RELATED-PERSON TRANSACTIONS POLICY AND PROCEDURES

In 2014, we adopted a written Related-Person Transactions Policy that sets forth our policies and procedures regarding the identification, review, consideration and approval or ratification of "related-persons transactions." For purposes of our policy only, a "related-person transaction" is a transaction, arrangement, or relationship (or any series of similar transactions, arrangements, or relationships) in which we and any "related person" are participants involving an amount that exceeds $100,000. Transactions involving compensation for services provided to us as an employee, director, consultant, or similar capacity by a related person are not covered by this policy. A related person is any executive officer, director, or more than 5% stockholder of our company, including any of their immediate family members, and any entity owned or controlled by such persons.

Under the policy, where a transaction has been identified as a related-person transaction, management must present information regarding the proposed related-person transaction to the Audit Committee (or, where Audit Committee approval would be inappropriate, to another independent body of the board of directors) for consideration and approval or ratification. The presentation must include a description of, among other things, the material facts, the interests, direct and indirect, of the related persons, the benefits to us of the transaction and whether any alternative transactions were available. To identify related-person transactions in advance, we rely on information supplied by its executive officers, directors, and certain significant stockholders. In considering related-person transactions, the Audit Committee takes into account the relevant available facts and circumstances including, but not limited to (i) the risks, costs and benefits to us, (ii) the impact on a director's independence in the event the related person is a director, immediate family member of a director or an entity with which a director is affiliated, (iii) the terms of the transaction, (iv) the availability of other sources for comparable services or products and (v) the terms available to or from, as the case may be, unrelated third parties or to or from employees generally. In the event a director has an interest in the proposed transaction, the director must recuse himself or herself form the deliberations and approval. The policy requires that, in determining whether to approve, ratify or reject a related-person transaction, the Audit Committee consider, in light of known circumstances, whether the transaction is in, or is not inconsistent with, the best interests of us and our stockholders, as the Audit Committee determines in the good faith exercise of its discretion.

In addition, we have established a Related Party Transactions Committee to review any transaction or series of transactions between our company and our directors or any entity controlled by a director or under common control with a director (an "Affiliate") in which we pay or receive in excess of $1 million (a "Transaction"). The Related Party Transactions Committee is comprised solely of directors who are neither participating in the Transaction nor having an Affiliate participate in the Transaction.

CERTAIN RELATED-PERSON TRANSACTIONS

The following is a summary of transactions since January 1, 2021 and all currently proposed transactions, to which we have been a participant, in which:

- the amounts exceeded or will exceed $120,000; and

- any of the directors, executive officers or holders of more than 5% of the respective capital stock, or any member of the immediate family of the foregoing persons, had or will have a direct or indirect material interest other than as set forth under "Executive Compensation" and "Director Compensation".

On December 31, 2020, we entered into a consulting agreement (the "Consulting Agreement") with Dr. Tabibiazar pursuant to which he has agreed to provide consulting services to us from time to time. The Consulting Agreement has a one-year term and automatically renews for successive one-year periods unless sooner terminated (the "Term"). The Consulting Agreement may be terminated by either party at any time without cause upon fifteen (15) days' written notice. As compensation, we agreed to amend the terms of Dr. Tabibiazar's option grants issued under our equity compensation plan(s) to extend the exercisability date of each option until the earlier of (1) one year following the termination by either Dr. Tabibiazar or us of the Consulting Agreement and (2) the latest date on which the options expire as set forth in the applicable award agreements. In addition, Dr. Tabibiazar has agreed not to (A) offer for sale, sell, pledge or otherwise transfer or dispose of any our securities, or securities convertible into or exercisable or exchangeable for shares of our common stock, (B) to enter into

any swap or other derivate transaction that transfers any of the economic benefits or risks of ownership of shares of our common stock or (C) to publicly disclose his intention to do any of the foregoing until April 5, 2021.

On February 12, 2021, we entered into the Purchase Agreement, with Eshelman Ventures relating to the issuance and sale of 2,875,000 shares of the Company's common stock at a price per share of $7.29. The Offering closed on February 18, 2021 and we received aggregate gross proceeds from the Offering of approximately $21.0 million.

In January 2022, we entered into and closed an investment agreement with Eshelman Ventures relating to the issuance of a pre-funded warrant to purchase up to 4,545,455 shares of the Company's common stock, par value $0.0001 per share, at a price of $2.20 per share, which was the consolidated closing bid price of our common stock on the Nasdaq on December 31, 2021, for an aggregate purchase price of $10 million. We also agreed to register for resale the shares and the issuance of the shares of common stock underlying the pre-funded warrants, which registration statement was declared effective on January 18, 2022 .

In March 2022, we entered into a securities purchase agreement with one institutional investor. We also entered into a securities purchase agreement with Eshelman Ventures in the offering pursuant to which we issued to Eshelman Ventures, in a registered direct offering priced at-the-market consistent with the rules of the Nasdaq Stock Market (i) 860,216 shares of our common stock, $0.0001 par value per share, and (ii) five-year warrants to purchase up to 860,216 additional shares of our common stock. The combined purchase price of each share of common stock and accompanying warrant was $2.325 per share. The exercise price of the accompanying warrants is $2.20, which was the consolidated closing bid price of our common stock on the Nasdaq on December 31, 2021. The aggregate proceeds from this securities purchase agreement with Eshelman Ventures was $2 million.

On October 24, 2022, we engaged in a private placement transaction (the "October Private Placement") and entered into a securities purchase agreement (the "October Purchase Agreement") with several institutional accredited investors (the "Investors") and with Eshelman Ventures, LLC ("Eshelman Ventures") and Dr. Giaccia, Dr. McIntyre. Dr. Ho, Mr. Howard and Mr. Zhang (the "Insiders" and together with Eshelman Ventures, the "Insider Investors"), pursuant to which we issued to Eshelman Ventures, Dr. Giaccia, Dr. McIntyre. Dr. Ho, Mr. Howard, and Mr. Zhang 16,306,120, 271,768, 54,353, 54,353, 10,870, and 543,537 shares of our common stock and accompanying Series A warrants (the "Series A Warrants") and Series B warrants (the "Series B Warrants", together with the Series A Warrants, the "Warrants") to purchase 16,306,120, 271,768, 54,353, 54,353, 10,870, and 543,537 shares of our common stock. The combined purchase price of each share of common stock and accompanying Warrants was $0.9199. The per share exercise price of the Warrants is $0.7949.The price per share and accompanying warrants being sold to the Insider Investors is based in part upon the consolidated closing bid price reported on the Nasdaq Global Select Market on October 24, 2022. The last reported closing price of the Common Stock on the Nasdaq Global Select Market on October 24, 2022 and the consolidated closing bid price reported on the Nasdaq Global Select Market on October 24, 2022 were the same price ($0.7949).

In connection with the October Private Placement, we entered enter into a registration rights agreement (the "Registration Rights Agreement") with the Insider Investors, pursuant to which we agreed to register for resale the shares and the issuance of the shares of common stock underlying the Warrants, which registration statement was declared effective on November 28, 2022.

Since January 1, 2021, there have been no transactions other than the transactions described above, the compensation arrangements which are described under "Executive Compensation" and "Director Compensation" and the entry into our standard form of indemnification agreements described below with directors and executive officers, and there are no proposed transactions, in which the amount involved exceeds $120,000 to which we or any of any of our subsidiaries was (or is to be) a party and in which any director, director nominee, executive officer, holder of more than 5% of our capital stock, or any immediate family member of or person sharing the household with any of these individuals, had (or will have) a direct or indirect material interest.

Indemnification Agreements

Our amended and restated certificate of incorporation contains provisions limiting the liability of directors and our amended and restated bylaws provide that we will indemnify each of our directors to the fullest extent permitted under Delaware law. Our amended and restated certificate of incorporation and amended and restated bylaws also provide the board of directors with discretion to indemnify our officers and employees when determined appropriate by the board. In addition, we have entered and expect to continue to enter into agreements to indemnify our directors and executive officers.

Independence of the Board of Directors

The board of directors undertook a review of the independence of the members of the board of directors and considered whether any director has a material relationship with our company that could compromise his or her ability to exercise independent judgment in carrying out his or her responsibilities. Based upon information requested from and provided by each director concerning their background, employment and affiliations, including family relationships, the board of directors has determined that all of our current directors, except Dr. McIntyre, due to her position as Chief Executive Officer of our company, is "independent" as that term is defined under the rules of Nasdaq. As a result, Dr. Giaccia, Dr. Ho, Dr. Hohneker, Mr. Kirk Mr. Rogers, and Mr. Zhang are deemed to be "independent" as that term is defined under the rules of Nasdaq. See the section of this Annual Report on Form 10-K entitled "Item 10. Directors, Executive Officers and Corporate Governance—Independence of the Board of Directors."

Item 14. Principal Accountant Fees and Services.

PRINCIPAL ACCOUNTANT FEES AND SERVICES

The following table sets forth the aggregate fees incurred by us for audit and other services rendered by BDO USA, LLP ("BDO") during the year ended December 31, 2022 and December 31, 2021:

	Fiscal Year Ended	
	2022	2021
	(in thousands)	
Audit Fees [1]	$ 388	$ 254
Audit-Related Fees [2]	—	—
Tax Fees [3]	49	34
All Other Fees [4]	20	—
Total Fees	$ 457	$ 288

(1) Audit fees consist of fees billed for professional services rendered for the audit of our consolidated annual financial statements, review of the interim consolidated financial statements, the issuance of consent and comfort letters in connection with registration statement filings with the SEC and all services that are normally provided by the accounting firm in connection with statutory and regulatory filings or engagements.
(2) None.
(3) Tax fees include fees billed in the fiscal periods shown for professional services for tax compliance.
(4) Fees associated with our section 382 study.

All fees described above were pre-approved by the Audit Committee.

Pre-Approval Policies and Procedures

The Audit Committee has adopted a policy and procedures for the pre-approval of audit and non-audit services rendered by our independent registered public accounting firm. The policy generally pre-approves specified services in the defined categories of audit services, audit-related services and tax services up to specified amounts. Pre-approval may also be given as part of the Audit Committee's approval of the scope of the engagement of the independent auditor or on an individual, explicit, case-by-case basis before the independent auditor is engaged to provide each service. The pre-approval of services may be delegated to one or more of the Audit Committee's members, but the decision must be reported to the full Audit Committee at its next scheduled meeting.

The Audit Committee has determined that the rendering of non-audit services by BDO in 2022 and 2021 is compatible with maintaining the principal accountant's independence.

PART IV

Item 15. Exhibits, Financial Statement Schedule.

Consolidated Financial Statements:

See Index to Consolidated Financial Statements at page F-1.

Financial Statement Schedule:

All schedules are omitted because they are not required or the required information is included in the consolidated financial statements or notes thereto.

Exhibits:

The exhibits listed in the accompanying index to exhibits are filed as part of, or incorporated by reference into, the 2022 Annual Report on Form 10-K.

ITEM 16. Form 10-K Summary

Not applicable.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Shareholders and Board of Directors
Aravive, Inc.
Houston, Texas

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Aravive, Inc. (the "Company") as of December 31, 2022 and 2021, the related consolidated statements of operations, stockholders' equity, and cash flows for 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 the years then ended**,** in conformity with accounting principles generally accepted in the United States of America.

Going Concern Uncertainty

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the consolidated financial statements, the Company has suffered recurring losses from operations and has not generated positive cash flows from operations. These factors raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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 a separate opinion on the critical audit matters or on the accounts or disclosures to which they relate.

Revenue Recognition – Collaboration and License Agreement

As described in Notes 2 and 5 to the Company's consolidated financial statements, on November 6, 2020 the Company entered into the 3D Medicines Agreement (the "Agreement") whereby the Company granted 3D Medicines an exclusive license to develop and commercialize products that contain batiraxcept as the sole drug substance, for the diagnosis, treatment or prevention of human oncological diseases in certain territories. The Company assessed the Agreement in accordance with *Accounting Standards Codification 606 - Revenue from Contracts with Customers* and identified the following performance

obligations: 1) license to intellectual property, and 2) research and development services, including conducting clinical trials. The Company recognizes revenue related to the research and development services based on the Company's estimate of total consideration to be received for such services and the pattern in which the Company performs the services. The pattern of performance is generally determined to be the amount of incurred costs related to the service portion of the contract with the customer as a percentage of total expected costs associated with the service portion of the contract. The Company recognized revenue of $6.3 million relating to the research and development services for the year ended December 31, 2022.

We have identified management's estimate of the total expected costs associated with the research and development services provided under the Agreement as a critical audit matter. Estimation of the total expected costs requires management to make judgments with respect to future development costs, including costs related to performing the product candidate's Phase III clinical trial. Auditing management's estimates with respect to the total expected costs required increased auditor judgment due to the inherent uncertainty involved in the clinical development process.

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

- Assessing management's estimate of the total expected costs for the Phase III clinical trial through a review of third-party evidence supporting estimated costs of the clinical trial based on the number of patients included in the trial as well as through discussions with the Company's clinical development professionals who are knowledgeable about the current progression of the product candidate through clinical development.

- Reviewing meeting minutes and development updates from Board of Director meetings as well as review of communications with manufacturing partners and clinical research organizations for consistency with information used by management to estimate the total expected costs.

Warrant Accounting

As described in Notes 2, 4 and 8 to the Company's consolidated financial statements, in connection with a January 2022 investment agreement, the Company issued pre-funded warrants to purchase up to 4,545,455 shares of the Company's common stock. In March 2022, the Company closed a registered direct offering pursuant to which the Company issued pre-funded warrants to purchase up to 1,665,025 shares of the Company's common stock and common stock warrants to purchase up to 4,850,241 shares of the Company's common stock. In an October 2022 private placement, the Company issued pre-funded warrants to purchase 15,870,199 shares of the Company's common stock and common stock warrants to purchase 45,178,811 shares of the Company's common stock. Pursuant to the terms of the respective warrant agreements, the January pre-funded warrants and the October common stock warrants were classified as derivative liabilities upon issuance. The March pre-funded warrants and common stock warrants and the October pre-funded warrants were classified in stockholders' equity upon issuance.

We identified the determination of the balance sheet classification of the pre-funded warrants and common stock warrants as a critical audit matter. Determination of the balance sheet classification of each series of warrants required evaluation of the complex terms and features of the warrants and the impact of those features on the accounting classification. Auditing these elements involved especially challenging and complex auditor judgment due to the nature and extent of auditor effort required, including the involvement of professionals with specialized skills and expertise.

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

- Evaluating the terms and features included in the respective pre-funded and common stock warrant agreements and other relevant agreements to determine their impact on the balance sheet classification of the warrants.

- Utilizing professionals with specialized knowledge and experience in accounting for complex debt and equity instruments to assist in the application of the relevant authoritative accounting guidance to the terms and features of the pre-funded and common stock warrants issued.

Clinical Trial Accruals

As described in Notes 2 and 3 to the Company's consolidated financial statements, the Company had accrued clinical expenses of $4.7 million as of December 31, 2022 included within accrued liabilities on the consolidated balance sheet. The Company estimates clinical trial expenses based on the services performed, pursuant to contracts with research institutions and Clinical Research Organizations ("CRO") that conduct and manage clinical trials on its behalf. In accruing service fees, the Company estimates the time period over which services will be performed and the level of patient enrollment and activity expended in each period.

We identified the clinical trial accruals as a critical audit matter due to the significant amount of management judgment required to estimate the progress toward completion of specific tasks that is dependent upon data and information provided by internal clinical personnel and third-party service providers. Auditing these elements involved 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 this critical audit matter included:

- Evaluating management’s process for estimating the clinical accrued liabilities and confirming certain amounts due directly with the Company’s CROs.

- Evaluating the Company's estimates of the clinical activities completed through the balance sheet date for certain clinical trial studies by (i) inspecting a sample of original contract terms change orders and the expected timeline for the related study, (ii) obtaining third party information detailing site visit activity, and (iii) evaluating the completeness of the accrued liabilities against invoices received prior and subsequent to the balance sheet date to determine proper consideration in the estimation of the accrual.

- Evaluating certain of the Company’s estimated clinical accrued liabilities for consistency with publicly available information, including press releases and investor presentations, and Board of Directors’ materials as well as inquiring of clinical personnel and certain members of management to gain an understanding of the status of significant on-going clinical trials.

/s/ BDO USA, LLP

We have served as the Company's auditor since 2018.

Raleigh, North Carolina

March 15, 2023

ARAVIVE, INC.
CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share amounts)

	December 31, 2022	December 31, 2021
Assets		
Current Assets		
Cash and cash equivalents	$ 53,689	$ 59,424
Prepaid expenses and other current assets	4,281	3,321
Total current assets	57,970	62,745
Restricted cash	2,445	2,431
Property and equipment, net	270	400
Operating lease right-of-use assets	1,462	2,207
Other assets	6	4
Total assets	$ 62,153	$ 67,787
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 8,765	$ 2,657
Accrued liabilities	6,738	8,416
Operating lease obligation, current portion	2,195	2,297
Current portion of deferred revenue	4,414	4,571
Total current liabilities	22,112	17,941
Deferred revenue, net of current portion	621	3,548
Operating lease obligation, net of current portion	1,882	4,076
Warrant liability	26,881	—
Total liabilities	51,496	25,565
Commitments and contingencies (Note 7)		
Stockholders' equity		
Common stock, $0.0001 par value, 100,000,000 shares authorized at December 31, 2022 and December 31, 2021; 59,844,850 and 21,039,594 shares issued and outstanding at December 31, 2022 and December 31, 2021, respectively	6	2
Additional paid-in capital	626,778	582,025
Accumulated deficit	(616,127)	(539,805)
Total stockholders' equity	10,657	42,222
Total liabilities and stockholders’ equity	$ 62,153	$ 67,787

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

ARAVIVE, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except per share amounts)

	Year Ended December 31,	
	2022	**2021**
Revenue		
Collaboration revenue	$ 9,137	$ 7,442
Total revenue	9,137	7,442
Operating expenses		
Research and development	66,938	37,541
General and administrative	13,036	10,550
Total operating expenses	79,974	48,091
Loss from operations	(70,837)	(40,649)
Other income (expense), net:		
Interest income	653	37
Change in fair value of warrant liability	(8,981)	—
Other income, net	2,843	1,461
Total other income (expense), net	(5,485)	1,498
Net loss	$ (76,322)	$ (39,151)
Net loss per share - basic and diluted	$ (2.10)	$ (1.95)
Weighted-average common shares used to compute basic and diluted net loss per share	36,372	20,070

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

ARAVIVE, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(In thousands, except share and per share amounts)

	Common Stock		Additional Paid-In	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	Equity
Balance at January 1, 2021	16,481,099	$ 2	$ 548,707	$ (500,654)	$ 48,055
Issuance of common stock upon exercise of options	219,109	—	308	—	308
Issuance of common stock under employee benefit plans	31,759	—	120	—	120
Issuance of common stock in direct offering, net of issuance costs of $98	2,875,000	—	20,866	—	20,866
Issuance of common stock in at the market offering, net of issuance costs of $250	1,432,627	—	9,767	—	9,767
Stock-based compensation	—	—	2,257	—	2,257
Net loss	—	—	—	(39,151)	(39,151)
Balances at December 31, 2021	21,039,594	2	582,025	(539,805)	42,222
Issuance of common stock under employee benefit plans	46,185	—	43	—	43
Issuance of common stock and common stock warrants in registered direct offering, net of issuance costs of $706	3,185,216	—	9,291	—	9,291
Issuance of common stock in at the market offering, net of issuance costs of $3	54,763	—	123	—	123
Issuance of common stock upon exercise of pre-funded warrants	6,210,480	1	8,592	—	8,593
Issuance of common stock and common stock warrants in private placement financing, net of issuance costs of $921	29,308,612	3	24,144	—	24,147
Stock-based compensation	—	—	2,560	—	2,560
Net loss	—	—	—	(76,322)	(76,322)
Balances at December 31, 2022	59,844,850	$ 6	$ 626,778	$ (616,127)	$ 10,657

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

ARAVIVE, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Year Ended December 31,	
	2022	**2021**
Cash flows from operating activities		
Net loss	$ (76,322)	$ (39,151)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	886	974
Stock-based compensation expense	2,560	2,257
Warrant issuance costs	728	—
Warrant liability fair value adjustment	8,981	—
Changes in assets and liabilities		
Prepaid expenses and other assets	(962)	(2,167)
Accounts payable	6,108	157
Deferred revenue	(3,084)	1,804
Accrued and other liabilities	(3,974)	3,949
Net cash used in operating activities	(65,079)	(32,177)
Cash flows from investing activities		
Purchase of property and equipment	(11)	—
Net cash used in investing activities	(11)	—
Cash flows from financing activities		
Proceeds from issuance of common stock in connection with employee benefit plans	43	120
Proceeds from issuance of common stock in connection with exercise of options	—	308
Proceeds from issuance of common stock and common stock warrants in direct offering, net of issuance costs	19,171	20,866
Proceeds from issuance of common stock and common stock warrants in private placement financing, net of issuance costs	40,032	—
Proceeds from issuance of common stock in at the market offering	123	9,767
Net cash provided by financing activities	59,369	31,061
Net change in cash, cash equivalents, and restricted cash	(5,721)	(1,116)
Cash, cash equivalents, and restricted cash at beginning of period	61,855	62,971
Cash, cash equivalents, and restricted cash at end of period	$ 56,134	$ 61,855
Supplemental disclosure of noncash items		
Warrant liability reclass to additional paid-in-capital upon warrant exercise	8,590	—

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

1. Formation and Business of the Company

Aravive, Inc. (“Aravive” or the “Company”) was incorporated on December 10, 2008 in the State of Delaware. Aravive Biologics, Inc. (“Aravive Biologics”), the Company's wholly owned subsidiary, was incorporated in 2007. Aravive is a clinical-stage oncology company developing transformative treatments designed to halt the progression of life-threatening diseases, including cancer and fibrosis.

Batiraxcept (formerly AVB-500), is an ultrahigh-affinity, decoy protein that targets the GAS6-AXL signaling pathway. By capturing serum GAS6, batiraxcept starves the AXL pathway of its signal, potentially halting the biological programming that promotes disease progression. AXL receptor signaling plays an important role in multiple types of malignancies by promoting metastasis, cancer cell survival, resistance to treatments, and immune suppression.

In July 2016, Aravive Biologics was approved for a $20.0 million Product Development Award from the Cancer Prevention and Research Institute of Texas (“CPRIT Grant”). The CPRIT Grant was expected to allow Aravive Biologics to develop the product candidate referenced above through clinical trials. The CPRIT Grant was effective as of June 1, 2016 and terminated on November 30, 2019. The Company has received all $20 million of the grant proceeds and has incurred all of the grant award proceeds by the termination date. Aravive Biologics’ royalty and other obligations, including its obligation to repay the disbursed grant proceeds under certain circumstances, survive the termination of the grant contract. The CPRIT Grant was subject to customary CPRIT funding conditions including a matching funds requirement where Aravive Biologics matched 50% of funding from the CPRIT Grant. Consequently, Aravive Biologics was required to raise $10.0 million in matching funds over the three-year project. Aravive Biologics raised all of its required $10.0 million in matching funds.

Aravive Biologics’ award from CPRIT requires it to pay CPRIT a portion of its revenues from sales of certain products, or received from its licensees or sublicensees, at tiered percentages of revenue in the low- to mid-single digits until the aggregate amount of such payments equals 400% of the grant award proceeds, and thereafter at a rate of less than one percent for as long as Aravive Biologics maintains government exclusivity. In addition, the grant contract also contains a provision that provides for repayment to CPRIT of the full amount of the grant proceeds under certain specified circumstances involving relocation of Aravive Biologics’ principal place of business outside Texas.

In April 2020, the Company entered into a license and collaboration agreement with WuXi Biologics (Hong Kong) Limited, the objective of which is to identify and develop novel high-affinity bispecific antibodies against CCN2, also known as connective tissue growth factor ("CTGF"), implicated in cancer and fibrosis, and identified from a similar target discovery screen that identified the significance of the AXL/GAS6 pathway in cancer. However, in August 2022, the Company temporarily halted work on the CTGF program with WuXi in an effort to focus all resources on the clinical programs.

In November 2020, the Company entered into a collaboration and license agreement with 3D Medicines Inc. ("3D Medicines") (the “Agreement or the 3D Medicine Agreement”), whereby the Company granted 3D Medicines an exclusive license to develop and commercialize products that contain batiraxcept as the sole drug substance for the diagnosis, treatment or prevention of human oncological diseases, in mainland China, Taiwan, Hong Kong and Macau (the "Territory") for an upfront cash payment of $12 million. During the second quarter of 2021, the Company received a $6 million development milestone from 3D Medicines, for completing our first clinical milestone with 3D Medicines, dosing the first patient in its Phase 3 trial of batiraxcept in PROC.

In August 2021, the Company received a $3 million development milestone payment from 3D Medicines based on the Center for Drug Evaluation ("CDE") of the China National Medical Products Administration ("NMPA") approval of the Investigational New Drug application ("IND") submitted by 3D Medicines to participate in the Company’s international batiraxcept Phase 3 PROC clinical trial.

In October 2022, the Company received a $6 million development milestone payment from 3D Medicines based on the initiation of the global Phase 3 platinum resistant ovarian cancer ("PROC") clinical trial in the Territory for the development of batiraxcept.

As consideration for the rights granted as part of a license agreement that Aravive Biologics entered into in 2012 with Leland Stanford Junior University ("Stanford University") for intellectual and tangible property rights relating to biologic inhibitors for therapeutic targeting the receptor tyrosine kinase AXL, Aravive Biologics is obligated to pay yearly license fees and milestone payments, and a royalty based on net sales of products covered by the patent-related rights. More specifically, Aravive Biologics is obligated to pay Stanford University (i) annual license payments (ii) milestone payments of up to an aggregate of $1,000,000 upon achievement of clinical and regulatory milestones, and (iii) royalties equal to a percentage (in the low single digits) of net sales of licensed products; provided that the annual license payments made will offset (and be credited against) any royalties due in such license year. In the event of a sublicense to a third party of any rights based on the patents that are solely owned by Stanford University, Aravive Biologics is obligated to pay royalties to Stanford University equal to a percentage of what Aravive Biologics would have been required to pay to Stanford University had it sold the products under sublicense itself. In addition, in such event it is required to pay to Stanford University a percent of sublicensing income. In the event of a termination, Aravive Biologics will be obligated to pay all amounts that accrued prior to such termination.

2. Summary of Significant Accounting Policies

Basis of Presentation and Use of Estimates

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP"). The preparation of the accompanying consolidated financial statements in accordance with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated financial statements, and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

The accompanying financial statements are consolidated for the years ended December 31, 2022 and 2021 and include the accounts of Aravive, Inc. and its wholly-owned subsidiary Aravive Biologics. All intercompany accounts and transactions have been eliminated in consolidation. The U.S. dollar is the functional currency for the Company's subsidiary and consolidated operations.

Going Concern Uncertainty

Since inception, the Company has incurred net losses and negative cash flows from operations. At December 31, 2022, the Company had an accumulated deficit of $616.1 million and working capital of $35.9 million. The Company expects to continue to incur losses from costs related to the development of batiraxcept and related administrative activities for the foreseeable future. These factors raise substantial doubt about the Company's ability to continue as a going concern. The accompanying consolidated financial statements do not include any adjustments relating to the recoverability of the recorded assets or the classification of liabilities that may be necessary should the Company be unable to continue as a going concern. As of December 31, 2022, the Company had a cash and cash equivalents balance of $53.7 million consisting of cash and investments in highly liquid U.S. money market funds. The Company intends to seek additional capital through equity and/or debt financings, collaborative or other funding arrangements with partners or through other sources of financing to fulfill its operating and capital requirement for the next 12 months to advance its clinical development program to later stages of development and potentially commercialize its clinical product candidate batiraxcept. Although management has been successful in raising capital in the past, there can be no assurance that the Company will be successful in raising capital in the future or that any needed financing will be available in the future at terms acceptable to the Company. If the Company is unable to raise additional funds when needed, the Company may be required to delay, reduce, or terminate some or all of its development programs and clinical trials. The Company may also be required to sell or license to others technologies or clinical product candidates or programs that it would prefer to develop and commercialize itself.

Nasdaq Compliance

On August 9, 2022, the Company received written notice from Nasdaq, indicating that, based upon the closing bid price of the Company's common stock for the 30 consecutive business day period between June 27, 2022, through August 8, 2022, the Company did not meet the minimum bid price of $1.00 per share required for continued listing on the Nasdaq Global Select Market pursuant to Nasdaq Listing Rule 5550(a)(2).

In order to regain compliance with Nasdaq's minimum bid price requirement, the Company's common stock must maintain a minimum closing bid price of $1.00 for at least ten consecutive business days during the Compliance Period.

On November 10, 2022, the Company received notification from the Nasdaq Listing Qualifications Staff (the "Staff") that the Company had regained compliance with the Nasdaq Stock Market Listing Rules. The Staff has determined that for 11 consecutive business days, from October 27, 2022 to November 10, 2022, the closing bid price of the Company's common stock has been at $1.00 per share or greater. Accordingly, the Company has regained compliance and this matter is now closed.

Segments

The Company operates in one segment. Management uses one measurement of profitability and does not segregate its business for internal reporting. All long-lived assets are maintained in the United States of America.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to a concentration of credit risk consist of cash and cash equivalents. All of the Company's cash and cash equivalents are held at several financial institutions that management believes are of high credit quality. Such deposits may exceed federally insured limits.

Risk and Uncertainties

The Company's future results of operations involve a number of risks and uncertainties. Factors that could affect the Company's future operating results and cause actual results to vary materially from expectations include, but are not limited to, uncertainty of results of clinical trials and reaching milestones, uncertainty of regulatory approval of the Company's potential drug candidates, uncertainty of market acceptance of the Company's products, competition from substitute products and larger companies, securing and protecting proprietary technology, strategic relationships and dependence on key individuals and sole source suppliers.

Products developed by the Company require clearances from the U.S. Food and Drug Administration ("FDA"), the Pharmaceuticals Medicines and Devices Agency ("PMDA"), or other international regulatory agencies prior to commercial sales. There can be no assurance that the products will receive the necessary clearances. If the Company is denied clearance, clearance is delayed or the Company is unable to maintain clearance, it could have a material adverse impact on the Company.

The Company expects to incur substantial operating losses for the next several years and will need to obtain additional financing in order to launch and commercialize any product candidates for which it receives regulatory approval.

The Company relies on third-party manufacturers to purchase from their third-party vendors the materials necessary to produce product candidates and manufacture product candidates for clinical studies. The Company also depends on third-party suppliers for key materials and services used in research and development, as well as manufacturing processes, and are subject to certain risks related to the loss of these third-party suppliers or their inability to supply adequate materials and services. The Company does not control the manufacturing processes of the contract development and manufacturing organizations (the "CDMOs"), with whom it contracts and is dependent on these third parties for the production of its therapeutic candidates in accordance with relevant regulations (such as current Good Manufacturing Practices, or cGMP, which includes, among other things, quality control, quality assurance and the maintenance of records and documentation. In addition, the Company is dependent upon third-party suppliers for the materials needed to construct its cGMP facility as well as the equipment that will be needed to run the facility.

Cash and Cash Equivalents, Restricted Cash

The Company considers all highly liquid investments purchased with an original maturity of three months or less to be cash equivalents. At December 31, 2022 and 2021 the Company's cash and cash equivalents were held in multiple institutions within the United States and included deposits in money market funds which were unrestricted as to withdrawal or use. Restricted cash consists of a letter of credit to secure the Company's obligations under the right-of-use lease.

Property and Equipment, Net

Property and equipment are stated at cost and depreciated using the straight-line method over the estimated useful lives of the assets, generally between three and five years. Leasehold improvements are amortized on a straight-line basis over the lesser of their useful life or the term of the lease. Maintenance and repairs are charged to expense as incurred, and improvements are capitalized. When assets are retired or otherwise disposed of, the cost and accumulated depreciation are removed from the consolidated balance sheets and any resulting gain or loss is reflected in operations in the period realized.

Leases

The Company leases all of its office space in conducting its business. At inception, the Company determines whether an agreement represents a lease and at commencement the Company evaluates each lease agreement to determine whether the lease is an operating or financing lease.

The Company records an operating lease right-of-use ("ROU") asset and an operating lease obligation on the consolidated balance sheet when entering into a lease. ROU assets represent the Company's ROU of the underlying asset for the lease term and the lease obligation represents the Company's commitment to make the lease payments arising from the lease. Lease obligations are recognized at the commencement date based on the present value of remaining lease payments over the lease term and ROU assets are calculated as the lease liability, adjusted by unamortized initial direct costs, unamortized lease incentives received, cumulative deferred or prepaid lease payments, and accumulated impairment losses. As the Company's leases do not provide an implicit rate, the Company has used an estimated incremental borrowing rate based on the information available at the lease inception date in determining the present value of lease payments. The lease term may include options to extend or terminate the lease and the Company includes renewal options in its calculation of the estimated lease term when it is reasonably certain that the Company will exercise that option. Operating lease expense is recognized on a straight-line basis over the lease term, subject to any changes in the lease or expectations regarding the terms. Variable lease costs such as common area costs and property taxes are expensed as incurred. Variable lease costs and short-term lease payments not included in the lease liability are classified within operating activities in the consolidated statements of cash flows. For all lease agreements, the Company has combined lease and non-lease components. Leases with an initial term of 12 months or less are not recorded on the consolidated balance sheet. These expenses are recognized within operating expenses in the consolidated statements of operations.

Warrant Liability

Warrants for the purchase of shares of common stock issued in connection with the January 2022 financing (the "January 2022 Warrants") were classified as derivative liabilities on the consolidated balance sheets as of March 31, 2022 because the warrants were not indexed to the Company's own common stock. On April 1, 2022, the warrants were exercised and converted to equity. The warrants were reclassified to additional paid-in-capital at their fair value on the warrant exercise date of April 1, 2022, with the change in estimated fair value during the period recognized as a component of other income (expense), net in our statement of operations and reflected accordingly in the reconciliation of net loss to net cash used in operating activities.

Warrants for the purchase of shares of common stock issued in connection with the October 2022 financing (the "October 2022 Warrants") were classified as liabilities on the consolidated balance sheets as of December 31, 2022, because the Company did not have enough authorized shares to cover the outstanding warrants, if exercised.. The change in estimated fair value during the period was recognized as a component of other income (expense), net in our statement of operations and reflected accordingly in the reconciliation of net loss to net cash used in operating activities.

The Company estimated the fair value of these liabilities using assumptions that are based on the individual characteristics of the warrants on the valuation date. The Company used the Black-Scholes option-pricing model and the fair value of the underlying stock to determine the fair value of these liabilities. The valuation model is based on inputs as of the valuation dates, including the estimated volatility of our stock, the remaining contractual term of the warrants and the risk-free interest rates. Refer to Note 4.

Impairment of Long-Lived Assets

The Company reviews property and equipment for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability is measured by the comparison of the carrying amount to the future net cash flows which the assets are expected to generate. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value (i.e., determined through estimating projected discounted future net cash flows or other acceptable methods of determining fair value) arising from the asset. There were no such impairments of long-lived assets during the year ended December 31, 2022.

Fair Value of Financial Instruments

The carrying value of the Company's cash and cash equivalents, restricted cash, accounts payable and accrued liabilities approximate fair value due to the short-term nature of these items.

Fair value is defined as the exchange price that would be received for an asset or an exit price paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs.

The fair value hierarchy defines a three-level valuation hierarchy for disclosure of fair value measurements as follows:

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

Level 2 - Inputs other than quoted prices included within Level 1 that are observable, unadjusted quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the related assets or liabilities; and

Level 3 - Unobservable inputs that are supported by little or no market activity for the related assets or liabilities.

The categorization of a financial instrument within the valuation hierarchy is based upon the lowest level of input that is significant to the fair value measurement.

The Company's financial instruments consist of Level 1 assets as of December 31, 2022 and 2021 and Level 3 liabilities as of December 31, 2022. Level 1 securities are comprised of highly liquid money market funds. Level 3 liabilities are comprised of warrant liabilities.

Clinical Trial Accruals

The Company's clinical trial accruals are based on estimates of patient enrollment and related costs at clinical investigator sites as well as estimates for the services received and efforts expended pursuant to contracts with multiple research institutions and CROs that conduct and manage clinical trials on the Company's behalf.

The Company estimates preclinical and clinical trial expenses based on the services performed, pursuant to contracts with research institutions and CROs that conduct and manage preclinical studies and clinical trials on its behalf. In accruing service fees, the Company estimates the time period over which services will be performed and the level of patient enrollment and activity expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, the Company will adjust the accrual accordingly. Payments made to third parties under these arrangements in advance of the receipt of the related services are recorded as prepaid expenses until the services are rendered.

Research and Development

Research and development costs are charged to operations as incurred. Research and development costs include, but are not limited to, payroll and personnel expenses, laboratory supplies, consulting costs, external research and development expenses and allocated overhead, including rent, equipment depreciation, and utilities. Costs to acquire technologies to be used in research and development that have not reached technological feasibility and have no alternative future use are expensed to research and development costs when incurred.

Income Taxes

The Company accounts for income taxes under the asset and liability approach. Under this method, deferred tax assets and liabilities are determined based on the difference between the financial statement and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amounts expected to be realized.

The Company assesses all material positions taken in any income tax return, including all significant uncertain positions, in all tax years that are still subject to assessment or challenge by relevant taxing authorities. Assessing an uncertain tax position begins with the initial determination of the position's sustainability and is measured at the largest amount of benefit that is more than likely to be realized upon ultimate settlement. As of each balance sheet date, unresolved uncertain tax positions must be reassessed, and the Company will determine whether (i) the factors underlying the sustainability assertion have changed and (ii) the amount of the recognized tax benefit is still appropriate. The recognition and measurement of tax benefits requires significant judgment. Judgments concerning the recognition and measurement of a tax benefit might change as new information becomes available.

Stock-Based Compensation

For stock options granted to employees, the Company recognizes compensation expense for all stock-based awards based on the grant-date estimated fair value. The value of the portion of the award that is ultimately expected to vest is recognized as expense ratably over the requisite service period. The fair value of stock options is determined using the Black-Scholes option pricing model. The determination of fair value for stock-based awards on the date of grant using an option pricing model requires management to make certain assumptions regarding a number of complex and subjective variables.

Stock-based compensation expense related to stock options granted to nonemployees is recognized based on the fair value of the stock options, determined using the Black-Scholes option pricing model, as they are earned. The awards generally vest over the time period the Company expects to receive services from the nonemployee.

Net Loss per Share of Common Stock

Basic net loss per common share is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of common shares outstanding during the period, without consideration for potentially dilutive securities. Diluted net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common shares and potentially dilutive securities outstanding for the period. For purposes of the diluted net loss per share calculation, stock options and restricted stock units are considered to be potentially dilutive securities. Because the Company has reported a net loss for the years ended December 31, 2022 and 2021, and the effect of the Company's common stock equivalents is anti-dilutive, diluted net loss per common share is the same as basic net loss per common share for those periods.

Collaborative Arrangements

The Company records the elements of its collaboration agreements that represent joint operating activities in accordance with ASC Topic 808, *Collaborative Arrangements* (ASC 808). Accordingly, the elements of the collaboration agreements that represent activities in which both parties are active participants and to which both parties are exposed to the significant risks and rewards that are dependent on the commercial success of the activities are recorded as collaborative arrangements. The Company considers the guidance in ASC 606-10-15, *Revenue from Contracts with Customers – Scope and Scope Exceptions*, in determining the appropriate treatment for the transactions between the Company and its collaborative partner and the transactions between the Company and third parties. Generally, the classification of transactions under the collaborative arrangements is determined based on the nature and contractual terms of the arrangement along with the nature of the operations of the participants. Currently, we have one collaboration agreement with 3D Medicines, see Note 5 for further discussion.

Revenue Recognition

The Company’s sole source of revenue for 2022 and 2021 has been generated through its collaboration and license agreement. The Company’s collaboration and license agreements frequently contain multiple elements including (i) intellectual property licenses, and (ii) research and development services. Consideration received under these arrangements may include upfront payments, research and development funding, cost reimbursements, milestone payments, payments for product sales and royalty payments. The Company’s customer includes 3D Medicines.

The Company follows ASC 606, *Revenue from Contracts with Customers* (ASC 606) for recognition of its collaboration and license agreements. Under ASC 606, revenue is recognized when a customer obtains control of promised goods or services. The amount of revenue recognized reflects the consideration that the Company expects to be entitled to receive in exchange for goods or services and excludes sales incentives and amounts collected on behalf of third parties. The Company analyzes the nature of these performance obligations in the context of individual agreements in order to assess the distinct performance obligations.

The Company applies the following five-step model to recognize revenue: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations, including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation.

i) Identify the contract with a customer. The Company considers the terms and conditions of its agreements to identify contracts within the scope of ASC 606. The Company concludes it has a contract with a customer when the contract is approved, each party's rights regarding the goods and services to be transferred can be identified, the payment terms for the

goods and services can be identified, it has been determined that the customer has the ability and intent to pay and the contract has commercial substance. The Company uses judgment in determining the customer's ability and intent to pay, which is based upon factors including the customer's historical payment experience or, for new customers, credit and financial information pertaining to the customers.

ii) Identify the performance obligations in the contract. Performance obligations in the agreements are identified based on the goods and services that will be transferred to the customer that are both capable of being distinct, whereby the customer can benefit from the service either on its own or together with other resources that are readily available from third parties or from the Company, and are distinct in the context of the contract, whereby the transfer of the services is separately identifiable from other promises in the contract. The Company's performance obligations generally consist of intellectual property licenses and research and development services with respect to license and service agreements, and the manufacture and supply of product for product sales agreements.

iii) Determine the transaction price. The Company determines the transaction price based on the consideration to which the Company expects to be entitled in exchange for transferring goods and services to the customer. In determining the transaction price, any variable consideration would be considered, to the extent applicable, if, in the Company's judgment, it is probable that a significant future reversal of cumulative revenue under the contract will not occur. In accordance with the royalty exception under ASC 606 for licenses of intellectual property, the transaction price excludes future royalty payments to be received from the Company's customers. None of the Company's revenue generating contracts contain consideration payable to its customer or a significant financing component.

iv) Allocate the transaction price to performance obligations in the contract. If the contract contains a single performance obligation, the entire transaction price is allocated to that performance obligation. Contracts that contain multiple performance obligations require an allocation of the transaction price to each performance obligation based on a relative standalone selling price.

v) Recognize revenue when or as we satisfy a performance obligation. Revenue is recognized at the time the related performance obligation is satisfied by transferring the promised goods or services to a customer. The Company recognizes revenue when control of the goods or services is transferred to the customers for an amount that reflects the consideration that the Company expect to receive in exchange for those goods or services.

Performance Obligations

The following is a general description of principal goods and services from which the Company generates revenue.

License to intellectual property

The Company generates revenue from licensing its intellectual property including know-how and development and commercialization rights. The license provides a customer with the right to further research, develop and commercialize internally-discovered or collaborated drug candidates, or the right to use batiraxcept to further research, develop and commercialize customer drug candidates. The consideration the Company receives is in the form of nonrefundable upfront consideration related to the functional intellectual property licenses and is recognized when the Company transfers such license to the customer unless the license is combined with other goods or services into one performance obligation, in which case the revenue is recognized over a period of time based on the estimated pattern in which the Company satisfies the combined performance obligation. The Company's licensing agreements are generally cancellable.

Research and development services

The Company generates revenue from research and development services it provides to its customers and primarily includes clinical trials, and assistance during regulatory approval application process. Revenue associated with these services is recognized based on the Company's estimate of total consideration to be received for such services and the pattern in which the Company perform the services. The pattern of performance is generally determined to be the amount of incurred costs related to the service portion of the contract with the customer as a percentage of total expected costs associated with the service portion of the contract.

Contracts with Multiple Performance Obligations

The Company's collaboration and license agreement with its customers contains multiple promised goods or services. Based on the characteristics of the promised goods and services the Company analyzes whether they are separate or combined performance obligations. The transaction price is allocated to the separate performance obligations on a relative standalone selling price basis. The estimated standalone selling price is based on the adjusted market assessment approach including estimated present value of future cash flows and cost-plus margin approach, taking into consideration the type of services, estimates of hourly market rates, and stage of the development.

Variable Consideration

The Company's contracts with customers primarily include two types of variable consideration: (i) development and regulatory milestone payments, which are due to the Company upon achievement of specific development and regulatory milestones and (ii) one-time sales-based payments and sales-based royalties associated with licensed intellectual property.

Due to uncertainty associated with achievement of the development and regulatory milestones, the related milestone payments are excluded from the contract consideration and the corresponding revenue is not recognized until the Company concludes it is probable that reversal of such milestone revenue will not occur. As part of the Company's evaluation of the constraint, the Company considers numerous factors, including whether the achievement of the milestone is outside of the Company's control, contingent upon regulatory approval or dependent on licensee efforts.

Product sales-based royalties under licensed intellectual property and one-time payments are accounted for under the royalty exception. The Company recognizes revenue for sales-based royalties under licensed intellectual property and one-time payments at the later of when the sales occur or the performance obligation is satisfied or partially satisfied.

The transaction price is reevaluated each reporting period and as uncertain events are resolved or other changes in circumstances occur.

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board, or FASB, or other standard setting bodies and adopted by us as of the specified effective date. Unless otherwise discussed, the impact of recently issued standards that are not yet effective is not expected to have a material impact on the Company's financial position or results of operations upon adoption.

In June 2016, the FASB issued ASU No. 2016-13, Measurement of Credit Losses on Financial Instruments, to require financial assets carried at amortized cost to be presented at the net amount expected to be collected based on historical experience, current conditions and forecasts. Subsequently, the FASB issued ASU No. 2018-19, Codification Improvements to Topic 326, to clarify that receivables arising from operating leases are within the scope of lease accounting standards. Further, the FASB issued ASU No. 2019-04, ASU No. 2019-05, ASU 2019-10, ASU 2019-11, ASU 2020-02 and ASU 2020-03 to provide additional guidance on the credit losses standard. Adoption of the ASUs is on a modified retrospective basis. The Company plans to adopt this ASU on January 1, 2023. The Company does not expect that the adoption of this new standard will have a material impact on the Company's consolidated financial statements and related disclosures.

3. Balance Sheet Components

Prepaid expenses and other current assets (in thousands)

	December 31,	
	2022	2021
Clinical	$ 4,196	$ 3,288
Lease receivable	85	33
Total	$ 4,281	$ 3,321

Property and equipment, net (in thousands)

	December 31,	
	2022	2021
Equipment and furniture	$ 1,441	$ 1,430
Buildings, leasehold and building improvements	2,673	2,673
	4,114	4,103
Less: Accumulated depreciation and amortization	(2,840)	(2,699)
Accumulated impairment loss	(1,004)	(1,004)
Property and equipment, net	$ 270	$ 400

Depreciation expense was approximately $0.1 million for the years ended December 31, 2022 and 2021.

Accrued liabilities (in thousands)

	December 31,	
	2022	2021
Payroll and related	$ 1,930	$ 1,397
Clinical	4,730	6,727
Sublease prepayment	—	227
Professional services	78	50
Other	—	15
Total	$ 6,738	$ 8,416

4. Fair Value Measurements

The Company’s warrant liability for the January 2022 warrants, which was classified as a derivative liability on the consolidated balance sheet as of March 31, 2022, contained unobservable inputs that reflected the Company’s own assumptions in which there was little, if any, market activity at the measurement date and was classified as a Level 3 input. Accordingly, the Company’s warrant liability was measured at fair value on a recurring basis using unobservable inputs at each reporting period. On April 1, 2022, the warrants were exercised and converted to equity. The warrants were reclassified to additional paid-in-capital at their fair value on the warrant exercise date of April 1, 2022, with the change in estimated fair value during the period being recognized as a component of other income (expense), net in our statement of operations. Refer to Note 2.

The fair value of the warrants was estimated using the Black-Scholes option-pricing model. For warrants that do not have a fixed termination date, the expected terms represent the periods that the warrants are expected to be outstanding based upon managements' estimate. The risk-free interest rates are based on the U.S. Constant Maturity treasury curve commensurate with the time outstanding. The expected dividend is zero as the Company has not paid nor does it anticipate paying any dividends on its common stock in the foreseeable future. The expected volatilities are estimated by our historical volatility over a similar time period.

The assumptions used in calculating the estimated fair value at the end of the reporting period and on the warrant exercise date represent the Company’s best estimate. However, inherent uncertainties are involved. If factors or assumptions change, the estimated fair value could be materially different.

The Company's financial instruments consist principally of cash and cash equivalents, prepaid expenses, accounts payable and accrued liabilities. The following financial instruments are reported on the Company's consolidated balance sheets at amounts that approximate current fair value. The following table sets forth the Company's financial instruments that were measured at fair value on a recurring basis by level within the fair value hierarchy (in thousands):

	Fair Value Measurements at December 31, 2022			
	Total	Level 1	Level 2	Level 3
Assets				
Money market funds	$ 52,905	$ 52,905	$ —	$ —
Liabilities				
Warrant liability	$ 26,881	$ —	$ —	$ 26,881

	Fair Value Measurements at December 31, 2021			
	Total	Level 1	Level 2	Level 3
Assets				
Money market funds	$ 49,217	$ 49,217	$ —	$ —

Warrant Liability

The Company's warrant liability for the October 2022 warrants which was classified as a derivative liability on the consolidated balance sheet as of December 31, 2022 contained unobservable inputs that reflected the Company's own assumptions in which there was little, if any, market activity at the measurement date and was classified as a Level 3 input. Accordingly, the Company's warrant liability was measured at fair value on a recurring basis using unobservable inputs at each reporting period. Refer to Note 2.

The fair value of the warrants was estimated using the Black-Scholes option-pricing model. The fair value of the common share has been adjusted for a discount for lack of marketability due to the uncertainty and timing of obtaining shareholder approval to increase our authorized number of common shares. For warrants that do not have a fixed termination date, the expected terms represent the periods that the warrants are expected to be outstanding based upon managements' estimate. The risk-free interest rates are based on the U.S. Constant Maturity treasury curve commensurate with the time outstanding. The expected dividend is zero as the Company has not paid nor does it anticipate paying any dividends on its common stock in the foreseeable future. The expected volatilities are estimated by our historical volatility over a similar time period.

The assumptions used in calculating the estimated fair value at the end of the reporting period represent the Company's best estimate. However, inherent uncertainties are involved. If factors or assumptions change, the estimated fair value could be materially different.

At December 31, 2022, the Company estimated the fair values of the financial liability arising from the October 2022 Warrants using the following weighted average assumptions:

	October 2022 Warrants
	December 31, 2022
Expected term (in years)	1.9
Expected volatility	49.9%
Risk-free interest rate	4.48%
Expected dividend yield	0.00%
Fair value of common share	$ 1.25
Exercise price	$ 0.7949

The following table provides a summary of changes in the estimated fair value of the Company's warrant liability (in thousands):

	January 2022 Warrants	October 2022 Warrants
Balance at January 1, 2022	$ —	$ —
Issuance of warrants	10,000	—
Change in fair value	(1,228)	—
Balance at March 31, 2022	8,772	—
Issuance of warrants	—	16,490
Change in fair value	(182)	10,391
Reclass to additional paid-in-capital upon exercise	(8,590)	—
Balance at December 31, 2022	$ —	$ 26,881

The Company recognizes transfers between levels of the fair value hierarchy as of the end of the reporting period. There were no transfers within the hierarchy during the years ended December 31, 2022 and 2021.

5. Collaboration and License Agreement

On November 6, 2020, the Company entered into the 3D Medicines Agreement, whereby the Company granted 3D Medicines an exclusive license to develop and commercialize products that contain batiraxcept as the sole drug substance, for the diagnosis, treatment or prevention of human oncological diseases, in China, Taiwan, Hong Kong and Macau (the "Territory").

Under the terms of the Agreement, the Company was paid $27 million (inclusive of $15 million in milestone payments) and is eligible to receive from 3D Medicines cash payments of up to an aggregate of $207 million (inclusive of the $27 million received) in clinical development, regulatory and commercial milestone payments. There can be no guarantee that any additional milestones will in fact be met. The Company is obligated to make certain payments to The Board of Trustees of Stanford University based on certain amounts received from 3D Medicines under the Agreement pursuant to the existing license agreement by and between the Company and Stanford, dated January 25, 2012, and as amended to date.

The Company will also be entitled to receive tiered royalties ranging from low double digits to mid-teens on sales in the Territory, if any, of products containing batiraxcept. Royalties are payable with respect to each jurisdiction in the Territory until the latest to occur of: (i) the last-to-expire of specified patent rights in such jurisdiction in the Territory; or (ii) ten (10) years after the first commercial sale of a product in such jurisdiction in the Territory. In addition, royalties payable under the Agreement will be subject to reduction on account of generic competition under certain specified conditions, with any such reductions capped at certain percentages of the amounts otherwise payable during the applicable royalty payment period.

Under the terms and conditions of the Agreement, 3D Medicines will be solely responsible for the development and commercialization of licensed products in the Territory.

If either the Company or 3D Medicines materially breaches the Agreement and does not cure such breach, the non-breaching party may terminate the Agreement in its entirety. Either party may also terminate the Agreement, upon written notice, if the other party files for bankruptcy, is dissolved or has a receiver appointed for substantially all of its property. The Company may terminate the Agreement if 3D Medicines, its affiliates or its sublicensees challenges the validity or enforceability of any of the Company's patents covering any of the licensed compounds or products or ceases substantially all development and commercialization of licensed products in the Territory for a specified period, subject to certain exceptions. 3D Medicines may also terminate the Agreement for convenience provided certain notice is provided to the Company.

The Agreement contemplates that the Company will enter into ancillary arrangements with 3D Medicines, including a clinical supply agreement and a manufacturing technology transfer agreement.

The Company assessed this arrangement in accordance with ASC 606 and identified the following performance obligations: 1) license to intellectual property, batiraxcept, and 2) research and development services, including conducting clinical trials. The Company concluded that each of these performance obligations were distinct because 3D Medicines can benefit from the good or service either on its own or together with other resources that are readily available, and each performance obligation is separately identifiable from other promises within the contract.

The estimated total transaction price was allocated between performance obligations based on their relative standalone selling prices. The Company uses a discounted cash flow approach and an expected cost plus a margin approach to estimate the standalone selling price for the performance obligations. The Company allocated the $27.0 million transaction price as such: $14.5 million to the research and development services performance obligation and $12.5 million to the license to intellectual property. Accordingly, the Company will recognize revenue related to the allocable research and development services obligation on a proportional performance basis as the underlying services are performed pursuant to the current development plan which is commensurate with the period and consistent with the pattern over which the Company's research and development services obligation is satisfied. The Company will recognize the revenue related to the license to intellectual property at a point in time. This is due to the fact the license was determined to be a functional license due to current stage in development of batiraxcept. Batiraxcept has been developed, dosing levels have already been determined and the drug is currently in a Phase III clinical trial related to its PROC study.

As of December 31, 2022, no clinical or regulatory milestones have been assessed as probable of being reached and thus have been fully constrained. The Company continues to re-assess the probability of achievement of future milestones at the end of each reporting period.

The Company recognized in revenue $6.3 and $3.2 million related to the research and development services for the years ended December 31, 2022 and 2021, respectively. The Company recognized in revenue $2.8 million and $4.2 million related to the license of intellectual property for the years ended December 31, 2022 and 2021, respectively. As of December 31, 2022, the Company had a contract liability balance of approximately $5.0 million of which approximately $4.4 million is classified as current and approximately $0.6 million is classified as long-term, consisting of deferred revenue related to a portion of the payment received from 3D Medicines. The Company recognized revenue of $5.3 million for the year ended December 31, 2022 related to the contract liability balance of $8.1 million as of December 31, 2021. As of December 31, 2022, the service period for the future research and development services is expected to occur over the next 2 years.

6. Leases

In March 2017, the Company entered into an operating facility lease agreement for approximately 34,500 rentable square feet located at the 1020 Marsh Facility. The lease commenced in August 2017 for a period of 87 months with one renewal option for a five-year term. The Company did not include the renewal option period as the Company determined it was not reasonably certain the lease would be renewed as of the modification date.

In August 2020, the Company entered into a lease agreement in North Carolina for approximately 4,128 square feet for office space. The monthly lease payments will be approximately $9 thousand per month for a period of 63 months with a three-month rent abatement period. The lease commenced in the fourth quarter of 2020.

The Company's rent expense including both short-term and variable lease components of $0.4 million associated with the facility leases was $1.8 million and $1.6 million for the years ended December 31, 2022 and 2021, respectively. Cash paid for amounts included in the measurement of lease obligations for operating cash flows from operating leases was $3.0 million and $2.5 million for the years ended December 31, 2022 and 2021, respectively. As of December 31, 2022, the Company's operating leases had a weighted average remaining lease term of 1.9 years and a weighted average discount rate of 7.62%, which approximates the Company's incremental borrowing rate.

As of December 31, 2022, minimum lease payments under non-cancelable operating leases by period were expected to be as follows (in thousands):

Year Ending December 31,	
2023	3,039
2024	2,620
2025	116
2026	30
Total future minimum lease payments	5,805
Less: discount	(1,728)
Total lease liabilities	$ 4,077

1020 Marsh Facility Sublease

On June 8, 2021, the Company entered into an operating sublease with a subtenant (the "Subtenant") for the 1020 Marsh Facility. The final agreement and consent received from the landlord was obtained on July 13, 2021. The term of the sublease has commenced on August 1, 2021 and continues through October 31, 2024, unless the master lease is terminated earlier due to a breach by Subtenant. Subtenant will also pay to the Company, as additional rent, an amount equal to the Company's share of operating expenses attributable to the subleased premises due under the master lease. The terms entered into for this sublease agreement did not result in an impairment of the Company's long-lived assets for the year ended December 31, 2022. Lease income associated with this sublease is recorded in other income in the accompanying consolidated statements of operations. The Company has recorded lease income associated with this sublease of approximately $2.9 million and $1.0 million for the years ended December 31, 2022 and 2021, respectively. During the years ended December 31, 2022 and 2021, cash received from the Subtenant was $2.8 million and $0.9 million, respectively, which amount was included in operating cash flows.

Future base rent the Subtenant shall pay to the Company over the sublease term as of December 31, 2022, are as follows (in thousands):

Year Ending December 31,	
2023	2,372
2024	2,029
Total	$ 4,401

7. Commitments and Contingencies

Purchase Commitments

The Company conducts research and development programs through a combination of internal and collaborative programs that include, among others, arrangements with contract manufacturing organizations and contract research organizations. The Company had contractual arrangements with these organizations including license agreements with milestone obligations and service agreements with obligations largely based on services performed.

In the normal course of business, the Company enters into various firm purchase commitments related to certain preclinical and clinical studies.

Contingencies

In the normal course of business, the Company enters into contracts and agreements that contain a variety of representations and warranties and provide for general indemnifications. The Company's exposure under these agreements is unknown because it involves claims that may be made against the Company in the future but have not yet been made. The Company accrues a liability for such matters when it is probable that future expenditures will be made and such expenditures can be reasonably estimated.

Indemnification

In accordance with the Company's amended and restated Certificate of Incorporation and amended and restated bylaws, the Company has indemnification obligations to its officers and directors for certain events or occurrences, subject to certain limits, while they are serving at the Company's request in such capacity. There have been no claims to date and the Company has a director and officer insurance policy that may enable it to recover a portion of any amounts paid for future claims.

Litigation

The Company may from time to time be involved in legal proceedings arising from the normal course of business. There are no pending or threatened legal proceedings as of December 31, 2022.

8. Common Stock and Common Stock Warrants

The Amended and Restated Certificate of Incorporation, as amended, authorizes the Company to issue 100,000,000 shares of common stock as of December 31, 2022. Common stockholders are entitled to dividends as and when declared by the Board of Directors, subject to the rights of holders of all classes of stock outstanding having priority rights as to dividends. There have been no dividends declared to date. The holder of each share of common stock is entitled to one vote.

The Company had reserved shares of common stock for future issuances as follows:

	December 31,	
	2022	2021
Issuance of equity-based awards under stock plan	1,001,087	2,131,671
Issuance upon exercise of options under stock plan	4,570,432	2,439,253
Warrants (Pre-funded and March 31, 2022 Warrants)	20,720,440	—
Total	26,291,959	4,570,924

At the Market Offering Program

In September 2020, the Company filed a shelf registration statement on Form S-3 with the SEC which was declared effective by the SEC on November 20, 2020 (the "Form S-3"). On September 4, 2020, the Company entered into an Equity Distribution Agreement with Piper Sandler & Co. and Cantor Fitzgerald to sell shares of the Company's common stock, par value $0.0001 per common share, from time to time, through an "at the market offering" program having an aggregate offering price of up to $60,000,000 through which Piper Sandler and Cantor Fitzgerald will act as sales agents. During the years ended December 31, 2022 and 2021, the Company sold 54,763 shares and 1,432,627 shares, respectively, of common stock that were registered under the Form S-3 pursuant to the terms of the Equity Distribution Agreement and received proceeds net of discounts and offering costs of $0.1 million and $9.8 million, respectively, under the Equity Distribution Agreement.

Registered Direct Offerings

Related Party Transactions

On February 12, 2021, the Company entered into a Securities Purchase Agreement, with Eshelman Ventures relating to the issuance and sale (the "Offering") of 2,875,000 shares of the Company's common stock at a price per share of $7.29. The Offering closed on February 18, 2021 and the Company received aggregate proceeds from the Offering of approximately $20.9 million, net of offering costs. Eshelman Ventures is an entity wholly owned by the Company's chairman of the board.

In January 2022, the Company entered into an investment agreement (the "Investment Agreement") with Eshelman Ventures, LLC ("Eshelman Ventures"), a related party and, solely for purposes of Article IV and Article V of the Investment Agreement, Dr. Eshelman. Pursuant to the Investment Agreement, Eshelman Ventures agreed to purchase pre-funded warrants of up to 4,545,455 shares of the Company's common stock, par value $0.0001 per share, at a price of $2.20 per share, which was the consolidated closing bid price of the Company's common stock on Nasdaq on December 31, 2021, for an aggregate purchase price of $10 million. On the issuance date, the January 2022 Warrants were valued at the aggregate purchase price of $10 million and the Company received $9.9 million in net proceeds. As of March 31, 2022, the 4,545,455 January 2022 Warrants were exercisable upon shareholder approval, which was obtained on April 1, 2022; thereafter, the January 2022 Warrants were exercisable at any time until all of the January 2022 Warrants were exercised in full and have an exercise price of $0.0001.

On April 1, 2022, the Company held a Special Meeting of Stockholders at which the Company's stockholders voted on the proposal and approved for the purposes of Nasdaq Listing Rule 5635(b), of the issuance of up to 4,545,455 shares of the Company's common stock, par value $0.0001 per share, in the aggregate (subject to adjustment under certain circumstances), pursuant to the January 2022 Warrants issued to Eshelman Ventures, LLC. On April 1, 2022, Eshelman Ventures, after obtaining the requisite approval from the Company's stockholders at the Special Meeting, exercised the January 2022 Warrants in full and the Company issued 4,545,455 shares of Common Stock to Eshelman Ventures.

On March 31, 2022, the Company closed a registered direct offering of the Company's common stock with a single healthcare-focused institutional investor and Eshelman Ventures, LLC a related party, pursuant to which the Company issued 3,185,216 shares of common stock (consisting of 2,325,000 shares for the investor and 860,216 shares for Eshelman Ventures), 1,665,025 pre-funded warrants issued to the investor and common stock warrants to purchase up to 4,850,241 shares of common stock (consisting of 3,990,025 common stock warrants for the investor and 860,216 common stock warrants for

Eshelman Ventures) in a registered direct offering priced at-the-market under Nasdaq rules. The combined purchase price of each share of common stock and accompanying common stock warrant was $2.005 for the institutional investor and $2.325 for Eshelman Ventures, LLC. The purchase price per pre-funded warrant and accompanying common stock warrant was $2.004 for the institutional investor. The net proceeds from the offering was $9.3 million, after deducting underwriting discounts, commission and offering expenses. The 3,990,025 common stock warrants issued to the institutional investor are exercisable immediately, will expire five years from the exercisable date and have an exercise price of $1.88 per share. The 860,216 common stock warrants issued to Eshelman Ventures, LLC are exercisable upon the approval by the Company's stockholders of the exercise of previously issued securities, the January 2022 Warrants, will expire five years following the exercise date and have an exercise price of $2.20 per share. The 1,665,025 pre-funded warrants are exercisable at any time until all of the pre-funded warrants are exercised in full and have an exercise price of $0.001. The Company evaluated the pre-funded warrants and the common stock warrants under ASC 480, *Distinguishing Liabilities from Equity*, and ASC 815, *Derivatives and Hedging*, and determined the warrants meet the requirements to be classified in permanent equity.

The 1,665,025 pre-funded warrants issued to the institutional investor were exercised on June 6, 2022.

As of December 31, 2022, the Company has outstanding common stock warrants related to the registered direct offering as set forth below:

Number of Shares	Exercise Price	Expiration Date
3,990,025	$ 1.88	March 30, 2027
860,216	$2.20	March 30, 2027

Private placement equity financing

On October 27, 2022, the Company closed on definitive agreements with new biotechnology investors, existing investors, Company management and certain Company Directors for the issuance and sale of an aggregate of 45,178,811 shares of its common stock (or pre-funded warrants in lieu thereof) and warrants to purchase up to an aggregate of 45,178,811 shares of common stock and/or pre-funded warrants in a private placement offering priced at-the-market under Nasdaq rules. The purchase price per share and accompanying warrant was $0.9199 for all who participated in the deal (or $0.9198 per pre-funded warrant and accompanying warrant). Fifty percent of the warrants have an exercise price of $0.7949 per share and will expire on the date that is the later of: (i) 15 months from the date an increase in the number of authorized shares of common stock is effected, or (ii) one month after the public announcement of the topline Phase 3 platinum-resistant ovarian cancer ("PROC") data. The remaining 50% of the warrants will have an exercise price of $0.7949 per share and will expire 30 months from the date an increase in the number of authorized shares of common stock is effected. All of the warrants other than the pre-funded warrants are exercisable for cash only. The Company evaluated the pre-funded warrants under ASC 480, *Distinguishing Liabilities from Equity*, and ASC 815, *Derivatives and Hedging*, and determined that the Pre-Funded Warrants meet the requirements to be classified in permanent equity, while the Series A and Series B warrants are classified as a liability on the Company's consolidated balance sheets as of December 31, 2022. The net proceeds from the private placement equity financing were approximately $40 million and will be used to fund the Company's clinical development programs.

As of December 31, 2022, the Company has outstanding common stock warrants related to the private placement as set forth below:

Security	Number of Shares	Exercise Price	Expiration Date
Pre-Funded	15,870,199	$ 0.0001	No expiration
Series A	22,589,410	$ 0.7949	April 16, 2024 (1)
Series B	22,589,401	$0.7949	July 16, 2025

(1) These warrants expire on the date that is the later of: (i) 15 months from the date an increase in the number of authorized shares of common stock is effected (which occurred on January 17, 2023), or (ii) one month after the public announcement of the topline Phase 3 platinum-resistant ovarian cancer PROC data.

9. Stock Based Awards

Equity Incentive Plans

The Company's Board of Directors (the "Board") and stockholders approved the 2019 Equity Incentive Plan (the "2019 Plan") which became effective on September 12, 2019. The 2019 Plan is a successor to and continuation of all prior plans including the Company's 2014 Equity Incentive Plan and Aravive Biologics 2017 Equity Incentive Plan and the 2010 Equity Incentive Plan, as amended (Prior Plans). As of December 31, 2022, the total number of shares of common stock available for issuance under the 2019 Plan was 673,591. In addition, if the shares subject to outstanding stock options or other awards under the Prior Plans: (I) terminate or expire prior to exercise or settlement; (II) are not issued because the award is settled in cash; (III) are forfeited because of failure to vest; (IV) or are reacquired or withheld (or not issued) to satisfy a tax withholding obligation or the purchase or exercise price, if any, such shares will become available for issuance under the 2019 Plan. Unless the Board provides otherwise, beginning January 1, 2020 with expiration of January 1, 2029, the total number of shares of common stock available for issuance will automatically increase annually on January 1 of each calendar year by 4.5% of the total number of issued and outstanding shares of common stock as of December 31 of the immediately preceding year. The 2019 Plan provides for granting of equity awards to employees, directors and consultants, including incentive stock options, nonstatutory stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards and performance awards.

Activity under the Company's stock option plans is set forth below:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value (in thousands)
Balances, January 1, 2022	2,439,253	$ 3.96		
Options granted	2,888,641	1.61		
Options cancelled	(757,462)	3.81		
Options exercised	—	—		
Balances, December 31, 2022	4,570,432	$ 2.50	7.2	$ 1,239
Outstanding and expected to vest as of December 31, 2022	4,100,681	$ 2.54	7.1	$ 1,184
Exercisable as of December 31, 2022	2,348,015	$ 2.89	5.3	$ 877

The intrinsic values of outstanding, vested and exercisable options were determined by multiplying the number of shares by the difference in exercise price of the options and the fair value of the common stock. The intrinsic value of stock options exercised during the year ended December 31, 2021 was $1.0 million. There were no stock options exercised during the year ended December 31, 2022.

Stock Options Granted to Employees

During the years ended December 31, 2022 and 2021, the Company granted stock options to officers, directors and employees to purchase shares of common stock with a weighted-average grant date fair value of $1.53 and $4.43 per share, respectively. The fair value is being expensed over the vesting period of the options, which is usually 4 years on a straight-line basis as the services are being provided. No tax benefits were realized from options and other share-based payment arrangements during the periods.

As of December 31, 2022, total unrecognized employee stock-based compensation related to stock options granted was $2.9 million, which is expected to be recognized over the weighted-average remaining vesting period of 2.5 years.

The fair value of employee stock options was estimated using the Black-Scholes model with the following weighted-average assumptions:

	December 31, 2022	December 31, 2021
Expected volatility	113.0%	114.2%
Risk-free interest rate	2.2%	0.8%
Dividend yield	0.0%	0.0%
Expected life (in years)	6.0	6.0

Determining Fair Value of Stock Options

The fair value of each grant of stock options was determined by the Company using the methods and assumptions discussed below. Each of these inputs is subjective and generally requires significant judgment to determine.

Expected Volatility – The expected volatility is based on the historical volatility of our common stock over the most recent period commensurate with the estimated expected term of our stock options.

Risk-Free Interest Rate – The risk-free rate assumption was based on the U.S. Treasury instruments with terms that were consistent with the expected term of the Company's stock options.

Expected Dividend – The expected dividend assumption was based on the Company's history and expectation of dividend payouts.

Expected Term – The expected term of stock options represents the weighted average period the stock options are expected to be outstanding. For option grants that are considered to be "plain vanilla", the Company has opted to use the simplified method for estimating the expected term as provided by the SEC. The simplified method calculates the expected term as the average time-to-vesting and the contractual life of the options.

Forfeiture Rate – Forfeitures were estimated based on historical experience.

Fair Value of Common Stock – The fair value of the underlying common stock is based upon quoted prices on Nasdaq.

Stock-based compensation expense, net of estimated forfeitures, is reflected in the statements of operations as follows (in thousands):

	Year Ended December 31,	
	2022	2021
Operating Expenses		
Research and development	$ 889	$ 932
General and administrative	1,671	1,325
Total	$ 2,560	$ 2,257

2014 Employee Stock Purchase Plan

The board of directors adopted, and the Company's stockholders approved, the 2014 Employee Stock Purchase Plan (the "ESPP") in March 2014. The ESPP became effective on March 20, 2014.

The maximum aggregate number of shares of common stock that may be issued under the ESPP per purchase period is 2,500 shares (which was adjusted for the reverse stock split that occurred in October 2018). Additionally, the number of shares of common stock reserved for issuance under the ESPP will increase automatically each year, beginning on January 1, 2015 and continuing through and including January 1, 2024, by the lesser of (i) 1% of the total number of shares of our common stock outstanding on December 31 of the preceding calendar year; and (ii) 50,000 shares of common stock (which was adjusted for the reverse stock split that occurred in October 2018). The Board may act prior to the first day of any calendar year to provide that there will be no January 1 increase or that the increase will be for a lesser number of shares than would otherwise occur. Shares subject to purchase rights granted under the ESPP that terminate without having been exercised in full will not reduce the number of shares available for issuance under the ESPP.

An employee may not be granted rights to purchase stock under the ESPP if such employee (i) immediately after the grant would own stock possessing 5% or more of the total combined voting power or value of the Company's common stock, or (ii) holds rights to purchase stock under the ESPP that would accrue at a rate that exceeds $25,000 worth of our stock for each calendar year that the rights remain outstanding.

The administrator may approve offerings with a duration of not more than 27 months and may specify one or more shorter purchase periods within each offering. Each offering will have one or more purchase dates on which shares of common stock will be purchased for the employees who are participating in the offering. The administrator, in its discretion, will determine the terms of offerings under the ESPP.

The ESPP permits participants to purchase shares of our common stock through payroll deductions with up to 15% of their earnings. The purchase price of the shares will be not less than 85% of the lower of the fair market value of our common stock on the first day of an offering or on the date of purchase. The fair value of the ESPP grants were immaterial for the years ended December 31, 2022 and 2021, respectively.

10. Income Taxes

The provision (benefit) for federal income taxes in 2022 and 2021 is as follows (in thousands):

	December 31,	
	2022	**2021**
Current		
Federal	$ —	$ —
State	—	—
	—	—
Deferred		
Federal	$ —	$ —
State	—	—
Total deferred tax expense	—	—
Total income tax expense	$ —	$ —

Income tax expense (benefit) in 2022 and 2021 differed from the amount expected by applying the statutory federal tax rate to the income or loss before taxes as summarized below:

	December 31,	
	2022	**2021**
Federal tax benefit at statutory rate	21%	21%
Change in valuation allowance	6.5%	(21)%
Section 382 limitation	(24.1)%	—
Other non-deductible expenses	—	(1)%
Stock based compensation	—	—
Other	(3.4)%	1%
Total	—	—

Deferred income taxes reflect the net tax effects of net operating loss and tax credit carryforwards and temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's net deferred tax assets at December 31, 2022 and 2021 are as follows (in thousands):

	December 31,	
	2022	2021
Net operating loss carry forwards	$ 504	$ 18,205
Research and development tax credits	232	404
Capitalized research and development	13,026	—
Stock based compensation and other	3,878	3,694
Operating lease obligation	856	1,339
Total deferred tax assets	18,496	23,642
Less: Valuation allowance	(18,189)	(23,179)
Deferred tax liabilities	—	—
Operating lease right-of-use assets	(307)	(463)
Net deferred tax assets	$ —	$ —

The Company's accounting for deferred taxes involves the evaluation of a number of factors concerning the realizability of its net deferred tax assets. The Company primarily considered such factors as its history of operating losses, the nature of the Company's deferred tax assets, and the timing, likelihood and amount, if any, of future taxable income during the periods in which those temporary differences and carryforwards become deductible. At present, the Company does not believe that it is more likely than not that the deferred tax assets will be realized; accordingly, a full valuation allowance has been established and no deferred tax asset is shown in the accompanying consolidated balance sheets.

The valuation allowance decreased by approximately $5.0 million in 2022 and increased $8.1 million in 2021.

At December 31, 2022, the Company has net operating loss carryforwards for federal income tax purposes of approximately $2.4 million. The Company also has state research and development tax credits of approximately $0.3 million, which begin to expire in 2036.

Due to the Company's lack of earnings history and uncertainties surrounding its ability to generate future taxable income, the net deferred tax assets have been fully offset by a valuation allowance. The deferred tax assets were primarily comprised of federal tax net operating losses and tax credit carryforwards. Utilization of net operating losses and tax credit carryforwards may be limited by the "ownership change" rules, as defined in Section 382 of the Internal Revenue Code (any such limitation, a "Section 382 limitation"). Similar rules may apply under state tax laws. The Company has performed an analysis to determine whether an "ownership change" occurred as of December 31, 2022. Based on this analysis, management determined that the Company did experience an ownership change as of April 1, 2022, which resulted in a significant impairment of the net operating losses and credit carryforwards.

The Company follows the provisions of FASB Accounting Standards Codification 740-10 (ASC 740-10), *Accounting for Uncertainty in Income Taxes*. ASC 740-10 prescribes a comprehensive model for the recognition, measurement, presentation and disclosure in consolidated financial statements of uncertain tax positions that have been taken or expected to be taken on a tax return. No liability related to uncertain tax positions is recorded in the consolidated financial statements. At December 31, 2022 and 2021, the Company's reserve for unrecognized tax benefits is approximately $165 thousand and $164 thousand, respectively. Due to the full valuation allowance at December 31, 2022, current adjustments to the unrecognized tax benefit will have no impact on the Company's effective income tax rate. The Company does not anticipate any significant change in its unrecognized tax benefits within 12 months of this reporting date. The Company includes penalties and interest expense related to income taxes as a component of other expense and interest expense, respectively, as necessary.

Because the statute of limitations does not expire until after the net operating loss and credit carryforwards are actually used, the statute is effectively open for all tax years. However, due to the above-mentioned ownership change and impairment of net operating loss and credit carryforwards, only net operating loss and credit carryforwards post April 1, 2022 are carried forward to future years for federal and state tax purposes.

A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows (in thousands):

	Amount
Balance at January 1, 2021	$ 164
Gross increase/ (decrease) related to prior year tax positions	—
Gross increase related to current year positions	—
Reductions to unrecognized tax benefits related to lapsing statute of limitations	—
Balance at December 31, 2021	$ 164
Gross increase/ (decrease) related to prior year tax positions	—
Gross increase related to current year positions	1
Reductions to unrecognized tax benefits related to lapsing statute of limitations	—
Balance at December 31, 2022	$ 165

All tax years remain open for examination by federal and state tax authorities.

11. Employee Benefit Plans

Defined Contribution Plan

The Company sponsors a 401(k) Plan, which stipulates that eligible employees can elect to contribute to the 401(k) Plan, subject to certain limitations of eligible compensation. The Company may match employee contributions in amounts to be determined at the Company's sole discretion. Employer contributions were $103 thousand and $88 thousand for the years ended December 31, 2022 and 2021, respectively.

12. Net loss per share of Common Stock

The following table summarizes the computation of basic and diluted net loss per share attributable to common stockholders of the Company (in thousands, except per share data):

	Year Ended December 31,	
	2022	**2021**
Net loss	$ (76,322)	$ (39,151)
Basic and diluted net loss per share	$ (2.10)	$ (1.95)
Weighted-average shares used to compute basic and diluted net loss per share	36,372	20,070

Basic net loss attributable to common stockholders per share is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common shares outstanding for the period. Weighted-average number of common shares outstanding for the period includes the weighted average effect of the Company's outstanding pre-funded warrants, the exercise of which is *not* subject to contingencies and requires little or *no* consideration. Diluted net loss attributable to common stockholders per share is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common shares and dilutive common stock equivalents outstanding for the period, determined using the treasury-stock method and the as-if converted method, for convertible securities, if inclusion of these is dilutive. Because the Company has reported a net loss for the years ended December 31, 2022 and 2021, the Company did not have dilutive common stock equivalents and therefore diluted net loss per common share is the same as basic net loss per common share for those years.

The following potentially dilutive securities outstanding at the end of the years presented have been excluded from the computation of diluted shares outstanding:

	Year Ended December 31,	
	2022	**2021**
Options to purchase common stock	4,570,432	2,439,253
Common stock warrants	50,029,052	—

13. Subsequent Events

On January 17, 2023, Aravive, Inc. the Company filed a Certificate of Amendment (the "Certificate of Amendment") of the Company's Amended and Restated Certificate of Incorporation with the Secretary of State of the State of Delaware to increase the number of the Company's authorized shares of common stock, par value $0.0001 per share, from 100,000,000 to 250,000,000. The Certificate of Amendment was approved by the Company's stockholders at the Company's 2023 Special Meeting of Stockholders held on January 13, 2023.

Exhibit Index

Exhibit Number	Description
1.1	Equity Distribution Agreement, dated as of September 4, 2020 between Aravive, Inc., Piper Sandler & Co. and Cantor Fitzgerald & Co. (Incorporated herein by reference to exhibit number 1.1 of the Registration Statement on Form S-3 (File No. 333-248612) as filed with the SEC on September 4, 2020).
3.1	Amended and Restated Certificate of Incorporation (Incorporated herein by reference to the same numbered exhibit of our current report on Form 8-K (File No. 001-36361), as filed with the SEC on March 26, 2014).
3.2	Certificate of Amendment of Amended and Restated Certificate of Incorporation of Versartis, Inc. (Incorporated herein by reference to exhibit number 3.1 of our current report on Form 8-K (File No. 001-36361), as filed with the SEC on June 1, 2017).
3.3	Certificate of Amendment of Amended and Restated Certificate of Incorporation of Versartis, Inc. (Incorporated herein by reference to exhibit number 3.1 of our current report on Form 8-K (File No. 001-36361), as filed with the SEC on September 12, 2017).
3.4	Certificate of Amendment of Amended and Restated Certificate of Incorporation of Versartis, Inc. (Incorporated herein by reference to exhibit number 3.1 of our current report on Form 8-K (File No. 001-36361), as filed with the SEC on October 16, 2018).
3.5	Certificate of Amendment of Amended and Restated Certificate of Incorporation of Versartis, Inc. (Incorporated herein by reference to exhibit number 3.2 of our current report on Form 8-K (File No. 001-36361), as filed with the SEC on October 16, 2018).
3.6	Certificate of Correction to Certificate of Amendment of Amended and Restated Certificate of Incorporation of Aravive, Inc. (Incorporated herein by reference to exhibit number 3.6 on our annual report on Form 10-K (File No. 001-36361), as filed with the SEC on March 15, 2019).
3.7	Amended and Restated Bylaws. (Incorporated herein by reference to Exhibit 3.4 of our registration statement on Form S-1, as amended (File No. 333-193997), as filed with the SEC on March 6, 2014).
3.8	Certificate of Amendment of Amended and Restated Certificate of Incorporation of Versartis, Inc. (Incorporated herein by reference to exhibit number 3.1 of our current report on Form 8-K (File No. 001-36361), as filed with the SEC on January 18, 2023).
4.1	Form of Stock Certificate. (Incorporated herein by reference to the same numbered exhibit of our quarterly report on Form 10-Q (File No. 001-36361), for the quarterly period ended March 31, 2014, as filed with the SEC on May 14, 2014).
4.2#	Description of Capital Securities.
4.3*	The Aravive, Inc. 2019 Equity Incentive Plan (incorporated by reference to Appendix A to the Definitive Proxy Statement on Schedule 14A filed with the Securities and Exchange Commission on August 9, 2019).
4.4	Form of Pre-Funded Common Stock Purchase Warrant of Aravive, Inc. (Incorporated herein by reference to Exhibit 4.1 of our current report on Form 8-K (File No. 001-36361 as filed with the SEC on January 4, 2022).
10.1*	The Versartis 2009 Stock Plan, as amended. (Incorporated herein by reference to the same numbered exhibit of our registration statement on Form S-1 (File No. 333-193997), as filed with the SEC on February 18, 2014).
10.2*	Form of Notice of Stock Option Grant and Incentive Stock Option Agreement under 2009 Stock Plan of Versartis, Inc. (Incorporated herein by reference to the same numbered exhibit of our registration statement on Form S-1 (File No. 333-193997), as filed with the SEC on February 18, 2014).

Exhibit Number	Description
10.3*	Form of Notice of Stock Option Grant and Non-Statutory Stock Option Agreement under 2009 Stock Plan. (Incorporated herein by reference to the same numbered exhibit of our registration statement on Form S-1 (File No. 333-193997), as filed with the SEC on February 18, 2014).
10.4*	2014 Equity Incentive Plan. (Incorporated herein by reference to Exhibit 10.6 of our registration statement on Form S-1, as amended (File No. 333-193997), as filed with the SEC on March 6, 2014).
10.5*	Form of 2014 Equity Incentive Plan Stock Option Grant Notice and Stock Option Agreement of Versartis, Inc. (Incorporated herein by reference to Exhibit 99.5 of our registration statement on Form S-8 (File No. 333-194949), as filed with the SEC on April 1, 2014).
10.6*	Form of 2014 Equity Incentive Plan Restricted Stock Unit Grant Notice and Restricted Stock Unit Award Agreement of Versartis, Inc. (Incorporated herein by reference to Exhibit 10.1 of our current report on Form 8-K (File No. 001-36361), as filed with the SEC on April 17, 2014).
10.7*	Change in Control Severance Plan Established by Versartis, Inc. (Incorporated herein by reference to Exhibit 10.7 of our registration statement on Form S-1, as amended (File No. 333-193997), as filed with the SEC on March 10, 2014).
10.8*	2014 Employee Stock Purchase Plan. (Incorporated herein by reference to Exhibit 10.9 of our registration statement on Form S-1, as amended (File No. 333-193997), as filed with the SEC on March 6, 2014).
10.9*	Form of Indemnification Agreement by and between the Company and each of its directors and officers. (Incorporated herein by reference to Exhibit 10.10 of our registration statement on Form S-1, as amended (File No. 333-193997), as filed with the SEC on March 6, 2014).
10.10	Agreement and Plan of Merger and Organization among Versartis, Inc., Velo Merger Sub, Inc. and Aravive Biologics, Inc. dated as of June 3, 2018 (Incorporated herein by reference to Exhibit 2.1 of our current report on Form 8-K (File No. 001-36361 as filed with the SEC on June 4, 2018).
10.11†	Cancer Research Grant Contract, dated December 1, 2015, by and between the Cancer Prevention and Research Institute of Texas and Ruga Corporation (Incorporated herein by reference to Exhibit 10.1 of our registration statement on Form S-4/A (File No. 333-226594 as filed with the SEC on August 24, 2018).
10.12†	Exclusive License Agreement, dated January 25, 2012, by and between The Board of Trustees of the Leland Stanford Junior University and Ruga Corporation (Incorporated herein by reference to Exhibit 10.2 of our registration statement on Form S-4/A (File No. 333-226594 as filed with the SEC on August 24, 2018).
10.13†	Amendment to the Exclusive License Agreement, dated July 26, 2012, by and between the Board of Trustees of Leland Stanford Junior University and Ruga Corporation (Incorporated herein by reference to Exhibit 10.3 of our registration statement on Form S-4 (File No. 333-226594 as filed with the SEC on August 3, 2018).
10.14†	Amendment No. 2 to the Exclusive License Agreement, dated September 25, 2017, by and between The Board of Trustees of the Leland Stanford Junior University and Ruga Corporation (Incorporated herein by reference to Exhibit 10.4 of our registration statement on Form S-4 (File No. 333-226594 as filed with the SEC on August 3, 2018).
10.15†	Amendment No. 3 to the Exclusive License Agreement, dated September 25, 2017, by and between The Board of Trustees of the Leland Stanford Junior University and Ruga Corporation (Incorporated herein by reference to Exhibit 10.5 of our registration statement on Form S-4 (File No. 333-226594 as filed with the SEC on August 3, 2018).
10.16†	Master Manufacturing Services Agreement, dated July 11, 2016, by and between WuXi Biologics (Hong Kong) Limited and Aravive Biologics, Inc. (Incorporated herein by reference to Exhibit 10.6 of our registration statement on Form S-4/A (File No. 333-226594 as filed with the SEC on August 24, 2018).

Exhibit Number	Description
10.17†	License Agreement dated December 1, 2017, by and between WuXi Biologics (Hong Kong) Limited and Aravive Biologics, Inc. (Incorporated herein by reference to Exhibit 10.7 of our registration statement on Form S-4 (File No. 333-226594 as filed with the SEC on August 3, 2018).
10.18*	Indemnification Agreement dated October 17, 2016, by and between Ruga Corporation and Vinay Shah (Incorporated herein by reference to Exhibit 10.8 of our registration statement on Form S-4 (File No. 333-226594 as filed with the SEC on August 3, 2018).
10.19	Sublease dated August 21, 2018, by and among Versartis, Inc. and Eva Automation, Inc. (Incorporated herein by reference to Exhibit 10.1 of our current report on Form 8-K (File No. 001-36361 as filed with the SEC on September 20, 2018).
10.20*	Aravive, Inc. 2017 Equity Incentive Plan (Incorporated herein by reference to Exhibit 4.9 of our registration statement on Form S-8 (File No. 333-227865), as filed with the SEC on October 17, 2018).
10.21*	Aravive, Inc. 2010 Equity Incentive Plan, as amended (Incorporated herein by reference to Exhibit 4.10 of our registration statement on Form S-8 (File No. 333-227865), as filed with the SEC on October 17, 2018).
10.31*	Amendment to Offer Letter dated as of April 8, 2020 by and between Aravive, Inc. and Gail McIntyre. (Incorporated herein by reference to Exhibit 10.7 of our current report on Form 8-K (File No. 001-36361 as filed with the SEC on April 9, 2020)
10.32††	Collaboration and License Agreement between Aravive, Inc. and 3D Medicines Inc. dated November 6, 2020 (Incorporated herein by reference to Exhibit 10.1 of our current report on Form 8-K (File No. 001-36361 as filed with the SEC on November 10, 2020)
10.33*	Consulting Agreement, dated December 31, 2020, between Aravive, Inc. and Ray Tabibiazar (Incorporated herein by reference to Exhibit 10.1 of our current report on Form 8-K (File No. 001-36361 as filed with the SEC on January 1, 2021)
10.34*	Offer Letter, dated September 8, 2020 between Reshma Rangwala and Aravive, Inc. (Incorporated herein by reference to Exhibit 10.48 of our Annual Report on Form 10-K (File No. 001-36361 as filed with the SEC on March 16, 2021)
10.35	Amendment to Offer Letter dated as of January 25, 2021 by and between Aravive, Inc. and Gail McIntyre (Incorporated herein by reference to Exhibit 10.1 of our current report on Form 8-K (File No. 001-36361 as filed with the SEC on January 27, 2021)
10.36	Securities Purchase Agreement dated as of February 12, 2021 by and between Aravive, Inc. and Eshelman Ventures, LLC (Incorporated herein by reference to Exhibit 10.1 of our current report on Form 8-K (File No. 001-36361 as filed with the SEC on February 16, 2021)
10.37	Sublease entered into as of June 8, 2021 by and between Aravive, Inc, and Grail, Inc. (Incorporated herein by reference to Exhibit 10.1 of our current report on Form 8-K (File No. 001-36361 as filed with the SEC on June 14, 2021)
10.38	Investment Agreement, dated as of January 3, 2022, by and among Aravive, Inc., Eshelman Ventures, LLC, and solely for purposes of Article IV and V of the Investment Agreement, Fredric N. Eshelman, Pharm.D. (Incorporated herein by reference to Exhibit 10.1 of our current report on Form 8-K (File No. 001-36361 as filed with the SEC on January 4, 2022)
10.39*	Offer Letter, dated February 20, 2022 and effective as of March 22, 2022, between Leonard Scott Dove and Aravive, Inc. (Incorporated herein by reference to Exhibit 10.1 of our current report on Form 8-K (File No. 001-36361 as filed with the SEC on March 22, 2022)

Exhibit Number	Description
10.40	Form of Securities Purchase Agreement, dated March 29, 2022 by and between Aravive, Inc. and the purchaser party thereto (Incorporated herein by reference to Exhibit 10.1 of our current report on Form 8-K (File No. 001-36361 as filed with the SEC on March 31, 2022).
10.41	Form of Securities Purchase Agreement, dated March 29, 2022 by and between Aravive, Inc. and Eshelman Ventures, LLC (Incorporated herein by reference to Exhibit 10.1 of our current report on Form 8-K (File No. 001-36361 as filed with the SEC on March 31, 2022).
10.42	Offer Letter, dated June 2, 2022, by and between Aravive, Inc. and Rudy C. Howard (Incorporated herein by reference to Exhibit 10.1 of our current report on Form 8-K (File No. 001-36361 as filed with the SEC on June 3, 2022).
10.43	Consulting Agreement, dated June 2, 2022, by and between Aravive, Inc. and Vinay Shah (Incorporated herein by reference to Exhibit 10.2 of our current report on Form 8-K (File No. 001-36361 as filed with the SEC on June 3, 2022).
10.44	Separation Agreement and Release, dated June 2, 2022, by and between Aravive, Inc. and Vinay Shah (Incorporated herein by reference to Exhibit 10.3 of our current report on Form 8-K (File No. 001-36361 as filed with the SEC on June 3, 2022).
10.45	Offer Letter, dated June 13, 2022, by and between Aravive, Inc. and Dr. Robert B. Geller (Incorporated herein by reference to Exhibit 10.2 of our current report on Form 8-K (File No. 001-36361 as filed with the SEC on July 5, 2022).
10.46	Form of Side Letter Agreement by and among Aravive, Inc. and the persons party thereto (Incorporated herein by reference to Exhibit 10.2 of our current report on Form 8-K (File No. 001-36361 as filed with the SEC on October 26, 2022).
10.47	Form of Side Letter Agreement by and among Aravive, Inc. and the BVF Investor party thereto (Incorporated herein by reference to Exhibit 10.3 of our current report on Form 8-K (File No. 001-36361 as filed with the SEC on October 26, 2022).
10.48	Form of Registration Rights Agreement by and among Aravive, Inc. and the persons party thereto (Incorporated herein by reference to Exhibit 10.4 of our current report on Form 8-K (File No. 001-36361 as filed with the SEC on October 26, 2022).
10.49	Form of Affiliate Registration Rights Agreement, by and among Aravive, Inc. and the persons party thereto (Incorporated herein by reference to Exhibit 10.5 of our current report on Form 8-K (File No. 001-36361 as filed with the SEC on October 26, 2022).
10.50	Form of Securities Purchase Agreement, dated October 24, 2022, by and among Aravive, Inc. and the purchasers party thereto (Incorporated herein by reference to Exhibit 10.1 of our current report on Form 8-K/A (File No. 001-36361 as filed with the SEC on October 28, 2022).
10.51	Amendment No. 3 to Offer Letter dated as of February 1, 2023 by and between Aravive, Inc. and Gail McIntyre, Ph.D. (Incorporated herein by reference to Exhibit 10.1 of our current report on Form 8-K (File No. 001-36361 as filed with the SEC on February 6, 2023).
10.52	Amendment No. 1 to Offer Letter dated as of February 1, 2023 by and between Aravive, Inc. and Rudy Howard (Incorporated herein by reference to Exhibit 10.2 of our current report on Form 8-K (File No. 001-36361 as filed with the SEC on February 6, 2023).
10.53	Amendment No. 1 to Offer Letter dated as of February 1, 2023 by and between Aravive, Inc. and Robert Geller, M.D. (Incorporated herein by reference to Exhibit 10.3 of our current report on Form 8-K (File No. 001-36361 as filed with the SEC on February 6, 2023).

Exhibit Number	Description
10.54	Amendment No. 1 to Offer Letter dated as of February 1, 2023 by and between Aravive, Inc. and Leonard Scott Dove, Ph.D. (Incorporated herein by reference to Exhibit 10.4 of our current report on Form 8-K (File No. 001-36361 as filed with the SEC on February 6, 2023).
21.1#	List of Subsidiaries.
23.1#	Consent of BDO USA, LLP.
24.1#	Power of Attorney (included in the signature page hereto).
31.1#	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2#	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1#	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2#	Certification of 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 (embedded within the Inline XBRL and contained in Exhibit 101)

Filed herewith

† Registrant has been granted confidential treatment for certain portions of this agreement. The omitted portions have been filed separately with the SEC.

†† Registrant has omitted certain portions of this exhibit in accordance with Item 601 (b)(10) of Regulation S-K. The Company agrees to furnish unredacted copies of these exhibits to the SEC upon request.

* Indicates management contract or compensatory plan.

SIGNATURES

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

Aravive, Inc.

Date: March 15, 2023

By: /s/ Gail McIntyre
Gail McIntyre
Chief Executive Officer
(Principal Executive Officer)

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

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Gail McIntyre and Vinay Shah, and each of them, his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to sign any and all amendments to this report, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the SEC, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or either of them, or their or his substitutes or substitute, may lawfully do or cause to be done by virtue hereof.

Signature	Title	Date
/s/ Gail McIntyre Gail McIntyre	Chief Executive Officer and Director (Principal Executive Officer)	March 15, 2023
/s/ Rudy Howard Rudy Howard	Chief Financial Officer (Principal Financial Officer & Principal Accounting Officer)	March 15, 2023
/s/ Fredric N. Eshelman, Pharm.D. Fredric N. Eshelman, Pharm.D.	Director (Executive Chairman of the Board of Directors)	March 15, 2023
/s/ Amato Giaccia, Ph. D. Amato Giaccia, Ph. D.	Director	March 15, 2023
/s/ Michael W. Rogers Michael W. Rogers	Director	March 15, 2023
/s/ Eric Zhang Eric Zhang	Director	March 15, 2023
/s/ Sigurd C. Kirk Sigurd C. Kirk	Director	March 15, 2023
/s/ John A. Hohneker, M.D. John A. Hohneker, M.D.	Director	March 15, 2023
/s/ Peter T. C. Ho, M.D., Ph.D. Peter T. C. Ho, M.D., Ph.D.	Director	March 15, 2023

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