Building a premier medical dermatology company focused on developing and commercializing innovative therapeutic products for skin diseases

NOVAN.COM

2022 Annual Report

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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 001-37880

Novan, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**20-4427682**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
4020 Stirrup Creek Drive, Suite 110 Durham, North Carolina	**27703**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: **(919) 485-8080**

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

Title of Each Class	Trading Symbol(s)	Name of Each Exchange on Which Registered
Common Stock, $0.0001 par value	**NOVN**	**The Nasdaq Stock Market LLC**

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

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

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 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 definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

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

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

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

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

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

As of June 30, 2022, the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of common stock held by non-affiliates of the registrant was approximately $49.3 million (based on a closing price of $2.33 per share as reported by the Nasdaq Capital Market on June 30, 2022). For purposes of this calculation, shares of common stock beneficially owned by the registrant's officers, directors and certain stockholders as of June 30, 2022 have been excluded in that such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes. The registrant has no non-voting common equity.

The number of shares of registrant's common stock outstanding as of March 16, 2023 was 28,015,371.

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Forward-Looking Statements and Summary of Principal Risk Factors

This Annual Report on Form 10-K, or this Annual Report, contains forward-looking statements concerning our business, operations and financial performance and condition, as well as our plans, objectives and expectations. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking statements. These statements are often identified by the use of words such as "believe," "contemplate," "continue," "due," "goal," "objective," "plan," "seek," "target," "expect," "believe," "anticipate," "intend," "may," "will," "would," "could," "should," "potential," "predict," "project," or "estimate," and similar expressions or variations. These statements are based on the beliefs and assumptions of management based on information currently available to management. Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Except as may be required by law, we undertake no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future. As a result, any or all of our forward-looking statements in this Annual Report may turn out to be inaccurate. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed below and under the section entitled "Risk Factors" in this Annual Report and those discussed elsewhere in this Annual Report. These forward-looking statements speak only as of the date of this Annual Report.

The following summary briefly highlights the principal risks and uncertainties facing our business that could affect an investment in our common stock, which represent only a select portion of those risks. A more complete statement of those risks and uncertainties is set forth in the section entitled "Risk Factors" in this Annual Report. This summary is qualified in its entirety by that more complete statement.

- We have incurred net losses since our incorporation and anticipate that we will continue to incur net losses for the foreseeable future.

- We will need significant additional funding to continue our commercial operating activities and for the advancement of our product development programs, including potential commercialization efforts for SB206, beyond what is currently included in our operating forecast and related cash projection. As of December 31, 2022, we had an accumulated deficit of $310.3 million and cash and cash equivalents of $12.3 million. If we are unable to raise capital, we would be forced to delay, reduce, terminate or eliminate our product development programs, or our current and future commercialization efforts and/or delay, defer, or reduce our cash expenditures, or we may need to dissolve and liquidate our assets or seek protection under bankruptcy laws. If we are forced to terminate or eliminate our product development programs or pursue other strategic alternatives or corporate transactions, there can be no assurance that such actions would result in any additional stockholder value. If we are forced to wind down our operations, liquidate or seek bankruptcy protection, it is unclear to what extent we will be able to pay our obligations, and, accordingly, it is further unclear whether and to what extent any resources would be available for distributions to our stockholders, whereby, our stockholders may lose some or all of their investment.

- In March 2022, we acquired EPI Health, LLC, or EPI Health, and such acquisition is referred to as the EPI Health Acquisition. Integrating the EPI Health and legacy Novan businesses is a continuing process that involves risks associated with acquisitions and integrating acquired businesses. Failure to do so effectively may have an adverse effect.

- Raising additional capital, including through the issuance of shares of our common stock through the March 11, 2022 Equity Distribution Agreement with Oppenheimer & Co. Inc., may reduce the trading price of our common stock. Any future additional issuances of equity, or debt convertible into equity, may result in significant dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies, product candidates or commercial products.

- The price of our common stock has been and may continue to be volatile and fluctuate significantly, which could result in substantial losses for our existing stockholders.

- Our revenue is dependent upon sales of our medical dermatology products, and setbacks relating to the sale of such commercial products have and may impair our operating results, including if our competitors develop treatments for our commercial portfolio's target indications or more effectively execute their commercialization strategies, which could limit our commercial opportunity and profitability.

- Our products and product candidates may pose safety issues, cause adverse events, have side effects or have other properties that could delay or prevent the regulatory approval for our product candidates, limit the commercial profile of an approved label or result in significant negative consequences.

- Our product candidates, if approved, and our commercial products may face significant competition, and our failure to effectively compete may prevent us from achieving significant market penetration or share. We face, and will continue to face, competition in the development and marketing of products from academic institutions, government agencies, research institutions and biotechnology and pharmaceutical companies, including specialty and other large pharmaceutical companies, and over-the-counter, or OTC, companies and generic manufacturers. The dermatology competitive landscape is highly fragmented, with many mid-size and smaller companies competing in the prescription sector. To successfully compete for business with managed care and pharmacy benefits management organizations, we must often demonstrate that our products offer not only medical benefits, but also cost advantages as compared with other forms of care.

- Our research and development activities relate solely to developing nitric oxide-based therapeutics to treat a range of diseases with significant unmet needs, and if we do not successfully achieve regulatory approval for any of our product candidates or successfully commercialize them, we may not be able to continue as a business.

- Clinical drug development involves a lengthy and expensive process with uncertain timelines and outcomes, and results of earlier studies and trials may not be predictive of future trial results. The results of any further development activities may not be sufficient to support a new drug application, or NDA, submission for or regulatory approval of any of our product candidates.

- Ongoing or future product development activities may not be successful, including that our preclinical studies may not demonstrate proof-of concept or may show adverse toxicological findings, and our clinical trials may not show the requisite safety and efficacy of our product candidates. The regulatory approval processes of the Food and Drug Administration, or FDA, are lengthy, time-consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates on a timely basis or at all, our business will be substantially harmed.

- Delays or disruptions in the qualification of manufacturing facilities and processes or in the manufacture of our (i) active pharmaceutical ingredients, or APIs, including berdazimer sodium or any other Nitricil new chemical entities, or NCEs, or (ii) clinical trial materials and commercial supplies of any approved products, whether by us or any third-party manufacturer with whom we contract, including any delays in the transfer of technology to third-party manufacturers, could adversely affect our development timelines and result in increased costs of our development programs or in our breaching our obligations to others.

- We currently rely on third-party suppliers to provide the raw materials, finished goods and equipment that are used by us and our third-party manufacturers in the manufacture of our product candidates and commercial products. There are a limited number of suppliers for raw materials, including nitric oxide, and the equipment used to manufacture our product candidates. Any delay or disruption, especially in light of current global supply chain constraints, or price increases related to such manufacturing could adversely impact the timing or cost of our manufacturing activities or other associated development and commercialization activities.

- We currently rely on third-party logistics vendors to transport our raw materials, API, drug product and commercial products through our supply chain. Certain materials, including our API for our products in development, have designated hazard classifications that limit available transportation modes or quantities. Third-party logistics vendors may choose to delay or defer transportation of materials from time to time, which could adversely impact the timing or cost of our manufacturing activities or other associated development and commercialization activities.

- Many factors could cause production or distribution interruptions with the manufacture and distribution of any of our products and product candidates, including human error, natural disasters, pandemics, inflation, labor disputes, acts of terrorism or war, equipment malfunctions, or raw material shortages. If our commercial distribution partners are not able to satisfy our requirements within the expected timeframe, or are unable to provide us with accurate or timely information and data, including inventories and sales, serious adverse events, and/or product complaints, our business may be at risk. In addition, if specialty pharmacy services, including our third-party call center services, which provide patient support and financial services, prescription intake and distribution, reimbursement adjudication, and ongoing compliance support, are not effectively managed, the continuance of our sales of our commercial products or our product candidates, if approved, may be delayed or compromised. Finally, our third-party manufacturers may not be able to manufacture the materials required for our products or product candidates at a cost or in quantities necessary to make them commercially viable and have had and may in the future experience delays in manufacturing our products.

- We continue to assess global supply chain constraints, including any further impact of the COVID-19 pandemic and the military conflict between Ukraine and Russia, on our suppliers and vendors. Any delay could impact available inventories of our commercial products and our ability to meet demand.

- We rely on third parties to conduct some of our preclinical studies, clinical trials, stability and analytical testing, and regulatory activities. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may be unable to obtain regulatory approval for or commercialize any of our product candidates as planned or at all.

- We have entered into and rely on, and may enter into and rely on other, strategic relationships for the further development and commercialization of our products and product candidates. If we are unable to enter into such relationships on favorable terms or at all, or if such relationships are unsuccessful, if disputes arise between us and our strategic partners or if we fail to trigger contingent payments under such strategic relationships, we may be unable to realize the potential economic benefit of our products and product candidates.

- Changes to our leadership team or operational resources, including with the EPI Health Acquisition and integration, could prove disruptive to our operations and have adverse consequences for our business and operating results.

- If we are unable to obtain and maintain patent protection for our product candidates and commercial products, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully commercialize our technology, product candidates and commercial products may be impaired.

- As a result of our operating losses and negative cash flows from operations, the report of our independent registered public accounting firm on our December 31, 2022 financial statements includes an explanatory paragraph indicating that there was substantial doubt about our ability to continue as a going concern.

- We may not be able to achieve the objectives or successfully execute our strategy described in the sections entitled "Business" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" below.

PART I

Item 1. Business.

Overview

Novan, Inc. is a medical dermatology company focused on developing and commercializing innovative therapeutic products for skin diseases. Our goal is to deliver safe and efficacious therapies to patients, including developing product candidates where there are unmet medical needs. We are developing SB206 (berdazimer gel, 10.3%) as a topical prescription gel for the treatment of viral skin infections, with a current focus on molluscum contagiosum, or molluscum. In the first quarter of 2022, we completed the EPI Health Acquisition. EPI Health equips us with a commercial infrastructure across sales, marketing, and communications, as well as a dedicated market access and pharmacy relations team, and positions us as a fully integrated dermatology company with a pipeline of development candidates focused primarily on dermatological indications supported by a commercial platform to market and sell therapeutic products for skin diseases.

Following the acquisition, we employ approximately 90 staff, including sales personnel currently covering 42 territories. Through our acquisition of EPI Health, we promote products for plaque psoriasis, rosacea and acne. We also have a pipeline of potential product candidates using our proprietary nitric oxide-based technology platform, Nitricil, to generate new treatments for multiple indications.

We will continue to need additional funding to support our planned and future operating activities and make further advancements in our product development programs beyond what is currently included in our operating forecast and related cash projection. We do not currently have sufficient funds to complete commercialization of any of our product candidates that are under development, and our funding needs will largely be determined by our commercialization strategy for SB206 (berdazimer gel, 10.3%), subject to the regulatory approval process and outcome. We are pursuing a broad range of financing options that could be used to extend our cash runway, including, among other things, to further prepare for commercialization of SB206 following approval.

Further advancement of our molluscum program, including through the NDA process and potential commercialization of SB206, or advancement of any other early-stage or late-stage clinical program across our platform, is subject to our ability to secure additional capital. Sources of additional capital may potentially include (i) debt or equity financings, such as through sales of common stock, or (ii) other sources, such as partnerships, collaborations, licensing, grants or other strategic relationships. Any issuance of equity, or debt convertible into equity, would result in further significant dilution to our existing stockholders.

In addition to the regulatory progression of SB206, including implementing prelaunch strategy and commercial preparation, subject to obtaining additional financing or strategic partnering, we may progress (a) SB204, a topical monotherapy for the treatment of acne, by commencing a pivotal Phase 3 study, or (b) SB019, as a potential intranasal treatment option for respiratory infections.

Please refer to the section entitled “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in this Annual Report for further discussion regarding our current liquidity and our future funding needs in addition to the impact of the COVID-19 pandemic on our operations.

Recent Highlights

- In March 2023, we announced that the FDA completed its filing review of our NDA submitted in early January seeking marketing approval for berdazimer gel, 10.3% (SB206) for the topical treatment of molluscum. The FDA determined our application was sufficiently complete, no filing review issues were identified, the substantive review process had commenced, and we were assigned a Prescription Drug User Fee Act goal date of January 5, 2024.

2022 Highlights

- For the year ended December 31, 2022, we demonstrated growth in total prescriptions for our actively marketed portfolio:
  - Rhofade (oxymetazoline hydrochloride) - 33% annual growth for the year ended December 31, 2022 with 156,664 total prescriptions.
  - Wynzora (calcipotriene and betamethasone dipropionate) - 41,023 total prescriptions for the year ended December 31, 2022, following launch of the product in the third quarter of 2021.
  - Minolira (minocycline hydrochloride) - 61% annual growth for the year ended December 31, 2022 with 40,641 total prescriptions.
- In late December 2022, we announced that we had entered into an exclusive license agreement with Sato Pharmaceutical Co., Ltd., or Sato, granting Sato the right to develop, manufacture and market Rhofade (oxymetazoline hydrochloride 1% cream) for rosacea in the Japan territory. Under the exclusive license agreement, we received an upfront payment of $5.0 million in January 2023 and are entitled to receive a $2.5 million milestone payment at the time of marketing approval in Japan and royalty payments on net sales of the product in Japan. Sato will be responsible for obtaining regulatory approval

in Japan and will have the right to use EPI Health's U.S. dossier for Rhofade. Sato will also have a right of first negotiation related to Rhofade in certain other countries in the Asia Pacific region. A portion of the amounts of the upfront and milestone payments are payable by us to a third party under contractual obligations related to Rhofade.

- In early December 2022, we announced that we entered into an accounts receivable-backed factoring agreement with Bay View Funding, a wholly owned subsidiary of Heritage Bank of Commerce. The new $15.0 million factoring facility provides working capital in an amount that is up to 70% of EPI Health's gross eligible receivables.
- In July 2022, we announced the publication of positive efficacy and safety data from our completed B-SIMPLE 4 pivotal Phase 3 clinical study evaluating berdazimer gel, 10.3% for the treatment of molluscum in the peer-reviewed journal, *JAMA Dermatology*. Berdazimer gel, 10.3%, Novan's potential first-in-class topical nitric oxide-based prescription treatment, demonstrated favorable efficacy and safety with low adverse event rates.
- In June 2022, we announced the closing of a $15.0 million registered direct offering priced at-the-market under Nasdaq rules with an institutional investor.
- In March 2022, we announced the acquisition of EPI Health, a specialty pharmaceutical company focused on the U.S. dermatology market. The acquisition provided the commercial infrastructure for Novan to become a fully-integrated specialty dermatology company with a solid pipeline of development candidates complemented by a commercial foundation. In July 2022, we announced that we had reached agreement with Evening Post Group, LLC, or EPG, regarding payment, satisfaction and termination of our $16.5 million secured promissory note and security agreement associated with the EPI Health Acquisition. Novan and EPG agreed that, upon EPG's receipt of $10.0 million, which Novan subsequently paid, all outstanding indebtedness and obligations of Novan under the promissory note were fully satisfied, and accordingly, the promissory note and related security agreements were terminated.

Commercial Portfolio

Our commercial portfolio includes six branded prescription drugs that we acquired in the EPI Health Acquisition. We actively promote three medical dermatological products in the United States and derive revenue from the sale of these branded products through pharmaceutical wholesalers as well as direct to pharmacies. These prescription dermatology therapies are targeted to patients with plaque psoriasis, rosacea, and acne. The branded and promoted product portfolio currently includes Wynzora, Rhofade, and Minolira.

The following summarizes our complete commercial product portfolio:

Wynzora Cream (calcipotriene and betamethasone dipropionate cream), or Wynzora, is a combination of calcipotriene, a vitamin D analog, and betamethasone dipropionate, a corticosteroid, indicated for the topical treatment of plaque psoriasis in patients 18 years of age or older. EPI Health entered into a collaboration agreement with MC2 Therapeutics, or MC2, in August 2020, as amended effective January 1, 2022, for the commercialization of Wynzora in the United States, or the MC2 Agreement. Under the MC2 Agreement, MC2 retains full ownership of Wynzora. In particular, we use our commercial infrastructure to promote and sell Wynzora in return for retaining a share of net sales of Wynzora in the United States. The portion of net sales we retain varies depending on the aggregate annual net sales of the product, and ranges from a percentage in the mid-teens to a mid-single digit percentage as net sales reach certain thresholds. Additionally, MC2 also pays for certain incremental costs incurred by us in commercialization activities according to a budget to be agreed annually between the parties. The term of the MC2 Agreement expires in June 2028, unless earlier terminated by either party under certain conditions.

Rhofade (oxymetazoline hydrochloride cream, 1%), or Rhofade, is an alpha1A adrenoceptor agonist indicated for the topical treatment of persistent facial erythema associated with rosacea in adults. EPI Health acquired the rights to Rhofade in October 2019. In connection with that acquisition and other historical acquisitions related to Rhofade, we are required to make certain milestone payments based on future net sales of Rhofade along with paying a combined royalty on net sales of Rhofade and related products initially in the low double digits, which rate may increase based on the thresholds of net sales we achieve.

Minolira (biphasic minocycline hydrochloride immediate release/extended release 105 mg and 135 mg tablets), or Minolira, is indicated to treat inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 12 years of age and older. EPI Health acquired the rights to Minolira in the United States in August 2018, and we are required to pay certain milestones based on future sales of Minolira.

Cloderm (clocortoline pivalate cream 0.1%), or Cloderm, is indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses. EPI Health acquired the rights to Cloderm in September 2018. In connection with that acquisition, EPI Health is required to pay minimum royalty payments on net sales of Cloderm, subject to meeting certain net sales milestones.

Sitavig (acyclovir 50mg buccal tablets), or Sitavig, is indicated for the treatment of recurrent herpes labialis (cold sores) in immunocompetent adults. We are party to a license agreement EPI Health entered into with Vectans Pharma, or Vectans, for the rights to commercialize Sitavig in the United States and Canada.

Nuvail (poly-ureaurethane 16% nail solution), or Nuvail, is indicated for managing signs and symptoms of nail dystrophy, i.e. nail splitting or nail fragility, for intact or damaged nails. We are party to a license agreement EPI Health entered into for the sale of Nuvail and serve as an exclusive distributor of this product in the United States.

Research and Development Portfolio

Our proprietary technology platform leverages nitric oxide's naturally occurring anti-viral, anti-bacterial, anti-fungal, and immunomodulatory mechanisms of action to treat a range of diseases with significant unmet needs. Nitric oxide plays a vital role in the natural immune system response against microbial pathogens and is a critical regulator of inflammation. Our ability to harness nitric oxide and its multiple mechanisms of action has enabled us to create a platform with the potential to generate differentiated product candidates. The two key components of our nitric oxide platform are our proprietary Nitricil technology, which drives the creation of macromolecular NCEs and our formulation science, both of which we use to tune our product candidates for specific indications. Our ability to deploy nitric oxide in a solid form, on demand and in localized formulations allows us the potential to improve patient outcomes in a variety of diseases.

We have clinical-stage dermatology and anti-infective drug candidates with multi-factorial (SB204), anti-viral (SB206), anti-fungal (SB208), and anti-inflammatory (SB414) mechanisms of action. We have also introduced a possible anti-viral product candidate for the treatment of external genital warts (SB207). We have conducted or are currently conducting preclinical work on NCEs, including berdazimer sodium, and formulations for the potential treatment of (i) respiratory infections, including SARS-CoV-2, the virus that causes COVID-19 (SB019), (ii) antimicrobial indications for the adjacent companion animal health market (NVN4100), (iii) cervical intraepithelial neoplasia caused by high-risk human papilloma virus, or HPV, in the men's and women's health field (WH504 and WH602), and (iv) inflammatory disorders.

Our primary programmatic focus is on our molluscum product candidate, SB206, and we intend to continue to focus our near term development efforts on this program.

Priority Development Pipeline

We are currently focusing our efforts on our Priority Development Pipeline. We presently maintain exclusive, worldwide commercial rights for all product candidates currently in our pipeline, with the exception of the rights we have licensed to Sato to develop, use and sell SB204 and SB206 in Japan.

SB206, a Topical Anti-viral Treatment for Molluscum Contagiosum (a Viral Skin Infection)

We are developing SB206 (12% berdazimer sodium, 10.3% berdazimer) as a topical gel with anti-viral properties for the treatment of viral skin infections, with a current focus on molluscum contagiosum. Molluscum is a contagious skin infection caused by the molluscipoxvirus that affects up to six million people in the United States annually. The greatest incidence is in children aged one to 14 years. The average time to resolution is 13 months; however, 13% of children experience lesions that may not resolve in 24 months. There is no FDA-approved prescription drug treatment for molluscum. More than half of patients diagnosed with the infection are untreated. The majority of patients in the United States that receive treatment are treated with potentially painful procedures and the remaining are often prescribed products indicated for the treatment of external genital warts.

Following positive results of our phase 3 B-SIMPLE4 trial for SB206, in April 2022, we held a pre-NDA meeting with the FDA, and subsequently received written minutes related to this interaction. Based on the information provided and our consideration thereof, in early January 2023 we submitted an NDA to the FDA seeking marketing approval for berdazimer gel, 10.3% (SB206). In March 2023, we announced that the FDA completed its filing review of our NDA seeking marketing approval for berdazimer gel, 10.3% (SB206). The FDA determined our application was sufficiently complete, no filing review issues were identified, the substantive review process had commenced, and we were assigned a Prescription Drug User Fee Act goal date of January 5, 2024.

SB204, for the Treatment of Acne Vulgaris

SB204 is a product candidate designed as a once-daily, topical monotherapy for the treatment of acne vulgaris, a multi-factorial disease with multiple aspects of the disease pathology (immunomodulatory and anti-bacterial). Acne vulgaris is the most common skin condition in the United States. The disease ranges in severity from mild to severe cystic acne and causes both physical and psychological effects, including permanent scarring, anxiety, depression and poor self-esteem. Acne is a multi-factorial disease with several mechanistic contributors to the disease pathology, often requiring multiple treatments that address more than one of the major causes of acne pathogenesis. Localized nitric oxide delivery may provide immunomodulatory (anti-inflammatory) and anti-bacterial mechanisms of action from a single active ingredient. We believe that acne continues to be characterized as an unmet medical need due to the difficulty of balancing efficacy, systemic safety and cutaneous tolerability, as well as the growing concerns with anti-bacterial resistance with existing therapies. In our SB204 clinical development program, topical application of SB204 has been well-tolerated with no significant safety concerns identified. In maximal-use pharmacokinetic trials that we have conducted in adult and pediatric patients with acne vulgaris, we observed no detectable systemic exposure from SB204 following its topical application.

Based on the positive pivotal Phase 3 results in the SB206 molluscum development program, we believe we can optimize the trial design of a pivotal Phase 3 study for SB204 that has the potential to serve as a second pivotal trial to support an NDA submission. As such, our intention is to progress SB204 by commencing a pivotal Phase 3 study, subject to obtaining additional financing or strategic partnering.

Sato Agreement

In January 2017, we licensed rights to Sato to develop, use, and sell SB204 in certain topical dosage forms in Japan for the treatment of acne vulgaris, and to manufacture the finished form of SB204 for sale in Japan. In 2018, we licensed rights to Sato to develop, use, and sell SB206 in certain topical dosage forms in Japan for the treatment of viral skin infections, and to manufacture the finished form of SB206 for sale in Japan. The significant terms and the related accounting considerations of our licensing arrangement with Sato are further described in Note 14—"License and Collaboration Revenues" to the accompanying consolidated financial statements.

Pipeline Expansion Opportunities

Our pipeline expansion opportunities are as follows:

SB019, an Intranasal Treatment Option for COVID-19 or Other Respiratory Infections

We previously explored the use of our proprietary Nitricil technology to progress SB019, a potential intranasal treatment option for COVID-19 or other respiratory infections, targeting the reduction of viral shedding and transmission. Nitric oxide has generally demonstrated the ability to inhibit viral replication of viruses within the *Coronaviridae* family, and we have an extensive body of *in vitro* and *in vivo* data demonstrating the efficacy of our proprietary technology for other anti-viral indications. Based on the scientific literature and data available to-date related to berdazimer sodium and SB206, we believe that nitric oxide may inhibit viral replication by disrupting protein function critical for viral replication and infection through generation of reactive intermediates.

Based on the positive preclinical and clinical data demonstrating anti-viral effect of berdazimer sodium against multiple viruses, as well as the public health need to reduce breakthrough infections and transmission of COVID-19 and on our interactions with the FDA, we believe there may be an opportunity to expand beyond our preclinical work for the SB019 product candidate. However, the SB019 program is currently on hold with further advancement subject to obtaining additional financing or strategic partnering.

SB414, for the Treatment of Inflammatory Skin Diseases, including Atopic Dermatitis and Psoriasis

SB414 is a product candidate designed as a topical cream for the treatment of inflammatory skin diseases, with a focus on the treatment of atopic dermatitis and psoriasis. The SB414 program is currently on hold with further advancement subject to obtaining additional financing or strategic partnering.

SB208, for the Treatment of Athlete's Foot (Tinea Pedis) and Fungal Nail Infections (Onychomycosis)

SB208 is a product candidate designed as a topical broad-spectrum anti-fungal gel for the potential treatment of fungal infections of the skin and nails, including athlete's foot (tinea pedis) and fungal nail infections (onychomycosis). The SB208 program is currently on hold with further advancement subject to obtaining additional financing or strategic partnering.

SB207, for the Treatment of External Genital Warts

Genital warts are among the world's most common sexually transmitted diseases. We have previously evaluated SB206's anti-viral activity against genital warts caused by HPV. In response to our identification of targeted viral opportunities of high unmet need where we believe our nitric oxide releasing technology could provide clinical benefit to patients, we developed SB207, a new anti-viral product candidate for the treatment of external genital warts. Further advancement of SB207 is subject to further evaluation of clinical plans and developmental timelines, as well as obtaining additional financing or strategic partnering.

Advancement in Men's and Women's Health

We have been awarded federal grants of approximately $1.3 million from the National Institutes of Health, or NIH, and approximately $1.1 million from the U.S. Department of Defense's, or DoD, Congressionally Directed Medical Research Programs, or CDMRP. These grants have enabled the conduct of IND-enabling toxicology and pharmacology studies and other preclinical activity of a nitric oxide containing intravaginal gel (WH602) designed to treat high-risk HPV infections that can lead to cervical intraepithelial neoplasias, or CIN, and a non-gel formulation product candidate (WH504). Under the terms of these grants, we are entitled to receive the grant funds in the form of periodic reimbursements of our allowable direct expenses, allocated overhead, general and administrative expenses and payment of other specified amounts.

Companion Animal Health

We have initiated exploratory work to evaluate our new chemical entity, NVN4100, as a potential product candidate for antimicrobial indications in companion animal health. This program is currently on hold, pending the engagement of potential collaborators or strategic partners to progress this asset, including the conduct of additional studies and formulation work.

Our Customers

We primarily sell our medical dermatology prescription products direct to pharmacies and to national wholesaler channels. Our wholesalers and distributors purchase products from us and, in turn, supply products to retail drug store chains, independent pharmacies and others. As of December 31, 2022, three of our wholesaler customers accounted for more than 10% of our total accounts receivable balance at 25%, 13% and 12%, respectively.

Seasonality of Business

Our business is affected by the standard annual insurance deductible resets, as well as the purchasing patterns and concentration of our customers. In addition, certain dermatological conditions, such as acne, may be impacted by the warmer months and prescriptions may also be impacted based on the activities of those who are prescribed our products, such as school and summer activities; however, our business is not materially impacted by seasonality. There are no assurances that these historical trends will continue in the future.

Competition

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. We consider our primary potential competition to be a broad base of existing providers and drug developers of therapeutics in the field of dermatology. Product competition includes pharmaceutical generics, branded generics, pharmaceutical brands, biologics as well as over-the-counter, or OTC, products.

We expect continued future competition across research and drug development in various different fields of innovation; capital and resource allocation to many of these areas appears to be continuous and of a global nature. In addition, there are certain instances where competition extends into the medical procedure and the medical device spectrums of human health care. Any product candidates that we successfully develop and commercialize will compete with these existing therapies as well as new therapies that may become available in the future. Our success will be based in part on our ability to identify, develop and manage a portfolio of product candidates that are safer and more effective than competing products and therapies.

Pharmaceutical Industry

Our competitors include pharmaceutical companies and biotechnology companies, as well as universities and public and private research institutions. In addition, companies that are active in different but related fields represent substantial competition for us. Many of our competitors have significantly greater capital resources, larger research and development staffs and facilities and greater numbers of personnel in drug development, regulation, manufacturing and marketing than we do. These organizations also compete with us to recruit qualified personnel, attract partners for joint ventures or other collaborations, and license technologies that are competitive with ours. To compete successfully in this industry, we must identify novel and unique drugs or methods of treatment and then complete the development of those drugs as treatments in advance of our competitors.

Dermatology Sector

The dermatology competitive landscape is highly fragmented, with a large number of midsize and smaller companies competing in both the prescription sector and the OTC sector. Our competitors are pursuing the development and/or acquisition of pharmaceuticals, medical devices and OTC products that target the same diseases and conditions that we are targeting in dermatology. Competitive factors vary by product line and geographic area in which our products are sold. The principal methods of competition for our products include quality, efficacy, market acceptance, price, and marketing and promotional efforts.

Branded products often must compete with therapeutically similar branded or generic products or with generic equivalents. Such competition frequently increases over time. For example, if competitors introduce new products, delivery systems or processes with therapeutic or cost advantages, our products could be subject to progressive price reductions and/or decreased volume of sales. To successfully compete for business, we must often demonstrate that our products offer not only medical benefits, but also cost advantages as compared with other forms of care. Accordingly, we face pressure to continually seek out technological innovations and to market our products effectively.

Our major competitors, including Galderma Laboratories, Dermavant, Sol-Gel Technologies, Almirall, Verrica Pharmaceuticals, Journey Medical Corporation, Sun Pharma, Leo Pharma, Arcutis Biotherapeutics, Mayne Pharma, and Ortho Dermatologics, among others, vary depending on therapeutic and product category, dosage strength and drug-delivery systems, among other factors.

Generic Competition

We face increased competition from manufacturers of generic pharmaceutical products, who may submit applications to the FDA seeking to market generic versions of our products. In connection with these applications, the generic drug companies may seek to challenge the validity and enforceability of our patents through litigation. When patents covering certain of our products (if applicable) expire or are successfully challenged through litigation or in USPTO proceedings, if a generic company launches a competing product “at risk,” or when the regulatory or licensed exclusivity for our products (if applicable) expires or is otherwise lost, we may face generic competition as a result. Generic versions are generally significantly less expensive than branded versions,

and, where available, may be required to be utilized before or in preference to the branded version under third-party reimbursement programs, or substituted by pharmacies. Accordingly, when a branded product loses its market exclusivity, it normally faces intense price competition from generic forms of the product. To successfully compete for business with managed care and pharmacy benefits management organizations, we must often demonstrate that our products offer not only medical benefits, but also cost advantages as compared with other forms of care. Generic products generally face intense competition from other generic equivalents (including authorized generics) and therapeutically similar branded or generic products.

Intellectual Property

Our success depends in large part upon our ability to obtain and maintain proprietary protection for our product candidates and technologies and to operate without infringing the proprietary rights of others. We seek to avoid the latter by monitoring patents and publications that may affect our business, and to the extent we identify such developments, evaluating and taking appropriate courses of action. With respect to the former, our policy is to protect our proprietary position by, among other methods, filing for patent applications on inventions that are important to the development and conduct of our business with the United States Patent and Trademark Office, or USPTO, and its foreign counterparts. We also use other forms of protection, such as trademark, copyright and trade secret protection and confidentiality policies and procedures, to protect our intellectual property, particularly where we do not believe patent protection is appropriate or obtainable.

We own or have a license to issued patents and pending patent applications in the United States and in foreign jurisdictions (including applications filed in foreign jurisdictions and international or Patent Cooperation Treaty, or PCT, applications that have not yet entered national phase). Patent coverage lasts for varying periods according to the date of filing of the patent application or the date of grant or issuance of the patent and the legal term of patents in various countries where patent protection is obtained. Generally, patents issued for regularly filed applications in the United States are granted a term of 20 years from the earliest filing date of a non-provisional patent application. In addition, in certain instances, the term of a patent can be extended to recapture a portion of the USPTO delay in issuing the patent or may be shortened if a patent is terminally disclaimed over another patent that expires earlier. The term of a patent may also be eligible for patent term extension to recapture a portion of the term effectively lost as a result of the FDA regulatory review period. However, as to the FDA component, the extension term cannot be longer than five years and the total patent term including the restoration period must not exceed 14 years following FDA approval. The duration of foreign patents varies in accordance with provisions of applicable local law, but typically is also 20 years from the earliest filing date of a non-provisional patent application. However, the actual protection afforded by a patent varies on a product by product basis from country to country and depends upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions, the availability of legal remedies in a particular country and the validity and enforceability of the patent. Four of our marketed products, Rhofade, Minolira, Wynzora, and Sitavig, currently have one or more patents listed in the U.S. Food & Drug Administration Orange Book, or the Orange Book.

Nitricil Technology

We exclusively license from the University of North Carolina at Chapel Hill, or UNC, issued patents and pending applications directed to our library of Nitricil compounds, including patents issued in the United States, Canada, Italy, Great Britain, France, Ireland, Germany, Finland, Spain, Sweden, Switzerland, Japan and Australia with claims intended to cover NVN1000, the NCE for our current clinical-stage product candidates. Additionally, one such issued patent in the United States has claims specifically directed to the composition of matter of NVN1000. These patents and pending applications, if issued, are projected to expire in 2026 without taking into account any patent term extensions that may be available to us. Additionally, NVN1000 has been classified as an NCE, and patent term extensions may be available to extend the life of a United States patent that covers NVN1000 beyond 2026. We also own patents issued in the United States, China, Germany, Spain, France, Great Britain, Ireland, Italy and Switzerland directed to methods of manufacturing Nitricil compounds. These patents are projected to expire in 2032.

Formulation Science and Therapeutic Uses

We own patents issued in the United States, Australia, Germany, Spain, France, Great Britain, Ireland, Italy, China, Mexico, South Korea, Brazil, Canada, and Japan directed to methods of reducing sebum production using nitric oxide-releasing macromolecules, including, in certain embodiments, through the use of Nitricil compounds. We also own issued patents in the United States, Australia, Germany, Spain, Great Britain, Italy, Finland, France, Japan, Brazil, Canada, and China and pending applications filed in the United States, Brazil, Canada, China, Europe and Japan directed to the alcohol gel component of SB204 and SB206 and/or the SB204 and SB206 two-component formulations. We own patents issued in the United States, Australia, Germany, Spain, France, Italy, Great Britain, Brazil, Canada, South Korea, and Japan and are pursuing patent applications in the United States, China, and Europe directed to the use of nitric oxide-releasing compounds, including, in certain embodiments, Nitricil compounds, for the treatment of viral skin infections.

Altogether, our issued United States and foreign patents and pending United States and foreign patent applications, if issued, relating to one or more of our clinical-stage product candidates are projected to expire between 2026 and 2037, without taking into account any patent term extensions that may be available to us and assuming that prosecution is pursued to issuance with no shortening of term.

Rhofade

We own or have a license to U.S. patents that are listed in the Orange Book for Rhofade cream that includes oxymetazoline hydrochloride. In addition, we own patents and pending applications directed to compositions including oxymetazoline and/or to methods of treating rosacea or a symptom thereof with a composition including oxymetazoline including patents issued in the United States, Austria, Belgium, Switzerland and Liechtenstein, Czech Republic, Germany, Denmark, Spain, France, the United Kingdom, Greece, Ireland, Italy, the Netherlands, Norway, Poland, Portugal, Romania, Sweden, Turkey, Australia, Canada, Japan, Hong Kong, South Korea, Russia, Mexico, and Taiwan and pending applications in the United States, Brazil, China, New Zealand, and Europe.

Our owned and licensed patents and pending applications, if issued, relating to oxymetazoline altogether are projected to expire between 2024 and 2035 without taking into account any patent term extensions that may be available to us and assuming that prosecution is pursued to issuance with no shortening of term.

Minolira

We have licenses to patents and pending applications in the United States for 105 mg and 135 mg dosage Minolira tablets. Altogether our licensed patents and pending applications, if issued, for Minolira are projected to expire between 2025 and 2036 without taking into account any patent term extensions that may be available to us and assuming that prosecution is pursued to issuance with no shortening of term.

Wynzora

We have an exclusive license from MC2 Therapeutics to patents and pending applications in the United States relating to Wynzora cream including to a United States patent listed in the Orange Book for Wynzora cream. The licensed patents and pending applications, if issued, for Wynzora are projected to expire in 2027 without taking into account any patent term extensions that may be available to us and assuming that prosecution is pursued to issuance with no shortening of term.

Sitavig

We own the United States patents listed in the Orange Book for Sitavig tablets, which include acyclovir as an active ingredient. We also own or have an exclusive license to patents directed to mucosal bioadhesive slow release carriers including an active ingredient such as acyclovir and/or to methods of treating orofacial herpes using mucoadhesive buccal tablets including issued patents in the United States and Canada. Altogether, the owned and licensed patents relating to Sitavig are projected to expire between 2027 and 2030 without taking into account any patent term extensions that may be available to us and assuming that prosecution is pursued to expiration with no shortening of term.

Other Patented Technology

In addition to the patents and pending applications we own or have an exclusive license related to Nitricil compounds and our product candidates, we also own or have exclusive licenses to issued patents and pending applications in the United States and in foreign jurisdictions covering other nitric oxide-based therapeutics and/or methods of use in indications for dermatological and oncovirus-mediated diseases.

Trade Secrets

We rely upon trade secrets and know-how and continuing technological innovation to develop and maintain our competitive position. We seek to protect our proprietary information by limiting access to such information on a need-to-know basis exclusively. In addition, we seek to protect our proprietary information, in part, by requiring our employees, consultants, contractors and other advisors to execute nondisclosure and assignment of invention agreements, or to include such provisions in their consulting agreement, upon commencement of their respective employment or engagement. These agreements are designed to protect our proprietary information and, in the case of the invention assignment agreements and provisions, to grant us ownership of technologies that are developed through a relationship with a third party. These agreements 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 commercial partners, collaborators, employees and consultants 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.

Trademarks

Novan® is a registered trademark of our company in the United States, and we own or have a license to use trademarks for our commercial products. In addition, we have pending trademark applications in the United States, including for Nitricil.

Research and Development Arrangements

On April 29, 2019, we entered into a royalty and milestone payments purchase agreement with Reedy Creek Investments LLC, or Reedy Creek, pursuant to which Reedy Creek provided us funding in an initial amount of $25.0 million, for us to use primarily to

pursue the development, regulatory approval and potential commercialization activities for SB206, for the treatment of molluscum, and advance programmatically other activities with respect to SB414, for atopic dermatitis, and SB204, for acne.

On May 4, 2019, we entered into a development funding and royalties agreement, or the Funding Agreement, with Ligand Pharmaceuticals Incorporated, or Ligand, pursuant to which Ligand provided us funding of $12.0 million, which we used to pursue the development and regulatory approval of SB206, for the treatment of molluscum.

Please see Note 15—"Research and Development Agreements" to the accompanying consolidated financial statements included in this Annual Report for additional information regarding these research and development arrangements, including our obligations under these agreements.

Collaboration and Licensing Agreements

Wynzora Agreement

Effective as of January 1, 2022, EPI Health entered into the MC2 Agreement relating to the commercialization of Wynzora for treatment of plaque psoriasis in adults in the United States. Pursuant to the MC2 Agreement, which sets forth the collaborative efforts between EPI Health and MC2 to commercialize and promote Wynzora with MC2 in the United States, MC2 granted EPI Health an exclusive right and license under MC2's intellectual property rights to sell, or detail (as defined in the MC2 Agreement), and engage in certain commercialization activities with respect to Wynzora in the United States.

In exchange for the provision of promotional and commercialization activities, under the terms of the MC2 Agreement, we are entitled to receive:

- Reimbursement for all incremental costs incurred by us for the promotion and commercialization of Wynzora, including the incremental portion of our personnel and commercial operating costs. The supply price of Wynzora product inventory is also considered to be an incremental cost that is reimbursed by MC2.
- A commercialization fee equivalent to a percentage of net sales ranging from the mid-teens for net sales less than or equal to $65.0 million to the upper single digits for annual net sales greater than $105.0 million. We collect this commercialization fee by retaining our portion of the Wynzora product net sales we collect from our customers, with the remainder of the net sales being remitted by us to MC2 periodically in the form of a royalty payment, pursuant to the MC2 Agreement.
- A contingent incentive fee equal to 5% of the first $30.0 million in net sales of Wynzora sold in the United States by EPI Health in each of the 2022 and 2023 calendar years; provided that such incentive fee shall not exceed $1.5 million each year and such incentive fee shall not be credited to us until the royalty payments paid to MC2 surpass the amount of certain commercialization payments made previously by MC2.

The term of the MC2 Agreement runs until the seventh anniversary of the first commercial sale of Wynzora (as defined in the MC2 Agreement) or June 30, 2028, whichever is earlier. Either party may terminate the MC2 Agreement for the other party's material uncured breach or the bankruptcy or insolvency of the other party. MC2 may terminate the MC2 Agreement under certain scenarios, including for convenience with twelve months' advance notice to us, provided that the termination is not effective unless MC2 pays any unpaid historical liabilities related to commercialization of Wynzora owed by MC2. In the case of such termination, MC2 is also required to make an additional sunset payment to us, paid in installments over the 24 month period following termination. We may terminate the MC2 Agreement for convenience with twelve months' advance notice to MC2 provided that the termination is not effective unless we provide MC2 with a guarantee of the payment of any outstanding royalty payments, to the extent such royalty payments owed by us exceeds any unpaid historical liabilities related to commercialization of Wynzora owed by MC2.

For additional information about the Wynzora and MC2 Agreement, please refer to Note 13—"Net Product Revenues" to the accompanying consolidated financial statements included in this Annual Report.

Sato Agreement - SB206 and SB204

On January 12, 2017, we entered into a license agreement, and related first amendment, with Sato, relating to SB204, our drug candidate for the treatment of acne vulgaris in Japan, or the Sato Agreement. Pursuant to the Sato Agreement, we granted to Sato an exclusive, royalty-bearing, non-transferable right and license under certain of our intellectual property rights, with the right to sublicense with our prior written consent, to develop, use and sell products in Japan that incorporate SB204 in certain topical dosage forms for the treatment of acne vulgaris, and to make the finished form of such products.

On October 5, 2018, we entered into the second amendment, or the Sato Amendment, to the Sato Agreement, or collectively, the Amended Sato Agreement. The Sato Amendment expanded the Sato Agreement to include SB206, our drug candidate for the treatment of viral skin infections. Pursuant to the Amended Sato Agreement, we granted to Sato an exclusive, royalty-bearing, non-transferable license under certain of our intellectual property rights, with the right to sublicense with our prior written consent, to develop, use and sell products in Japan that incorporate SB204 or SB206 in certain topical dosage forms for the treatment of acne vulgaris or viral skin infections, respectively, and to make the finished form of such products. We or our designated contract manufacturer will supply finished product to Sato for use in the development of SB204 and SB206 in the licensed territory. The rights granted to Sato do not include the right to manufacture the API of SB204 or SB206; rather, we agreed to negotiate a commercial supply agreement pursuant to which we or our designated contract manufacturer would be the exclusive supplier to Sato of the API for the commercial manufacture of licensed products in the licensed territory. Under the terms of the Amended Sato Agreement, we also have exclusive rights to certain intellectual property that may be developed by Sato in the future, which we could choose to use for our own development and commercialization of SB204 or SB206 outside of Japan.

The term of the Amended Sato Agreement (and the period during which Sato must pay royalties under the amended license agreement) expires on the twentieth anniversary of the first commercial sale of a licensed product in the licensed field in the licensed territory (adjusted from the tenth anniversary of the first commercial sale in the Sato Agreement). The term of the Amended Sato Agreement may be renewed with respect to a licensed product by mutual written agreement of the parties for additional 2-year periods following expiration of the initial term. All other material terms of the Sato Agreement remain unchanged by the Sato Amendment.

Sato is responsible for funding the development and commercial costs for the program that are specific to Japan. We are obligated to perform certain oversight, review and supporting activities for Sato, including: (i) using commercially reasonable efforts to obtain marketing approval of SB204 and SB206 in the United States; (ii) sharing all future scientific information we may obtain during the term of the Amended Sato Agreement pertaining to SB204 and SB206; (iii) performing certain additional preclinical studies if such studies are deemed necessary by the Japanese regulatory authority, up to and not to exceed a total cost of $1.0 million; and (iv) participating in a joint committee that oversees, reviews and approves Sato's development and commercialization activities under the Amended Sato Agreement. Additionally, we have granted Sato the option to use our trademarks in connection with the commercialization of licensed products in the licensed territory for no additional consideration, subject to our approval of such use.

The Amended Sato Agreement may be terminated by (i) Sato without cause upon 120 days' advance written notice to us; (ii) either party in the event of the other party's uncured material breach upon 60 days' advance written notice; (iii) force majeure; (iv) either party in the event of the other party's dissolution, liquidation, bankruptcy or insolvency; and (v) by us immediately upon written notice if Sato challenges the validity, patentability, or enforceability of any of our patents or patent applications licensed to Sato under the Amended Sato Agreement. In the event of a termination, no portion of the upfront fees received from Sato is refundable.

For additional information about the Amended Sato Agreement, please refer to Note 14—"License and Collaboration Revenues" to the accompanying consolidated financial statements included in this Annual Report.

Sato Rhofade Agreement

In December 2022, we entered into a license agreement with Sato in which Sato was granted an exclusive, royalty-bearing, non-transferable right and license under certain of our intellectual property rights to develop, manufacture and market Rhofade for the treatment of rosacea in Japan, or the Sato Rhofade Agreement. In addition, per the Sato Rhofade Agreement, during a specified time period, Sato has an exclusive option to negotiate the terms under which its license would be expanded to include certain other countries in the Asia-Pacific region.

In exchange for the license granted to Sato, Sato agreed to pay us the following: (i) an upfront payment of $5.0 million; and (ii) a milestone payment of $2.5 million upon receipt of marketing approval of Rhofade for rosacea in the Japan territory. Sato also agreed to pay tiered royalty payments on net sales of the licensed product ranging over time from a percentage of net sales in the mid-teens to a percentage of net sales in the low single digits.

In addition, we are required to pay 25% of the upfront and milestone payment amounts to a third party under existing contractual obligations related to Rhofade and will also be required to pay a portion of the royalty amounts received under the Sato Rhofade Agreement to third parties, after which we will retain net royalties in the low single digits. For additional information about the Sato Rhofade Agreement related payment to a third party, please see below.

The initial term of the Sato Rhofade Agreement expires on the fifteenth anniversary of the first marketing approval of the licensed product for rosacea in the Japan territory. The term of the Sato Rhofade Agreement automatically extends for a further period of two years, unless either party gives one year's notice before the end of the initial term.

The Sato Rhofade Agreement may be terminated, among other reasons, (i) by Sato without cause upon 120 days' advance written notice to us; (ii) by either party in the event of the other party's uncured material breach upon 60 days' advance written notice; and (iii) by us if Sato challenges the validity, patentability or enforceability of any of our patents licensed to Sato under the Sato Rhofade Agreement.

For additional information about the Sato Rhofade Agreement, please refer to Note 14—"License and Collaboration Revenues" to the accompanying consolidated financial statements included in this Annual Report.

Rhofade Agreements

In connection with the Rhofade Acquisition Agreement that is described in Note 9—"Commitments and Contingencies" to the accompanying consolidated financial statements included in this Annual Report, EPI Health acquired rights to that certain Assignment and License Agreement, and through the Assignment and License Agreement, we license certain intellectual property from Aspect Pharmaceuticals, LLC, or Aspect, and such agreement, the Aspect Agreement. Under the terms of the Aspect Agreement, we, through EPI Health, have exclusive rights to, and are required to use commercially reasonable efforts to, commercialize the Rhofade product. We, through EPI Health, also have a duty to certain other parties to use commercially reasonable efforts to commercialize the Rhofade product based on historical acquisition agreements for Rhofade that were assumed by EPI Health.

The Aspect Agreement expires upon the last-to-expire of patent claims made under the assigned and licensed patents under the Aspect Agreement. Aspect may terminate the agreement upon a material breach by EPI Health after providing an opportunity to cure. Upon such termination by Aspect, EPI Health will cease all development and commercialization of Rhofade and EPI Health will assign and convey to Aspect its entire right, title and interest in and to the assigned intellectual property transferred under the Aspect Agreement.

Additionally, under the Aspect Agreement, the Rhofade Acquisition Agreement and the other historical acquisitions related to Rhofade, we are also required to pay a combined royalty on net sales of Rhofade and related products initially in the low double digits, which rate may increase based on the thresholds of net sales we achieve. We are also required to pay 25% of any upfront, license, milestone or other related payments received by EPI Health related to any sublicenses of Rhofade and related products.

In connection with two abbreviated new drug application, or ANDA, settlement agreements that EPI Health entered into in connection with Rhofade in 2021, EPI Health granted two ANDA filers a license to launch their own generic product for the treatment of erythema in rosacea. The actual timing of the launch of such generic products is uncertain because the launch dates of such products under the settlement agreements are subject to acceleration under certain circumstances. In the absence of any circumstances triggering acceleration, the earliest launch of such a generic product would be in the third quarter of 2026.

For additional information about the Rhofade Agreements, please refer to Note 12—"License and Collaboration Agreements" and Note 9—"Commitments and Contingencies" to the accompanying consolidated financial statements included in this Annual Report.

Minolira Agreements

In connection with the Minolira acquisition that is described in Note 9—"Commitments and Contingencies", EPI Health assumed the royalty obligation related to an ANDA settlement in connection with Minolira. Accordingly, we, through EPI Health, are required to pay a royalty to an ANDA filer in the low double digits of any generic form of Minolira that is the pharmaceutical equivalent of the 105 mg or 135 mg strength Minolira product.

For additional information about the Minolira Agreements, please refer to Note 12—"License and Collaboration Agreements" and Note 9—"Commitments and Contingencies" to the accompanying consolidated financial statements included in this Annual Report

UNC Agreements

We acquired exclusive rights to our library of Nitricil compounds pursuant to license agreements with UNC entered into in July 2007 and October 2009, which were subsequently amended, restated and consolidated in June 2012. We amended the consolidated license agreement in November 2012 to expand the scope of licensed patents to cover additional nitric oxide technologies in consideration for an upfront cash payment. We may obtain similar amendments to the consolidated license agreement to expand the scope of licensed patents to cover future additional nitric oxide technologies or as improvements on licensed technology and, if such amendments were executed, we may be required to pay additional upfront cash payments. In April 2016, November 2018 and November 2021, we amended the agreement to clarify the scope of the intellectual property of the consolidated license agreement and to make modifications to certain milestones under the consolidated license agreement.

Under the consolidated license agreement with UNC, we are granted an exclusive, worldwide license, with the ability to sublicense, under the licensed UNC patents, including those directed to Nitricil compounds, to develop and commercialize products utilizing the licensed technology. As partial consideration for the consolidated license agreement, we issued 19,105 shares of our common stock to UNC and a nominal upfront cash payment. Additionally, under the consolidated license agreement, we are obligated to pay UNC a running royalty percentage in the low single digits on net sales of licensed products (by us or any of our sublicensees, such as Sato), and to pay up to $425,000 to UNC in regulatory and commercial milestones on a licensed product by licensed product basis.

Under the consolidated license agreement, UNC controls prosecution activities with respect to licensed patents owned solely by UNC, we control prosecution activities with respect to licensed patents jointly owned by us and UNC and we are obligated to reimburse UNC for reasonable prosecution and maintenance costs. Pursuant to the consolidated license agreement, we have the first

right to defend against third-party claims of patent infringement with respect to the licensed products and to enforce the licensed patents against third-party infringers.

Unless earlier terminated by us at our election, or if we materially breach the agreement or become bankrupt, the consolidated license agreement remains in effect on a country by country and licensed product by licensed product basis until the expiration of the last to expire issued patent covering such licensed product in the applicable country, and upon such expiration, we receive a perpetual, unrestricted, fully-paid and royalty free right to develop and commercialize such licensed product in such country. As of December 31, 2022, the last to expire issued patent licensed to us under the consolidated license agreement is projected to expire in 2036. UNC may terminate the agreement or render the license granted thereunder non-exclusive for our material breach of the agreement that remains uncured after 90 days of receipt of written notice thereof from UNC and may also terminate the agreement or render the license granted thereunder non-exclusive upon providing written notice for our bankruptcy or insolvency-related events within 30 days of the occurrence of such events. We may terminate the agreement at any time for convenience upon providing written notice of not less than 30 days to UNC.

Other Research and Development Agreements

We have entered into various licensing agreements with universities and other research institutions under which we receive the rights, and in some cases substantially all of the rights, of the inventors, assignees or co-assignees to produce and market technology protected by certain patents and patent applications. In addition to the UNC License Agreement, which is our primary license agreement, the counterparties to our various other licensing agreements are the University of Akron Research Foundation, Hospital for Special Surgery, Strakan International S.a.r.l., which is a licensee of the University of Aberdeen, KIPAX AB and KNOW Bio.

We are required to make payments based upon achievement of certain milestones and will be required to make royalty payments based on a percentage of future sales of covered products or a percentage of sublicensing revenue. As future royalty payments are directly related to future revenues (either sales or sublicensing), future commitments cannot be determined. No accrual for future payments under these agreements has been recorded, as we cannot estimate if, when or in what amount payments may become due.

Separation Transaction and Licensing Arrangements with KNOW Bio, including Amendments

2015 Separation Transaction and Licensing Arrangements

In connection with the December 2015 separation of our non-dermatology assets to KNOW Bio, we granted to KNOW Bio, through two separate agreements, exclusive licenses, with the right to sublicense, to certain United States and foreign patents and patent applications controlled by us as of the execution date of the agreement, and, under one of the agreements, patents and patent applications which became controlled by us during the three years immediately following the execution date of such agreement, directed towards nitric oxide-releasing compositions and methods of manufacturing thereof, including methods of manufacturing Nitricil compounds, and other nitric oxide-based therapeutics.

Under the exclusive licenses, the following rights were retained by Novan or conveyed to KNOW Bio:

- Novan retained exclusive development and commercialization rights in all fields for any products containing certain specified particles, referred to as the Novan Particles, including those in our NVN1000 API and in other NCEs we are developing.
- Novan retained exclusive rights to develop and commercialize products utilizing the licensed technology in the Retained Dermatology Field, which is defined as the diagnosis, treatment, prevention, and palliation of diseases, conditions, or disorders of the skin, nails, hair or scalp in humans or animals, and all cosmetic uses for the skin, nails, hair or scalp, other than (i) for wound care through formulations of therapeutic product specifically designed to treat chronic wounds, thermal burns, radiation injury, accidental injury, surgical sites or scars, and (ii) therapeutic uses for treating cancer, excluding basal cell carcinoma, squamous cell carcinoma, precancerous conditions of the skin, actinic keratosis, actinic cheilitis, cutaneous horn, Bowen disease, radiation dermatosis, and dysplastic nevi. The Retained Dermatology Field was amended in 2017 as described in the section entitled “2017 Amendments to KNOW Bio Licensing Arrangements” in this Annual Report.
- KNOW Bio received exclusive rights to develop and commercialize products utilizing the licensed technology, excluding products containing the Novan Particles, in the KNOW Bio Field, which is defined as all fields of use except for the Retained Dermatology Field. The KNOW Bio Field was amended in 2017 as described in the section entitled “2017 Amendments to KNOW Bio Licensing Arrangements” in this Annual Report.

Under one of these exclusive license agreements, KNOW Bio granted to us an exclusive license, with the right to sublicense, under any patents and patent applications which became controlled by KNOW Bio during the three years immediately following the execution date of such agreement and directed towards nitric oxide-releasing compositions and methods of manufacturing thereof, including methods of manufacturing Nitricil compounds, and other nitric oxide-based therapeutics, but not towards medical devices, for use in the diagnosis, treatment, prevention, and palliation of diseases, conditions, or disorders in the Retained Dermatology Field, including but not limited to SB204, SB206, SB208, SB414 and our other presently-contemplated dermatology pipeline candidates. KNOW Bio granted us a right of first negotiation to obtain a license under any patents and patent applications generated

by KNOW Bio during the first three years following the execution date of the agreement and directed towards medical devices to develop and commercialize licensed products in the Retained Dermatology Field. Additionally, Novan and KNOW Bio also agreed that neither party would commercialize any products in the other's field of use during the first three years following the execution date of the agreement. The three-year period in which new patents and patent applications controlled by us or by KNOW Bio are added to the exclusive licenses and the three-year term of the commercialization non-compete both expired on December 29, 2018. Neither we nor, to our knowledge, KNOW Bio commercialized a product in the other party's field during this period.

Additionally, we granted to KNOW Bio exclusive sublicenses, with the ability to further sublicense, under certain of the United States and foreign patents and patent applications exclusively licensed to us from UNC and another third party directed towards nitric oxide-releasing compositions, including certain Nitricil compounds, to develop and commercialize products utilizing the licensed technology in the KNOW Bio Field. Under the exclusive sublicense to the UNC patents and applications, KNOW Bio is subject to the terms and conditions under the consolidated license agreement with UNC, including diligence obligations and milestone payment obligations.

Under the exclusive license agreements and sublicense agreements, we retain all rights under our owned and exclusively licensed patents and patent applications with respect to development and commercialization of products for use in the Retained Dermatology Field. The exclusive license agreements and sublicense agreements will continue for so long as there is a valid patent claim under the respective agreement, unless earlier terminated, and upon expiration continues as a perpetual non-exclusive license. Under each agreement, Novan and KNOW Bio have the right to terminate the agreement by written notice for the other party's material breach which remains uncured within 30 days of receipt of notice thereof. Novan also has the right to terminate each such agreement immediately upon written notice if KNOW Bio, its affiliates or sublicensees challenge the validity of any patent licensed in such agreement. KNOW Bio has the right to terminate each such agreement, with notice, for any reason upon ninety days advance written notice to the Company. The licenses granted by KNOW Bio to the Company in the agreements survive termination of the agreements.

2017 Amendments to KNOW Bio Licensing Arrangements

In October 2017, we entered into certain amendments, or the KNOW Bio Amendments, to the original license and sublicense agreements described above between us and KNOW Bio, or the Original KNOW Bio Agreements. Pursuant to the terms of the KNOW Bio Amendments, we re-acquired from KNOW Bio exclusive, worldwide rights under certain United States and foreign patents and patent applications controlled by us as of the execution date of the Original KNOW Bio Agreements, and patents and patent applications which became controlled by us during the three years immediately following the execution date of the Original KNOW Bio Agreements, directed towards nitric oxide-releasing compositions and methods of manufacturing thereof, including methods of manufacturing Nitricil compounds, and other nitric oxide-based therapeutics, to develop and commercialize products for all diagnostic, therapeutic, prophylactic and palliative uses for any disease, condition or disorder caused by certain oncoviruses, or the Oncovirus Field. KNOW Bio also granted to us an exclusive license, with the right to sublicense, under any patents and patent applications which became controlled by KNOW Bio during the three years immediately following the execution date of the Original KNOW Bio Agreements and directed towards nitric oxide-releasing compositions and methods of manufacturing thereof, including methods of manufacturing Nitricil compounds, and other nitric oxide-based therapeutics, but not towards medical devices, to develop and commercialize products for use in the Oncovirus Field. Additionally, KNOW Bio agreed that KNOW Bio would not commercialize any products in the Oncovirus Field during the first three years following the execution date of the Original KNOW Bio Agreements. The three-year period in which new patents and patent applications controlled by KNOW Bio are added to the exclusive license and the three-year term of the commercialization non-compete both expired on December 29, 2018.

The rights granted to us in the Oncovirus Field in the KNOW Bio Amendments continue for so long as there is a valid patent claim under the Agreements, and upon expiration continue on a perpetual non-exclusive basis, and are subject to the termination rights of KNOW Bio and us that are set forth in the Original KNOW Bio Agreements. In addition, under the KNOW Bio Amendments, KNOW Bio may terminate the rights granted to the Company in the Oncovirus Field without terminating the Original KNOW Bio Agreements.

Government Regulation

The FDA and comparable regulatory authorities in state and local jurisdictions and in other countries impose substantial and burdensome requirements upon companies involved in the clinical development, manufacture, marketing and distribution of drugs, such as those we are currently commercializing and those we are developing. These agencies and other federal, state and local entities regulate, among other things, the research and development, testing, manufacture, quality control, safety, effectiveness, labeling, storage, record keeping, approval, advertising and promotion, distribution, post-approval monitoring and reporting, sampling and export and import of our products and product candidates.

United States Government Regulation

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or FDCA, and its implementing regulations. The process of obtaining regulatory approvals and the subsequent compliance with applicable federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources.

The process required by the FDA before a drug may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests, animal studies and formulation studies in compliance with the FDA's Good Laboratory Practice, or GLP, regulations;
- submission to the FDA of an IND which must become effective before human clinical trials may begin;
- approval by an independent Institutional Review Board, or IRB, or ethics committee at each clinical site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with good clinical practice, or GCP, requirements to establish the safety and efficacy of the proposed drug product for each indication;
- submission to the FDA of an NDA after completion of all pivotal clinical trials;
- satisfactory completion of an FDA advisory committee review, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with current good manufacturing practice, or cGMP, requirements and to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity, and of selected clinical investigation sites to assess compliance with GCPs; and
- FDA review and approval of the NDA to permit marketing of the product for particular indications for uses in the United States.

Preclinical Studies

Preclinical studies include laboratory evaluation of product chemistry, toxicity and formulation, as well as animal studies to assess potential safety and efficacy. Prior to beginning the first clinical trial with a product candidate in the United States, a sponsor must submit an IND to the FDA, which is a request for authorization from the FDA to administer an investigational drug product to humans. To support an IND to conduct clinical trials, a sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data and any available clinical data or literature, among other things, to the FDA as part of an IND. Some preclinical testing may continue even after the IND is submitted. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to one or more proposed clinical trials and places the clinical trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, submission of an IND may not result in the FDA allowing clinical trials to commence.

Clinical Trials

Clinical trials involve the administration of the IND to human subjects under the supervision of qualified investigators in accordance with GCP requirements, which include the requirement that all research subjects provide their informed consent in writing for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. While the IND is active, progress reports summarizing the results of the clinical trials and non-clinical studies performed since the last progress report, among other information, must be submitted at least annually to the FDA, and written IND safety reports must be submitted to the FDA and investigators for serious and unexpected suspected adverse events, findings from other studies suggesting a significant risk to humans exposed to the drug, findings from animal or in vitro testing suggesting a significant risk to humans exposed to the drug, and any clinically important increased rate of a serious suspected adverse reaction compared to that listed in the protocol or investigator brochure.

In addition, an IRB at each institution participating in the clinical trial must review and approve the protocol for any clinical trial before it commences at that institution. Some clinical trials are overseen by an independent group of qualified experts organized by the sponsor, known as a data safety monitoring board or committee. Depending on its charter, this group may determine whether a trial may move forward at designated check points based on access to certain data from the trial. The FDA or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients 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 drug has been associated with unexpected serious harm to patients. In addition, information about certain clinical trials must be submitted within specific timeframes to the National Institutes of Health for public dissemination on its www.clinicaltrials.gov website.

Human clinical trials are typically conducted in three sequential phases, which may overlap or be combined:

- Phase 1 clinical trial: The drug is initially introduced into healthy human subjects or patients with the target disease or condition and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion and, if possible, to gain an early indication of its effectiveness.
- Phase 2 clinical trial: The drug is administered to a limited patient population with the specified disease or condition 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 and optimal dosage.
- Phase 3 clinical trials: The drug is administered to an expanded patient population with the specified disease or condition, generally at geographically dispersed clinical trial sites, in well-controlled clinical trials to generate enough data to statistically evaluate the efficacy and safety of the product for approval, to establish the overall risk-benefit profile of the product and to provide adequate information for the labeling of the product.

Post-approval trials, sometimes referred to as Phase 4 studies, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of an NDA.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final drug. In addition, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

Marketing Approval

Assuming successful completion of the required testing in accordance with all applicable regulatory requirements, the results of the preclinical studies and clinical trials, together with detailed information relating to the product's chemistry, manufacture, controls and proposed labeling, among other things, are submitted to the FDA as part of an NDA requesting approval to market the product for one or more indications for use. In most cases, the submission of an NDA is subject to a substantial application user fee.

In addition, under the Pediatric Research Equity Act of 2003, or PREA, as amended and reauthorized, certain NDAs or supplements to an NDA must contain data that are adequate to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements.

The FDA conducts a preliminary review of all NDAs within the first 60 days after submission, before accepting them for filing, to determine whether they are sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also 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. Under the Prescription Drug User Fee Act VII, or PDUFA, guidelines that are currently in effect, the FDA has a goal of ten months from the date of "filing" of a standard NDA for a new molecular entity to review and act on the submission. This review typically takes twelve months from the date the NDA is submitted to the FDA because the FDA has approximately two months to make a "filing" decision as to whether it will accept the application for filing. The actual review time may be significantly longer, depending on the complexity of the review, FDA requests for additional information and the sponsor's submission of additional information.

The FDA reviews an NDA to determine, among other things, whether the drug is safe and effective and whether the facility in which it is manufactured, processed, packaged or held meets standards designed to assure the product's continued safety, quality and purity. During its review, the FDA may raise additional issues or request additional data or information, during which time, the review period is generally suspended until such requests are received. This can delay, sometimes substantially, the FDA's review and potential approval of an application.

The FDA may refer an application for a novel drug to an advisory committee. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides 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.

Before approving an NDA, the FDA typically will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application 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 an NDA, the FDA may inspect one or more clinical trial sites to assure compliance with GCP requirements.

After evaluating the NDA and all related information, including the advisory committee recommendation, if any, and inspection reports regarding the manufacturing facilities and clinical trial sites, the FDA may issue an approval letter, or, in some cases, a complete response letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. A complete response letter generally contains a statement of specific conditions that must be met in order to secure final approval of the NDA and may require additional clinical or preclinical testing in order for FDA to reconsider the application. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when those conditions have been met to the FDA's satisfaction, the FDA will typically issue an approval letter.

Even if the FDA approves a product, it may limit the approved indications for use of the product, require that contraindications, warnings or precautions be included in the product labeling, require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess a drug's safety after approval, or require testing and surveillance programs to monitor the product after commercialization. The FDA may also place other conditions on approval, including the requirement for a risk evaluation and mitigation strategy, or REMS, to assure the safe use of the drug. If the FDA concludes a REMS is needed, the sponsor of the NDA must submit a proposed REMS. The FDA will not approve the NDA without an approved REMS, if required. A REMS could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools.

The FDA may prevent or limit further marketing of a product based on the results of post-marketing studies or surveillance programs or if unexpected safety or efficacy concerns arise. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval. In addition, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could impact the timeline for regulatory approval or otherwise impact ongoing development programs.

Special FDA Expedited Review and Approval Programs

The FDA offers a number of expedited development and review programs for qualifying product candidates. To be eligible for a fast track designation, the FDA must determine, based on the request of a sponsor, that a product is intended to treat a serious or life-threatening disease or condition and demonstrates the potential to address an unmet medical need for such disease or condition. Fast Track designation applies to the combination of the product candidate and the specific indication for which it is being studied. The sponsor of a Fast Track designated product candidate has opportunities for more frequent interactions with the applicable FDA review team during product development. In addition, the FDA may review sections of the NDA for a fast track designated product candidate on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA.

A product candidate intended to treat a serious or life-threatening disease or condition may also be eligible for breakthrough therapy designation to expedite its development and review. A product candidate can receive breakthrough therapy designation if preliminary clinical evidence indicates that the product candidate, alone or in combination with one or more other drugs or biologics, may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation includes all of the fast track program features, as well as more intensive FDA interaction and guidance beginning as early as Phase 1, and an organizational commitment to expedite the development and review of the product candidate, including involvement of senior managers.

Any marketing application for a drug submitted to the FDA for approval, including a product candidate with a fast track designation or breakthrough therapy designation, may also be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. An NDA is eligible for priority review if the product candidate is designed to treat a serious or life-threatening disease or condition, and, if approved, would provide a significant improvement in safety or effectiveness compared to available alternatives for such disease or condition. A priority review means that the goal for the FDA to review an application is six months, rather than the standard review of ten months under current PDUFA guidelines. Under the new PDUFA agreement, these six and ten-month review periods are measured from the "filing" date rather than the receipt date for NDAs for new molecular entities, which typically adds approximately two months to the timeline for review and decision from the date of submission.

In addition, product candidates studied for their safety and effectiveness in treating serious or life-threatening illnesses may be eligible for accelerated approval and may be approved upon a determination that the product candidate has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA generally requires a sponsor of a drug receiving accelerated approval to perform confirmatory studies to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical endpoint, and the drug may

be subject to accelerated withdrawal procedures if the sponsor fails to conduct the required confirmatory studies in a timely manner or if such studies fail to verify the predicted clinical benefit. In addition, the FDA currently requires, as a condition for accelerated approval, pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

Fast track designation, breakthrough therapy designation, priority review, and accelerated approval do not change the standards for approval and approval is not guaranteed. Such designation may, however, expedite the development or approval process. Even if a product candidate qualifies for one or more of these programs, the FDA may later decide that the product candidate no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

Post-Approval Requirements

Drugs manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences associated with the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims are subject to prior FDA review and approval. There also are continuing, annual program fee requirements for any marketed products.

The FDA may impose a number of post-approval requirements as a condition of approval of an NDA. For example, the FDA may require post-marketing testing, including Phase 4 clinical trials, and surveillance to further assess and monitor the product's safety and effectiveness after commercialization. The FDA may also limit the indications for use or may impose labeling or other requirements on the product.

In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and state agencies and are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP requirements and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance.

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

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

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties.

Other Health Care Laws

In addition to FDA restrictions on marketing of pharmaceutical products, other United States federal and state healthcare regulatory laws restrict business practices in the pharmaceutical industry, which include, but are not limited to, state and federal anti-kickback, false claims, and transparency laws with respect to drug pricing and payments and other transfers of value made to physicians and other healthcare providers.

The federal Anti-Kickback Statute prohibits, among other things, any person or entity from knowingly and willfully offering, paying, soliciting, receiving or providing any remuneration, directly or indirectly, overtly or covertly, to induce or in return for purchasing, leasing, ordering, or arranging for or recommending the purchase, lease, or order of any item or service reimbursable, in whole or in part, under Medicare, Medicaid or other federal healthcare programs. The term "remuneration" has been broadly

interpreted to include anything of value. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. In addition, 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.

The federal False Claims Act prohibits any person or entity from, among other things, knowingly presenting, or causing to be presented, a false, fictitious or fraudulent claim for payment to, or approval by, the federal government or knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government, or from knowingly making a false statement to avoid, decrease or conceal an obligation. A claim includes "any request or demand" for money or property presented to the United States government. Violation of the federal Anti-Kickback Statute may also constitute a false or fraudulent claim for purposes of the federal civil False Claims Act. Actions under the civil False Claims Act may be brought by the Attorney General or as a "*qui tam"* action by a private individual in the name of the government. Violations of the civil False Claims Act can result in very significant monetary penalties and treble damages. In addition, the civil monetary penalties statute imposes penalties against any person who 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. Many states also have similar fraud and abuse statutes or regulations that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Given the significant size of actual and potential settlements, it is expected that the government authorities will continue to devote substantial resources to investigating healthcare providers' and manufacturers' compliance with applicable fraud and abuse laws.

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, prohibits, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up 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.

In addition, there has been a recent trend of increased federal and state regulation of payments made to physicians and certain other healthcare providers. Under the federal Physician Payments Sunshine Act, certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, are required to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to payments and "transfers of value" provided to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician practitioners such as physician assistants and nurse practitioners, and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. In addition, certain states require implementation of compliance programs and compliance with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, impose restrictions on marketing practices, and/or tracking and reporting of pricing information and marketing expenditure as well as gifts, compensation and other remuneration or items of value provided to physicians and other healthcare professionals and entities.

Violation of any of such laws or any other governmental regulations that may apply to us can result in penalties, including, without limitation, administrative, civil and criminal penalties, damages, fines, disgorgement, contractual damages, reputational harm, diminished profits and future earnings, the curtailment or restructuring of our operations, exclusion from participation in federal and state healthcare programs and individual imprisonment.

Coverage and Reimbursement

Sales of our currently marketed products (and any other product candidates, if approved) by us or our commercial partners depend, in part, on the extent to which such products are covered by third-party payors, such as government healthcare programs, commercial insurance and managed healthcare organizations. These third-party payors are increasingly limiting coverage or reducing reimbursements for medical products and services. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products. Sales of our currently marketed products (and any other products for which we receive regulatory approval for commercial sale) therefore depend, in part, on the availability of coverage and adequate reimbursement from third-party payors. Third-party payors include government authorities, managed care plans, private health insurers and other organizations.

The process for determining whether a third-party payor will provide coverage for a drug typically is separate from the process for setting the price of such product or for establishing the reimbursement rate that the payor will pay for the product once coverage is approved. 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. A decision by a third-party payor not to cover our products or product candidates could reduce a physician's willingness to prescribe our products once approved and have a material adverse effect on our sales, results of operations and financial condition. Moreover, a third-party payor's decision to provide coverage for a

drug does not imply that an adequate reimbursement rate will be approved. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development. Additionally, coverage and reimbursement for products can differ significantly from payor to payor. One third-party payor's decision to cover a particular medical product or service does not ensure that other payors will also provide coverage for the medical product or service, or will provide coverage at an adequate reimbursement rate.

In addition, the United States government, state legislatures and foreign governments have continued implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results. Third-party payors are increasingly challenging the prices charged for medical products and services, examining the medical necessity and reviewing the cost-effectiveness of drugs, in addition to questioning safety and efficacy. If these third-party payors do not consider our products to be cost-effective compared to other available therapies, they may not cover our products after FDA approval or, if they do, the level of payment may not be sufficient to allow us to sell our products at a profit.

Healthcare Reform

A primary trend in the United States healthcare industry and elsewhere is cost containment. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medical products. For example, the Affordable Care Act, or ACA, among other things, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program; introduced 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; extended the Medicaid Drug Rebate Program to utilization of prescriptions of individuals enrolled in Medicaid managed care plans; subjected drug manufacturers to new annual fees based on pharmaceutical companies' share of sales to federal healthcare programs; and created a new Patient Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

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

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. This included aggregate reductions of Medicare payments to providers, which went into effect on April 1, 2013 and, due to subsequent legislative amendments, will stay in effect through 2032, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022, unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act was signed into law, which, among other things, further reduced Medicare payments to several providers, including hospitals and imaging centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. In addition, on March 11, 2021, the American Rescue Plan Act of 2021 was signed into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, beginning January 1, 2024.

Recently there has also been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies. On August 16, 2022, the Inflation Reduction Act of 2022, or IRA, was enacted into law. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023), and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Secretary of the Department of Health and Human Services to implement many of these provisions through guidance, as opposed to regulation, for the initial years. For that and other reasons, it is currently unclear how the IRA will be effectuated.

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

increased interest by third party payors and governmental authorities in reference pricing systems and publication of discounts and list prices.

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 and services, which could result in reduced demand for our products once approved or additional pricing pressures. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our product candidates.

Data Privacy and Security

Pharmaceutical companies may be subject to United States federal and state and foreign data privacy, security and data breach notification laws governing the collection, use, disclosure and protection of health-related and other personal information. In the United States, numerous federal and state laws and regulations, including data breach notification laws, health information privacy and security laws and consumer protection laws and regulations govern the collection, use, disclosure, and protection of health-related and other personal information. In addition, certain foreign laws govern the privacy and security of personal data, including health-related data. Privacy and security laws, regulations, and other obligations are constantly evolving, may conflict with each other to complicate compliance efforts, and can result in investigations, proceedings, or actions that lead to significant civil and/or criminal penalties and restrictions on data processing.

Supply Chain

We continue to assess the impact of COVID-19 and related constraints on the global workforce on our supply chain and related vendors and global supply chain constraints across various industries, including interruption of, or delays in receiving, supplies of raw materials, API, drug product or finished goods from third-party manufacturers due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems and potential price increases. We are also continuing to evaluate the impacts of COVID-19 and global supply chain constraints on our new facility. We have completed the commissioning of our new facility to support various research and development and cGMP activities, including small-scale manufacturing capabilities for API and drug product. We are in the process of, and proceeding with the related preparatory activities associated with, qualifying and validating the manufacturing equipment for use in API production.

We currently rely on third-party suppliers to provide the raw materials that are used by us and our third-party manufacturers in the manufacture of our product candidates and commercial products. There are a limited number of suppliers for raw materials, including nitric oxide, that we use to manufacture our product candidates and commercial products. We also rely on third-party logistics vendors to transport our raw materials, API, and drug products through our supply chain. Certain materials, including our API, have designated hazard classifications that limit available transportation modes or quantities. Third-party logistics vendors may choose to delay or defer transportation of materials from time to time, especially in light of global supply chain constraints, which could adversely impact the timing or cost of our manufacturing supply chain activities or other associated development activities.

Manufacturing and Supplies

We have adopted a strategy of engaging with, utilizing and relying on third parties through partnerships, collaborations, licensing or other strategic relationships for the performance of activities, processes and services that (i) do not typically result in the generation of significant new intellectual property and (ii) can leverage their existing robust infrastructure, systems and facilities, as well as associated subject matter expertise. A parallel and inter-related strategic objective has been to manage our own internal resources, including our manufacturing capabilities.

Manufacturing and Supply of Commercial Products

We currently rely upon contract manufacturers to produce our commercial product portfolio and expect to continue to rely upon these contract manufacturers for any current and future EPI Health legacy product production. As with any supply agreement with contract manufacturers, obtaining finished goods of appropriate quality cannot be guaranteed. Our third-party manufacturers have other customers, depend on other third party suppliers for materials and may have other priorities that could affect their ability to perform their supply obligations to us satisfactorily and on a timely basis. Any of these occurrences would be beyond our control. For example, due to a manufacturing delay with one supplier, we expect that the Rhofade commercial product may be on back order in mid-March 2023 until at least early April 2023. We believe that this temporary "stock out" of Rhofade may impact the overall prescription volume for Rhofade, but we expect that there will be a temporary increase in prescription volume when the product is back in stock. We expect to similarly rely on contract manufacturing relationships for any products that we may acquire in the future.

Preparatory Work for Product Candidates in Development

For our product candidates that are currently in development, which generally use the drug substance berdazimer sodium as the API, we have adopted a dual approach of working with third parties and developing certain focused internal manufacturing capabilities. With third parties, we are conducting manufacturing process feasibility studies with a full-scale API manufacturer that, if successfully completed, could lead to full-scale production of our API, while also establishing a strategic alliance with Orion

Corporation, or Orion, a Finnish full-scale pharmaceutical company with broad experience in drug manufacturing, to enable technology transfer and manufacturing of clinical trial materials for future clinical trials with our topical product candidates, and if any of our product candidates are approved, commercial supply of our nitric oxide-based drug products. Importantly, the Orion alliance is being structured to support major global markets in which we and our partners may pursue regulatory approvals for our product candidates. Within these arrangements with third parties, however, there are risks associated with these manufacturers that are similar to the manufacturing arrangements for our commercial products described above. Moreover, given the stage of these relationships, there are risks associated with the complexity, time and expense of technical transfer.

Internally, we have also worked to complete commissioning of our new facility to support various research and development and cGMP activities, including small-scale manufacturing capabilities for API and drug product. While we have more control over our internal manufacturing capabilities as compared to our relationships with third parties, we do face risks associated with operating a manufacturing facility, including supply chain matters, which have impacted and may further impact the validation of our new facility, and the inherent limitations that come from our internal capabilities being limited to small-scale manufacturing capabilities.

As we move forward with these initiatives, we will need significant additional funding to continue our operating activities, including these technical transfer projects, potential utilization and development of internal capabilities and cost structure changes, and to make further advancements in our product development programs, as described in the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources."

Business Segments

We manage our operations and allocate resources in two reporting segments, which represent (i) the promotion of commercial products for the treatment of medical dermatological conditions, or the Commercial Operations segment, and (ii) research and development activities related to the Company's nitric oxide-based technology to develop product candidates, or the Research and Development Operations segment.

We disclose information about our reportable segments based on the way that we organize segments within the Company for making operating decisions and assessing financial performance. See Note 20—"Segment Information" to the accompanying consolidated financial statements for certain financial information related to our reportable segments.

Human Capital

Employees

As of December 31, 2022, we had a total of 89 full-time employees, in addition to 1 part-time employee.

Of the 89 full-time employees as of December 31, 2022, 44 were our dermatology sales specialists, 9 were dedicated to our Nitricil technology and formulation science research and development, 7 were dedicated to our manufacturing capability and product operations, 8 were in clinical, medical, quality and regulatory operations, 7 were in commercial operations, marketing and market access, and 14 were in general and administrative functions including executives, human resources, finance and information technology. Our 1 part-time employee as of December 31, 2022 was in our technology and formulation science research and development function.

We also utilize consultants and contractors to support our operating activities and our employees.

Recruiting and retaining qualified personnel and key talent is critical to our success. Our business results depend in part on our ability to successfully manage our human capital resources. Factors that may affect our ability to attract and retain qualified employees include employee morale, competition from other employers and availability of qualified individuals. We recruit for talent in the biotechnology and pharmaceutical industry, which periodically experiences higher turnover rates than other industries. For example, in 2022, we experienced turnover, including within our commercial sales specialists. This turnover was mitigated by a robust recruiting effort, including extensive efforts to source and interview a talented and diverse pipeline of candidates.

Compensation and Benefits

We strive to provide robust compensation and benefits to our employees, while balancing the operational needs of the Company. In addition to salaries, compensation and benefit programs include annual bonuses, stock-based compensation awards, a 401(k) plan with employee matching opportunities, healthcare and insurance benefits, health savings and flexible spending accounts, paid time off and other employee assistance programs. Our ability to attract and retain key personnel who are necessary to the operation of the business and the development of our product candidates is critical to our success.

Other Information

We were incorporated under the laws of the State of Delaware in 2006. Our principal executive offices are located at 4020 Stirrup Creek Drive, Suite 110, Durham, NC 27703, and our telephone number is 919-485-8080.

We maintain an internet website at www.novan.com and make available free of charge through our website our Annual Report, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to

Sections 13(a) and 15(d) of the Securities Exchange Act of 1934, as amended, or the Exchange Act. We make these reports available through our website as soon as reasonably practicable after we electronically file such reports with, or furnish such reports to, the Securities and Exchange Commission, or the SEC. Additionally, the SEC maintains an internet website at www.sec.gov that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC. The information contained on, or that can be accessible through, our website is not incorporated by reference into, and should not be considered to be a part of, this Annual Report.

Item 1A. Risk Factors.

Our operations and financial results are subject to a high degree of risk. These risks include, but are not limited to, those described below, each of which may have a material and adverse effect on our business, results of operations, cash flows, financial condition and the trading price of our common stock. You should carefully consider the risks described below, together with all of the other information included in this Annual Report. The realization of any of these risks could have a significant adverse effect on our reputation, business, including our financial condition, results of operations and growth, which we refer to collectively in this section as our business, and ability to accomplish our strategic objectives. In that event, the trading price of our common stock could decline, and you may lose part or all of your investment.

Risks Related to Our Current Financial Position and Need for Additional Capital

We have incurred net losses since our inception and anticipate that we will continue to incur net losses for the foreseeable future. We will need significant additional funding to continue our business operations and for the advancement of our product development programs. If we are unable to raise capital when needed, we would be forced to delay, reduce, terminate or eliminate our product development programs or the commercialization efforts for our products and/or delay, defer, or reduce our cash expenditures, or we may need to dissolve and liquidate our assets or seek protection under bankruptcy laws.

We are a commercial-stage medical dermatology company with a limited operating history. Investment in pharmaceutical and biotechnology product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, obtain regulatory approval or become commercially viable. We have a history of losses and have not generated sufficient revenue to result in a profit from product sales. We have incurred losses in each period since inception, and may never achieve or maintain sustained profitability. For the years ended December 31, 2022, and December 31, 2021, we reported a net loss of $31.3 million and $29.7 million, respectively. As of December 31, 2022, and December 31, 2021, we had an accumulated deficit of $310.3 million, and $279.0 million, respectively, and there is substantial doubt about our ability to continue as a going concern.

Even with revenues derived from sales of our marketed products, we expect to continue to incur significant losses for the foreseeable future as we continue to spend substantial amounts on research and development, manufacturing and to commercialize our products and product candidates, if approved. We may also encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. Although we recognize revenue from product sales and we continue to earn amounts under our license and collaboration agreements, our revenue and profit potential is unproven and our future operating results are difficult to predict. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Additional financing may not be available to us on acceptable terms, or at all. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.

If we are forced to terminate or eliminate our product development programs or pursue other strategic alternatives or corporate transactions, there can be no assurance that such actions would result in any additional stockholder value. If we are forced to wind down our operations, liquidate or seek bankruptcy protection, it is unclear to what extent we would be able to pay our obligations, and, accordingly, it is further unclear whether and to what extent any resources would be available for distributions to our stockholders, whereby, our stockholders may lose some or all of their investment.

Raising additional capital may cause significant dilution to our existing stockholders, reduce the trading price of our common stock, restrict our operations or require us to relinquish rights to our technologies, products or product candidates.

Until such time as we can generate substantial product revenues, if ever, our ability to continue to operate our business, including our ability to advance our development programs, is dependent upon our ability to access additional capital through other sources, including partnerships, collaborations, licensing, grants or other strategic relationships, and/or through the issuance of debt or equity securities. Any issuance of equity or debt that could be convertible into equity would result in significant dilution to our existing stockholders. Debt financing, if available, involves and may involve agreements that include covenants requiring that we place liens on some or all of our assets or limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, effecting a change in control or declaring dividends. There can be no assurance that we will be able to obtain additional capital on terms acceptable to us, on a timely basis or at all. We currently do not have any committed sources of financing other than our accounts receivable factoring agreement, which requires us to meet certain conditions to utilize and there can be no assurance that we will meet those conditions.

Additionally, we have outstanding and exercisable warrants and options that if exercised may result in dilution to the interests of other stockholders and may reduce the trading price of our common stock. As of December 31, 2022, we had warrants to purchase approximately 5.5 million shares of common stock outstanding and exercisable with a weighted average exercise price of $2.86 per share. In addition, we had outstanding and exercisable options to purchase approximately 0.4 million shares of common stock as of December 31, 2022 with a weighted average exercise price of $18.70 per share.

We have entered into and rely on, and may enter into, engage in and rely on other, strategic relationships and transactions for the further development and commercialization of our products and product candidates and the expansion of our business, and if we are unable to enter into such relationships or transactions on favorable terms or at all, or if such are unsuccessful or if disputes arise between us and our strategic partners, we may be unable to realize the potential economic benefit of those products and product candidates.

We have entered into and rely on, and may enter into, engage in and rely on other, strategic relationships and transactions for the further development and commercialization of our products and product candidates and the expansion of our business, including out-licenses for commercialization of certain of our products and product candidates. In certain potential scenarios, the counterparty(ies) to such a strategic transaction have assumed and may assume responsibility for the planning, execution, or oversight of the clinical development and regulatory requirements for the associated products or product candidates and/or the commercialization of the products or product candidates. If we decide to engage in such a transaction and, as a result, no longer have significant involvement or responsibility for late-stage clinical development activities or commercialization, we would adjust our business strategy, operating plans, resources and capabilities accordingly. Alternatively, we may pursue a transaction in which the counterparty agrees to finance the continued development of one or more products or product candidates in exchange for future milestone or royalty payments.

However, there can be no assurance that we will be able to establish or enter into such arrangements on favorable terms, if at all, or that our current or future arrangements will be successful. If we are unable to establish successful agreements with suitable partners, we would face significant incremental costs, we may be required to limit the scope and number of our products and product candidates we can commercially develop or the territories in which we commercialize them or we might fail to commercialize products or programs for which a suitable collaborator or arrangement cannot be found.

Any strategic relationship or transaction may entail numerous risks, including taking on indebtedness or contingent liabilities; the issuance of equity securities which would result in dilution to our stockholders; assimilation of acquired operations, intellectual property, products and product candidates, including difficulties associated with integrating new personnel; risks and uncertainties associated with the other party to such a transaction, and our inability to generate revenue from acquired intellectual property, technology, products or operations sufficient to meet our objectives or even to offset the associated transaction and maintenance costs. Additionally, our current and future collaboration partners may not dedicate sufficient resources to the development and commercialization of our products and product candidates or may otherwise fail in their development and commercialization due to factors beyond our control. If we breach or fail to comply with any provision of a strategic arrangement, a collaborator may have the right to terminate, in whole or in part, such agreement or to seek damages. Some of our strategic arrangements are complex and involve sharing of certain data, know-how and intellectual property rights amongst the parties. Additionally, collaborators may not accept the transfer of critical methods and processes in order for development and commercialization work for our products and product candidates to take place. Our strategic partners could interpret certain provisions differently than we do, which could lead to unexpected or inadvertent disputes with such partners. Any one of our strategic partners could breach obligations, covenants or restrictions in our agreements, leading us into disputes and potential breaches of our agreements with other parties, which could have direct or indirect financial implications. If a strategic relationship terminates or is otherwise unsuccessful, we may need to identify and establish an alternative arrangement. This may not be possible, or we may not be able to do so on terms which are acceptable to us, in which case, it may be necessary for us to cease the development of the applicable product candidate, or conduct the remaining clinical development or commercialization of any product candidate on our own and with our own funds.

Our process of considering financial and strategic alternatives could adversely affect our business, financial condition, and results of operations.

We from time to time consider various financial and strategic alternatives to deliver value to our stockholders. Such alternatives might include, among other things, strategic acquisitions or in-licenses, out-licensing some or all of our products or product candidates, the sale of some or all of our assets, or a sale of our company, but there can be no assurance that we will be able to enter into such a transaction or transactions on a timely basis or at all or on terms that are favorable to us. We may pursue such alternatives at the same time as we seek to secure additional funding. This process could disrupt and create uncertainty concerning our business, regardless of whether we are able to obtain additional funding or complete any strategic alternatives, and poses other risks to our business, including:

- potential uncertainty in the marketplace concerning our ongoing viability as a business
- the possibility of disruption to our business and operations, including diversion of significant management time and resources towards the pursuit of funding and strategic alternatives
- impairment of our ability to attract and retain key personnel who are necessary to the operation of the business and the development of its product candidates

- restrictions on our business operations and ability to explore other strategic alternatives under any definitive agreement we may enter into as a result of this process; and
- potential future stockholder litigation relating to the strategic process that could prevent or delay the strategic process, and the related costs of such litigation.

If any of the foregoing risks were realized, our business, financial condition, and results of operations could be adversely affected.

Amounts under our factoring arrangement are subject to terms that may adversely affect our operations and financial condition.

Our wholly owned subsidiary, EPI Health, entered into a factoring agreement in December 2022. The factoring agreement provides for an up to $15.0 million credit facility which we may draw upon to the extent we have qualifying accounts receivable as defined in the agreement. The lender has the right to demand repayment of advances under the facility if the accounts receivable purchased by the lender remain unpaid after the payment period or if such accounts receivable are disputed, and amounts owed under the agreement are secured by the assets of EPI Health. Novan is not a party to the agreement, but in connection with EPI Health entering into the agreement, Novan guaranteed payment and performance of all obligations of EPI Health to the lender under the agreement pursuant to the terms of a continuing guaranty agreement. If the lender demands repayment and EPI Health fails to make such repayment, or if EPI Health causes or permits any other event of default as defined in the agreement, or fails to comply with covenants set forth in the agreement (including restrictions on incurring other debt under unsecured loans), EPI Health would be subject to additional expenses (and Novan would be responsible if such payments were not made by EPI Health) or possible foreclosure on EPI Health's assets that secure the obligations under the agreement. Such results could have a material adverse effect on our operations and financial condition.

The report of our independent registered public accounting firm on our consolidated financial statements for the year ended December 31, 2022, contains an explanatory paragraph regarding going concern, and we will need additional financing to execute our business plan, to fund our operations and to continue as a going concern.

Since inception, we have experienced recurring operating losses and negative cash flows and we expect to continue to generate operating losses and consume significant cash resources in the foreseeable future. These conditions raise substantial doubt about our ability to continue as a going concern without additional financing. As a result, our independent registered public accounting firm included explanatory paragraphs in its report on our 2022 consolidated financial statements, with respect to this uncertainty. Substantial doubt about our ability to continue as a going concern may materially and adversely affect the price per share of our common stock and we may have a more difficult time obtaining financing.

Integrating the EPI Health and legacy Novan businesses is a continuing process that involves risks associated with acquisitions and integrating acquired businesses. Failure to do so effectively may have an adverse effect.

Since our acquisition of EPI Health in March 2022, we have been working to integrate the EPI Health businesses, operations, processes, and systems with our own. Achieving the anticipated benefits of the EPI Health Acquisition depends in significant part upon our ability to integrate the businesses, operations, processes, and systems in an efficient and effective manner. This effort has required the dedication of significant management and external resources and significant expenditures that we expect will continue as we work to complete our integration efforts. Any inability of management to successfully integrate the companies could have a material adverse effect on the business and results of operations of the combined company.

Risks Related to the Development and Regulatory Approval of our Current and Future Product Candidates

We may expend our limited resources to pursue one or more product candidates or indications within our product development strategy, which has and may continue to change over time, and thus fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we intend to focus the work within our Research & Development segment on developing product candidates for specific indications that we identify as most likely to succeed, in terms of their potential both to gain regulatory approval and to achieve commercialization. As a result, we may forego or delay the pursuit of opportunities with other product candidates or in other indications with greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable product candidates. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to the product candidate.

If we do not successfully achieve regulatory approval for any of our product candidates or successfully commercialize them, all of which is a lengthy and expensive process with uncertain timelines and outcomes, we may not be able to continue as a business.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure or delay can occur at any time during the clinical trial process. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful. A number of companies in the pharmaceutical industry, and specifically the dermatology sector, have suffered significant setbacks in clinical trials, even after obtaining promising results in earlier preclinical studies or clinical trials. These setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway and safety or efficacy observations made in clinical trials, including previously unreported adverse events.

The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show the required safety profile or meet the efficacy endpoints despite having progressed through preclinical studies and initial clinical trials. Notwithstanding any potential promising results in earlier testing, we cannot be certain that we will not face similar setbacks. Even if our clinical development is completed for any of our product candidates, the results may not be sufficient to obtain regulatory approval for our product candidates.

On June 11, 2021, we announced positive top-line results from the Phase 3 B-SIMPLE4 clinical trial for SB206 for the treatment of molluscum contagiosum; however, we cannot assure you that the results from B-SIMPLE4 will be sufficient for the FDA to approve the NDA submitted for SB206 in January 2023 or that any additional clinical trials we may conduct for any of our other product candidates will achieve results that are sufficient to support an NDA submission for the applicable product candidates or regulatory approval of the product. We also cannot assure you that we will be able to obtain financing sufficient to advance development of one or more of our product candidates. In addition, our ongoing or future preclinical studies may not prove successful in demonstrating proof-of concept, or may show adverse toxicological findings, and even, if successful, may not necessarily predict that subsequent clinical trials will show the requisite safety and efficacy of our product candidates. Moreover, all of our clinical development efforts to date in our Research & Development segment have focused on the development of nitric oxide-based topical therapies. There can be no assurance that the intended or anticipated results from the use of nitric oxide-based therapies will be reaped, and that we, or our existing or potential future commercial partners, will successfully bring our product candidates to market. Because all of our current product candidates are based on nitric oxide and our Nitricil technology, the failure of our Nitricil technology to be safe or efficacious generally will have adverse implications for our entire product candidate pipeline. If, for any reason, our intended use of nitric oxide does not materialize, we may not be able to redeploy our resources to alternative components or raw materials, efficiently or at all.

Delay or termination of planned clinical trials for our product candidates would result in unplanned expenses and significantly adversely impact our remaining developmental activities and potential commercial prospects with respect to, and ability to generate revenues from, such product candidates.

We may experience delays in completing ongoing trials and initiating planned trials and we cannot be certain whether these trials or any other future clinical trials for our product candidates will begin on time, need to be redesigned, enroll an adequate number of patients on time or be completed on schedule, if at all. Clinical trials can be delayed or terminated for a variety of reasons, including delays or failures related to:

- the FDA disagreeing as to the design or implementation of our clinical trials;
- reaching agreement on acceptable terms with prospective clinical research organizations, or CROs, clinical trial sites and prospective strategic partners, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs, trial sites and partners;
- obtaining institutional review board, or IRB, approval at each site;
- adverse events occurring in clinical studies of our product candidates;
- recruiting suitable patients to participate in a trial;
- having patients complete a trial or return for post-treatment follow-up;
- clinical sites deviating from trial protocol;
- how we address patient safety concerns that arise during the course of a trial;
- adding a sufficient number of clinical trial sites;
- manufacturing sufficient quantities of product candidate for use in clinical trials;
- utilizing an adequate container and delivery device for the product candidate; or

- changes to our financial priorities or insufficient capital available to fund clinical trials.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by the Data Safety Monitoring Board, or DSMB, for such trial or by the FDA or other regulatory authorities for a variety of reasons.

If we encounter difficulties or delays enrolling patients in our clinical trials, our clinical development activities would be delayed or otherwise adversely affected.

The timely completion of clinical trials in accordance with their protocols depends on, among other things, the ability to enroll a sufficient number of patients who remain in the trial until its conclusion. The enrollment of patients depends on many factors, including:

- the patient eligibility criteria defined in the protocol;
- the size of the patient population required for analysis of the trial's primary endpoints;
- the proximity of patients to trial sites;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating;
- our ability to obtain patient consents; and
- the risk that patients enrolled in clinical trials will drop out of the trials before completion.

In addition, our clinical trials may compete for the recruitment of patients with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition may reduce the number and types of patients available to us, to the extent patients who might have opted to enroll in our trials instead opt to enroll in a trial being conducted by one of our competitors.

If we experience delays in enrollment for or the completion, or termination, of our clinical trials for our product candidates, we may experience increased costs, have difficulty raising capital through non-dilutive or dilutive sources, and have to slow down our product candidate development and regulatory approval process timelines. Further, the commercial prospects of our product candidates may be harmed and our ability to generate product revenues from any of these product candidates could be delayed or not realized at all. Any of these occurrences may significantly harm our business, financial condition and prospects. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

We rely on third parties to conduct some of our preclinical studies and our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may be unable to obtain regulatory approval for or commercialize any of our product candidates.

We currently do not have the ability to independently conduct preclinical studies that comply with the regulatory requirements known as good laboratory practice, or GLP, requirements. We also do not currently have the ability to independently conduct any clinical trials. The FDA and regulatory authorities in other jurisdictions require us to comply with regulations and standards, commonly referred to as good clinical practice, or GCP, requirements for conducting, monitoring, recording and reporting the results of clinical trials, in order to ensure that the data and results are scientifically credible and accurate and that the trial subjects are adequately informed of the potential risks of participating in clinical trials. We rely on medical institutions, clinical investigators, contract laboratories and other third parties, such as CROs, to conduct GLP-compliant preclinical studies and GCP-compliant clinical trials on our product candidates properly and on time. While we will have agreements governing their activities, we control only certain aspects of their activities and have limited influence over their actual performance. The third parties with whom we contract for execution of our GLP preclinical studies and our GCP clinical trials play a significant role in the conduct of these studies and trials and the subsequent collection and analysis of data. These third parties are not our employees and, except for restrictions imposed by our contracts with such third parties, we have limited ability to control the amount or timing of resources that they devote to our programs. Although we rely on these third parties to conduct our GLP-compliant preclinical studies and GCP-compliant clinical trials, we remain responsible for ensuring that each of our GLP preclinical studies and GCP clinical trials is conducted in accordance with its investigational plan and protocol and applicable laws and regulations, and our reliance on the third parties does not relieve us of our regulatory responsibilities. In addition, if any of our third parties terminate their involvement with us for any reason, we may not be able to enter into similar arrangements with alternative third parties within a short period of time or do so on commercially reasonable terms.

Many of the third parties with whom we contract 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 that could harm our competitive position. In addition, since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials in such clinical trial site. If the third parties conducting our GLP preclinical studies or our GCP clinical trials do not perform their contractual duties or obligations, experience work stoppages, do not meet expected deadlines, terminate their agreements with us or need to be replaced, or if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to our clinical trial protocols, GLPs or GCPs, or for any other reason, we may need to enter into new arrangements with alternative third parties. This could be difficult, costly or impossible, and our preclinical studies or clinical trials may need to be extended, delayed, terminated or repeated. As a result, we may not be able to obtain regulatory approval in a timely fashion, or at all, for the applicable product candidate, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase, and our ability to generate revenues could be delayed.

In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and may receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or the FDA concludes that the financial relationship may have affected the interpretation of the trial, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection by the FDA of any NDA we submit. Any such delay or rejection could prevent us from commercializing our future product candidates.

Our product candidates may pose safety issues, cause adverse events, have side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label or result in significant negative consequences following marketing approval, if any.

We, any partner with whom we may collaborate in the future, or the FDA may suspend, delay, require modifications to or terminate our clinical trials at any time, for various reasons, including the discovery of serious or unexpected toxicities or other safety issues experienced by trial participants. In addition, adverse events caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of adverse events or unexpected characteristics. To date, patients treated with our product candidates have experienced instances of drug-related cutaneous intolerability observations, including dryness, scaling, burning, erythema, itching, pain or irritation, and adverse events, including irritation and contact dermatitis.

If safety issues or unacceptable adverse events arise in the development of our product candidates, we, the FDA, the IRBs at the institutions in which our trials are conducted, or the DSMB could suspend or terminate our clinical trials or the FDA or comparable foreign regulatory authorities could order us to cease clinical trials or deny approval of our product candidates for any or all targeted indications. Treatment-related adverse events could also affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. In addition, these adverse events may not be appropriately recognized or managed by the treating medical staff. Any of the foregoing events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and may result in the loss of significant revenues to us, which would materially and adversely affect our results of operations and business.

The regulatory approval processes of the FDA are lengthy, time-consuming and inherently unpredictable, and if we, or a potential future partner, are ultimately unable to obtain regulatory approval for our product candidates on a timely basis or at all, our business will be substantially harmed.

The time required to obtain approval by the FDA is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any product candidate and it is possible that none of our existing product candidates or any product candidates we may seek to develop in the future ourselves or with a potential future strategic partner will ever obtain regulatory approval. Neither we nor any future collaborator is permitted to market any of our product candidates in the United States until we receive regulatory approval of an NDA from the FDA.

Prior to obtaining approval to commercialize a product candidate in the United States or abroad, we or our collaborators must demonstrate with substantial evidence from well-controlled clinical trials, and to the satisfaction of the FDA or foreign regulatory authorities, that such product candidates are safe and effective for their intended uses. Results from preclinical studies and clinical trials can be interpreted in different ways. Even if we believe the preclinical or clinical data for our product candidates are promising, such data may not be sufficient to support approval by the FDA and other regulatory authorities. For example, there are multiple methodologies for handling missing data and other statistical considerations to take into account

that the FDA may utilize when analyzing the robustness of any data set during NDA review. The FDA may also require us to conduct additional preclinical studies or clinical trials for our product candidates either prior to or post-approval, or it may object to elements of our clinical development program.

The FDA can delay, limit or deny approval of our product candidates or require us to conduct additional preclinical or clinical testing or abandon a program for many reasons, including:

- the FDA's disagreement with the design or implementation of our clinical trials;
- unfavorable or ambiguous results from our clinical trials;
- results that may not meet the level of statistical significance required by the FDA for approval;
- serious and unexpected drug-related adverse events experienced by participants in our clinical trials or by individuals using drugs similar to our product candidates;
- our inability to demonstrate to the satisfaction of the FDA that our product candidates are safe and effective for the proposed indication;
- the FDA's disagreement with the interpretation of data from preclinical studies or clinical trials;
- our inability to demonstrate that the clinical and other benefits of our product candidates outweigh any safety or other perceived risks;
- the FDA's requirement for additional preclinical studies or clinical trials;
- the FDA's disagreement regarding the formulation, container, dosing delivery device, labeling or the specifications of our product candidates;
- the FDA's failure to approve the manufacturing processes or facilities of third-party manufacturers with which we contract; or
- the potential for approval policies or regulations of the FDA to significantly change in a manner rendering our clinical data insufficient for approval.

Of the large number of drugs in development, only a small percentage successfully complete the FDA approval process and become commercialized. The lengthy approval process as well as the unpredictability of outcomes from future clinical trials may result in our failing to obtain regulatory approval to market our product candidates.

Even if we or a potential future partner, eventually complete clinical testing and receive approval of an NDA or foreign marketing application for our product candidates, the FDA may grant approval contingent on the performance of costly additional clinical trials, including Phase 4 clinical trials, or the implementation of a Risk Evaluation and Mitigation Strategy, or REMS, which may be required to ensure safe use of the drug after approval. The FDA also may approve a product candidate for a more limited indication or patient population than we originally requested, and the FDA may not approve the labeling that we believe is necessary or desirable for the successful commercialization of a product candidate. Any delay in obtaining, or inability to obtain, applicable regulatory approval would delay or prevent commercialization of that product candidate.

Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved, or commercialized in a timely manner, or at all, which could negatively impact our business.

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

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

Separately, in response to the COVID-19 pandemic, the FDA postponed most inspections of domestic and foreign manufacturing facilities at various points. Even though the FDA has since resumed standard inspection operations of domestic facilities where feasible, the FDA has continued to monitor and implement changes to its inspectional activities to ensure the safety of its employees and those of the firms it regulates as it adapts to the evolving COVID-19 pandemic, and any resurgence

of the virus or emergence of new variants may lead to further inspectional delays Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Interim, top-line or preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose interim, top-line, or preliminary data from our clinical trials, which are based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a full analyses of all data related to the particular trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the interim, top-line, or preliminary results that we report may differ from future results of the same trials, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Top-line and preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, top-line and preliminary data should be viewed with caution until the final data are available.

We may also disclose interim data from our clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between interim, top-line, or preliminary data and final data could significantly harm our business prospects.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our business in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular drug, product candidate or our business. If the interim, top-line, or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for and commercialize our product candidates, our business, operating results, prospects or financial condition may be harmed.

Regulatory approval of our product candidates by foreign regulatory authorities may be delayed or denied. We, or our current or potential future partners, may be subject to pricing controls imposed by foreign governments and regulatory authorities.

We, or any current or potential future partners, may seek regulatory approval of our product candidates from foreign regulatory authorities. Such regulatory authorities may impose additional regulations and guidelines that differ in form and substance from those imposed by their counterparts in the United States and with which we are more familiar. Accordingly, the regulatory approval of our product candidates in those foreign jurisdictions could be delayed, limited or denied altogether. This could limit the scope of or prevent the commercialization of our products in the future and adversely affect our financial performance. Further, in some countries, the pricing of pharmaceutical prescriptions is subject to governmental control, including, for example, Japan. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product candidate. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after coverage and reimbursement have been obtained. Reference pricing used by various countries and parallel distribution or arbitrage between low-priced and high-priced countries can further reduce prices. To obtain reimbursement or pricing approval in some countries, we or our current or potential future partners may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies, which is time-consuming and costly. If coverage and reimbursement of our product candidates are unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed.

Risks Related to the Commercialization of Our Products and Product Candidates, if such Product Candidates Complete Development and Receive Regulatory Approval

Our products face significant competition and our failure to effectively compete may prevent us from achieving significant market penetration.

The pharmaceutical industry and the markets in which our approved products compete are characterized by rapidly advancing technologies, intense competition and a strong emphasis on developing proprietary therapeutics. Numerous companies are engaged in the development, patenting, manufacturing and marketing of healthcare products competitive with those that we are commercializing and developing. We face competition from a number of sources, such as pharmaceutical companies, generic drug companies, biotechnology companies and academic and research institutions, many of which have greater financial resources, marketing capabilities, sales forces, manufacturing capabilities, research and development capabilities, clinical trial expertise, intellectual property portfolios, experience in obtaining patents and regulatory approvals for product candidates and other resources than we do. Some of the companies that offer competing products also have a broad range of other product offerings, large direct sales forces and long-term customer relationships with our target physicians, which could inhibit our market penetration efforts. In addition, certain of our products compete with other products, including OTC treatments, for a share of some patients' discretionary budgets and for physicians' attention within their clinical practices. To compete successfully in the marketplace, our approved products must demonstrate that the relative cost, safety and efficacy of such products provide an attractive alternative to existing and other new therapies. Such competition could lead to reduced market share for our products and contribute to downward pressure on the pricing of our products. Any of our product candidates that receive regulatory approval will be subject to the same risks.

Due to less stringent regulatory requirements in certain foreign countries, there are many more products and procedures available for use in those international markets than are approved for use in the United States. In certain international markets, there are also fewer limitations on the claims that our competitors can make about the effectiveness of their products and the manner in which they can market them. As a result, we expect our products and product candidates, if approved, could face more competition in these markets than in the United States.

If we are unable to maintain sales, marketing and distribution capabilities for our products and any future product candidate that receives regulatory approval, either through a commercial partner or internally, we may not be successful in commercializing and generating revenues from those products and product candidates, if approved.

Our ability to generate revenue from product sales and our prospects for profitability are substantially dependent on our and our collaborators' ability to effectively commercialize our products and expand their utilization. Following our acquisition of EPI Health, we have a sales, marketing and distribution infrastructure to support the commercialization of our products and product candidates, if approved. Our products and any future product candidates that receive regulatory approval depend on this commercial infrastructure, or any commercial or strategic partner with whom we collaborate, to achieve commercial success. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

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

- an 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 persuade adequate numbers of physicians to prescribe our approved products and any future products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with maintaining and potentially expanding an independent sales and marketing organization.

We may enter into arrangements with third parties to perform sales, marketing and distribution services, which could decrease our revenue and our profitability. In addition, we may not be successful in entering into such arrangements with third parties or may be unable to do so on terms that are favorable to us. We may not have adequate control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. In addition, such third parties will be subject to the commercialization risks described above. If we do not maintain sales, marketing and distribution capabilities, either on our own or in collaboration with third parties, we will not be successful in commercializing our products and product candidates.

Additionally, we have entered into exclusive license agreements in Japan with Sato relating to certain of our products and product candidates, and we expect to continue to evaluate strategic partnerships to commercialize our dermatology products in select international markets. We may not be sufficiently familiar or have the requisite resources to penetrate international markets where some of our competitors have already achieved broad recognition and have established commercialization strategies in place. Moreover, we may not succeed in targeting healthcare providers, including physicians, who may not be familiar with our product candidates.

Our product revenues are dependent on sales to a few significant wholesale customers and the loss of, or substantial decline in, sales to one of these wholesale customers could have a material adverse effect on our expected future revenues and profitability.

Our product revenues are dependent on sales to a few significant wholesale customers and the loss of, or substantial decline in, sales to one of these wholesale customers could have a material adverse effect on our expected future revenues. Wholesale customers that purchase our products account for a substantial percentage of net sales revenue, and the loss of all or a portion of the sales to any one of these customers could have a material adverse effect on the results of operations generated by product sales. In particular, as of and for the year ended December 31, 2022, one of our wholesaler customers accounted for more than 10% of our annual total gross product revenue at 12%, and three of our wholesaler customers accounted for more than 10% of total accounts receivable at 25%, 13% and 12%, respectively. We expect that a small group of wholesale customers will continue to account for a significant portion of our net product revenues for the foreseeable future. Although we have developed long-standing relationships with our wholesale customers, we generally do not, consistent with industry norms, have advance commitments that require these wholesale customers to buy from us or to purchase a minimum amount of our products. A substantial decrease in sales to any of our wholesale customers could have a material adverse effect on our business and our financial condition and operating results.

Our Rhofade product currently represents a significant portion of our product revenues, and in the future a relatively small group of products may represent a significant portion of our revenues, gross profit, or net earnings from time to time.

Although we sell several approved products and have other product candidates in development, sales of our Rhofade products currently represents a significant portion of our product revenues. For the fiscal year ended December 31, 2022, sales of Rhofade, in the aggregate, represented approximately 73% of our total net product revenues. If the volume or pricing of our largest selling product declines in the future for anything more than a temporary delay, our business, financial condition, results of operations, cash flows, utilization of our accounts receivable-backed factoring agreement and/or share price could be materially adversely affected.

Our products, and any future product candidates that receive regulatory approval, may fail to achieve the broad degree of physician and patient adoption and use necessary for commercial success.

The commercial success of our approved products, and any future product candidates that receive regulatory approval, depends significantly on the broad adoption and use of such products by physicians and patients for approved indications. The degree and rate of physician and patient adoption of our approved products and any future product candidates, if approved, depends on a number of factors, including:

- the clinical indications for which the product is approved and patient demand for approved products that treat those indications;
- the effectiveness of our product as compared to other available therapies;
- the availability of coverage and adequate reimbursement from managed care plans and other healthcare payors for any of our products and product candidates that may be approved;
- the cost of treatment with our products and product candidates in relation to alternative treatments and willingness to pay for such products on the part of patients;
- acceptance by physicians, major operators of clinics and patients of the product as a safe and effective treatment;
- physician and patient willingness to adopt a new therapy over other available therapies to treat approved indications;
- overcoming any biases physicians or patients may have toward particular therapies for the treatment of approved indications;
- patient satisfaction with the results and administration of our products and any of our product candidates that may be approved and overall treatment experience;
- the willingness of patients to pay for certain of our products and product candidates relative to other discretionary items, especially during economically challenging times;
- the revenue and profitability that our products and any product candidates that may be approved may offer a physician as compared to alternative therapies;
- the prevalence and severity of adverse events;
- limitations or warnings contained in the FDA-approved labeling for our products and product candidates;
- any FDA requirement to undertake a REMS;

- the effectiveness of our sales, marketing and distribution efforts;
- adverse publicity about our products and product candidates or favorable publicity about competitive products; and
- potential product liability claims.

If any of our products or product candidates are approved for use but fail to achieve the broad degree of physician and patient adoption necessary for commercial success, our operating results and financial condition will be adversely affected, which may delay, prevent or limit our ability to generate revenue and continue our business.

Our relationships with healthcare providers, customers and third-party payors, as well as our general business operations, are subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, and failure to comply with such regulations could expose us to penalties including criminal sanctions, civil penalties, exclusion from government healthcare programs, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, customers and third-party payors play a primary role in the recommendation and prescription of our products and any product candidates for which we, or a potential future partner, may obtain marketing approval. Our arrangements with third-party payors, healthcare providers and customers and general operations mean we are subject to broadly applicable fraud and abuse and other healthcare laws and regulations that constrain the business or financial arrangements and relationships through which we, or our partners, market, sell and distribute our products and any product candidates for which we, or a potential future partner, obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations include the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation.
- the federal false claims laws, including the civil False Claims Act, which impose criminal and civil penalties, including through civil whistleblower or *qui tam* actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government; in addition, the government may assert that a claim including items and services resulting from a violation of the United States federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for, among other things, executing or attempting to execute a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. 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;
- the federal Physician Payments Sunshine Act, which requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the government information related to certain payments or other ''transfers of value'' made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician practitioners such as physician assistants and nurse practitioners, and teaching hospitals, and requires applicable manufacturers to report annually to the government ownership and investment interests held by the physicians described above and their immediate family members; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; and state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or report marketing expenditures and pricing information.

Efforts to ensure that our internal operations and business arrangements with third parties comply with applicable healthcare laws and regulations involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of

interpretations. Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available under such laws, it is possible that some of our business activities, including our relationships with physicians and other healthcare providers, some of whom recommend, purchase or prescribe our products, could be subject to challenge under one or more of such laws.

If our operations are found to be in violation of any of these laws or any other governmental laws and regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion of products from government funded healthcare programs, such as Medicare and Medicaid, disgorgement, contractual damages, reputational harm, diminished profits and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we do business are 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, which would adversely impact our statement of operations and cash flows.

Our products may cause side effects which could delay or prevent their commercialization.

If we or other companies developing similar products identify undesirable side effects caused by our or similar products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw their approval of the product;
- we may be required to recall a product or change the way such product is administered to patients;
- additional restrictions may be imposed on the marketing of the particular product or the manufacturing processes for the product or any component thereof;
- regulatory authorities may require the addition of labeling statements, such as a ‘‘black box’’ warning or a contraindication;
- we may be required to implement a REMS or create a Medication Guide outlining the risks of such adverse events for distribution to patients;
- we could be sued and held liable for harm caused to patients;
- the product may become less competitive; and
- our reputation may suffer.

We work to educate and train medical personnel so they know how to use our products and product candidates to understand their potential side effect profiles. Inadequate training in recognizing or managing the potential side effects of our products and product candidates could result in patient injury.

We face product liability exposure, and if successful claims are brought against us, we may incur substantial liability if our insurance coverage for those claims is inadequate.

Despite all reasonable efforts to ensure safety, it is possible that we or our distributors will sell products that are defective, to which patients/customers react in an unexpected manner, or which are alleged to have side effects or otherwise not work for the product’s intended purpose. We face an inherent risk of product liability as a result of the commercialization of our products and the clinical testing of our product candidates. This risk exists even though a product is approved for commercial sale by the FDA or an applicable foreign regulatory authority and manufactured in facilities licensed and regulated by the FDA or an applicable foreign regulatory authority. Our products and product candidates are designed to affect important bodily functions and processes. Any adverse events, manufacturing defects, misuse or abuse associated with our products or product candidates could result in injury to a patient or even death. We cannot offer any assurance that we will not face product liability suits in the future, nor can we assure you that our insurance coverage will be sufficient to cover our liability under any such cases. In addition, a liability claim may be brought against us even if our products or product candidates merely appear to have caused an injury. Product liability claims may be brought against us by consumers, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with our products or product candidates, among others. If we cannot successfully defend ourselves against product liability claims we will incur substantial liabilities and reputational harm. In addition, regardless of merit or eventual outcome, product liability claims may result in circumstances that are materially adverse to our business, including:

- withdrawal of clinical trial participants;
- decreased enrollment rates of clinical trial participants;
- termination of clinical trial sites or entire trial programs;
- the inability to commercialize our product candidates;

- decreased demand for our products and product candidates;
- impairment of our business reputation;
- product recall or withdrawal from the market or labeling, marketing or promotional restrictions;
- substantial costs of any related litigation or similar disputes;
- distraction of management's attention and other resources from our primary business;
- substantial monetary awards to patients or other claimants against us that may not be covered by insurance; or
- loss of revenue.

We have obtained product liability insurance coverage. Large judgments have been awarded in class action or individual lawsuits based on drugs that had unanticipated adverse events. Our insurance coverage may not be sufficient to cover all of our product liability related expenses or losses and may not cover us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, and, in the future, we may not be able to maintain insurance coverage at a reasonable cost, in sufficient amounts or upon adequate terms to protect us against losses due to product liability, or at all. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could decrease our cash, negatively impact our statement of operations and harm our financial condition.

Our products may become subject to unfavorable third-party coverage or reimbursement policies, which would harm our business.

The success of our products and our product candidates, if approved, depends on the availability of adequate coverage and reimbursement from government authorities and third-party payors, such as private health insurers and health maintenance organizations. Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to product acceptance.

Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which drugs and treatments they will cover and the amount of reimbursement that will be provided. Coverage decisions may depend on clinical and economic standards that disfavor new products when more established or lower cost therapeutic alternatives are already available or subsequently become available. Third-party payors may refuse to include a particular branded product in their formularies or lists of medications for which third-party payors provide coverage and reimbursement, or otherwise restrict patient access through formulary controls or otherwise to a branded product when a less costly generic equivalent or alternative is available. Coverage may be more limited than the purposes for which a product is approved by the FDA or similar regulatory authorities outside the United States.

Any change in coverage of our products may result in reimbursement rates not being adequate to cover our costs, including research, development, manufacture, sale and distribution, or achieve or sustain profitability, or may require co-payments that patients find unacceptably high. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products. Increasingly, third-party payors are requiring that pharmaceutical companies provide them with predetermined discounts from list prices and are challenging the prices charged for products. There is significant uncertainty related to insurance coverage and reimbursement of newly approved products. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our product candidates.

In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. Therefore, coverage and reimbursement for a product can differ significantly from payor to payor. As a result, obtaining and maintaining coverage and reimbursement for a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide supporting scientific, clinical and cost-effectiveness data for the use of our products to each payor separately, with no assurance that adequate coverage and reimbursement will be applied consistently or obtained in the first instance.

Governmental and third-party payors in the United States and abroad are developing increasingly sophisticated methods of controlling healthcare costs. Further, we believe that future coverage and reimbursement will likely be subject to increased restrictions both in the United States and in international markets. Third-party coverage and reimbursement for our product candidates for which we may receive regulatory approval may not be available, limited, or adequate in either the United States or international markets.

Risks Related to Our Operations and Manufacturing

Delays or disruptions in our supply chain and manufacturing of our products and product candidates could adversely affect our sales and marketing efforts and our development and commercialization timelines and result in increased costs or in our breaching our obligations to others.

Our ability to make, move, and sell our products is critical to our success. Historically, we have utilized internal small-scale manufacturing operations to support our research and development efforts. In acquiring EPI Health, we have expanded our product offerings and operations with several existing commercial relationships that supply the products we acquired in the EPI Health Acquisition. With this larger operational business and range of product offerings comes additional opportunity for us as well as corresponding risk in certain areas. Our subsidiary, EPI Health, uses third party contract manufacturers and suppliers to obtain substantially all raw materials, components, and packaging products and to manufacture finished products. Damage or disruption to our supply chain, including third-party manufacturing, assembly or transportation and distribution capabilities, due to weather, including any potential effects of climate change, natural disaster, fire or explosion, terrorism, pandemics (such as the COVID-19 pandemic), strikes, government action, inflation, war or other reasons beyond our control or the control of our suppliers and business partners, could impair our ability to manufacture or sell our products. Failure to take adequate steps to mitigate the likelihood or potential impact of such events, or to effectively manage such events if they occur, particularly where our product is sourced from a single supplier or location, could adversely affect our business or financial results. Any interruption or failure by our suppliers, distributors and other partners to meet their obligations on schedule or in accordance with our expectations, misappropriation of our proprietary information, including trade secrets and know-how, or any termination by these third parties of their arrangements with us, which, in each case, could be the result of one or many factors outside of our control, could delay or prevent the manufacture or commercialization of our products, disrupt our operations or cause reputational harm to our company, particularly with wholesale customers, any or all of which could have a material adverse effect on our business, financial condition, results of operations and cash flows. In addition, except for the terms and conditions specified in our contractual arrangements with our contract manufacturers, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our API or drug products or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for, market and sell our products and product candidates, if approved.

We are required to identify the supplier(s) of all the raw materials for our products in our applications with the FDA. To the extent practicable, we attempt to identify more than one supplier in each drug application. However, some products and raw materials are available only from a single source and, in some of our drug applications, only one supplier of products and raw materials has been identified, even in instances where multiple sources exist. To the extent any difficulties experienced by our suppliers cannot be resolved within a reasonable time and at reasonable cost, or if raw materials for a particular product become unavailable from an approved supplier and we are required to qualify a new supplier with the FDA, our profit margins and market share for the affected product could decrease and our development and sales and marketing efforts could be delayed.

We have never produced at a commercial scale any products that utilize any of our Nitricil NCEs, and any delay or disruptions in the qualification of manufacturing facilities and process or in the manufacture of our (i) APIs, including berdazimer sodium, the API of our SB206 product candidate, or (ii) clinical trial materials or commercial supplies of any approved product candidates utilizing any of our Nitricil NCEs, could adversely affect our development and commercialization timelines and results or result in increased costs or in our breaching our obligations to others.

We have internally manufactured the berdazimer sodium API, one of our Nitricil NCEs that is utilized in our SB206 product candidate, for all of our current clinical stage product candidates, and at this stage, we intend to pursue a dual strategy of identifying and designating a partner to become the primary third-party external supplier of our proprietary berdazimer sodium drug substance to support short-term and long-term manufacturing needs, while continuing internal capabilities to provide optionality and support certain small-scale and short-term manufacturing needs. Any delays or disruptions in our third-party manufacturers' performance and completion of the required technology transfer of the manufacturing processes and analytical methods for API development and commercial manufacturing under cGMP guidelines and regulations, or our inability to deliver such capabilities internally, could impact the development and commercialization timelines of our product candidates, as well as increase costs. Further, if we do not appropriately coordinate with, project manage, or provide adequate internal expertise, resources and documentation to a third-party API manufacturer, we may not be successful, or may be delayed, in transferring the activities, processes, capabilities and services. For example, in 2021, we entered into development services agreements with third-party full-scale API manufacturers for certain manufacturing process feasibility services including process familiarization, safety assessments, preliminary engineering studies, and initial process and analytical methods determinations. As we have internally manufactured the API necessary to support the NDA submission for SB206, we are now in the process of planning to proceed with a third-party API manufacturer beyond the initial stages noted above to support the commercial launch of SB206, if approved and expect to incur substantial costs associated with technical transfer efforts, capital expenditures, manufacturing capabilities, and ultimately, potential large-scale commercial quantities of our drug substance. If we are not able to successfully complete the stages noted above, we will need to be able to produce sufficient quantities of API

internally in order to support a commercial launch of SB206, if approved. We have a limited number of personnel who have experience in drug substance manufacturing and possess the expertise necessary to manufacture berdazimer sodium.

We believe increased utilization of and reliance upon third-party vendors and strategic partners for the performance of activities, processes and services can ultimately provide enhanced capabilities and operating efficiencies for us and any potential partnerships, collaborations, licensing or other strategic relationships we may enter. However, there can be no assurance that the technology transfer process with any of these potential API manufacturing partners, or with Orion, with whom we have formed a strategic alliance to enable Orion to manufacture our topical nitric oxide-releasing product candidates on our behalf and on behalf of our global strategic partners, will be successful or that it will take place within the time period needed to meet our targeted development and approval timeframes for our product candidates. For instance, we may not be successful in realizing the intended operating efficiencies from these arrangements based on a number of factors, including, among other things, (i) delays or failures, including delays in our ability to transition applicable technology and processes to our vendors or partners, (ii) reduced quality, (iii) delayed receipt of goods or services, (iv) increased and unexpected costs on the part of the third-party vendors or strategic partners, and (v) certain incremental and discrete costs to effect this strategy upon resumption of the manufacturers' transfer activities. If we are unsuccessful in partnering with third-party manufacturers, we could experience delays in the development and commercialization timelines of our product candidates, as well as increased costs, in connection with shifting a greater portion of manufacturing to our internal resources or entering into new third party manufacturing arrangements.

Additionally, to date, we and our third-party manufacturers have only manufactured SB206 in limited quantities in batch sizes appropriate for our clinical trials and registration batches to support the NDA, for which batch sizes are a fraction of the size that will be necessary for commercialization. The manufacturing processes for commercial scale are in development and have not been fully tested and the process validation requirement has not yet been satisfied. There are risks associated with scaling up manufacturing to commercial volumes including, among others, cost overruns, technical or other problems with process scale-up, process reproducibility, stability issues, lot consistency and timely availability of raw materials. There is no assurance that our manufacturers will be successful in establishing a larger-scale commercial manufacturing process for SB206, if approved, that achieves our objectives for manufacturing capacity and cost of goods, in a timely manner, or at all.

The continuing effects of the COVID-19 pandemic have had an impact on our operations and could continue, directly or indirectly, to adversely affect our business, results of operations and financial condition.

We may experience disruptions from the continuing effects of the COVID-19 pandemic (and any changes or developments in the pandemic) that could impact our business, results of operations and financial condition, including impacting the supply chain for our products and product candidates, the sales of our products, our clinical trials and our work to develop commercialization plans for SB206. To the extent our suppliers and third-party manufacturers are unable to comply with their obligations under our agreements with them or if supply chain or other disruptions cause them to be unable to deliver or are delayed in delivering raw materials, API or drug products to us due to COVID-19-related effects, our ability to continue our sales, marketing and commercial operations may become impaired, and our ability to pursue regulatory approval, implement our commercialization efforts for SB206, if approved, or advance development of our product candidates may also become impaired.

Changes to our leadership team or operational resources, including our sales team, could prove disruptive to our operations and have adverse consequences for our business and operating results.

From time to time, we undergo changes and transitions among the ranks of senior executives and other senior-level managers, including in connection with the EPI Health Acquisition. Managing transitions with senior executives or other senior-level managers may divert our existing management team's attention from our core operations, and the recent transitions we have experienced may make it more difficult for us to retain existing employees. In addition, the recent transitions we have experienced have increased our dependency on key members of the senior executive team and other senior-level managers within the organization. We have incurred costs related to transitions in our management team, including severance payments, and have required departing executives to agree to certain obligations in their separation agreements. We also expect to incur recruitment costs related to the hiring of new executives or engaging other operational resources from time to time.

Moreover, recruiting and retaining qualified personnel, including in sales and operational roles, is critical to our success. We have experienced and many continue to experience turnover among our workforce, including within our salesforce, and we may not be able to attract and retain these personnel on acceptable terms given our current financial position, recent market trends, and the competition among numerous pharmaceutical and biotechnology companies for similar personnel. In addition, we rely on consultants and advisors, including commercial, scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategies. Our consultants and advisors may be engaged by companies other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us.

Unexpected results in the analysis of raw materials, the API or drug product or problems with the execution of or quality systems supporting the analytical testing work, whether conducted internally or by third-party service providers, could adversely affect our development and commercialization timelines and result in increased costs of our development programs.

Third parties engaged directly by us or by our API and drug product contract manufacturing organizations, or CMOs, test all of the raw materials and finished API and drug products. It is a regulatory requirement that raw materials are tested and there are a limited number of suppliers for testing these raw materials. There may be a need to assess alternate suppliers to prevent a possible disruption of the supply of these raw materials for the manufacture of API or drug product. Additionally, the analytical equipment used by these third parties must be maintained and operational. Except for the terms established within our, or our CMOs', contracts with the third parties responsible for testing raw materials and finished API and drug products, we have limited ability to control the process or timing of their testing work. Additionally, if the results do not meet specifications, then obtaining additional raw materials may jeopardize our or the CMOs' ability to manufacture API and/or drug product, the start or overall conduct of preclinical studies and clinical trials, the timing of regulatory submissions, or the commercialization of our products and product candidates, if approved. We and our CMOs currently engage third parties to perform analytical tests to ensure the API and drug product meets quality specifications. The analytical equipment used by us or our CMOs to perform these tests must be maintained, qualified, calibrated and operational. If there are testing execution delays, equipment problems or if the results of the analytical testing do not meet our quality specifications, then manufacturing additional API or drug product may increase costs and may jeopardize our or the CMOs' ability to manufacture API and/or drug product, which may cause delays in the start or overall conduct of preclinical studies and clinical trials, the submission of regulatory filings, or the commercialization of our products and product candidates, if approved.

Our business involves the use of hazardous materials and we and our third-party suppliers and manufacturers must comply with environmental laws and regulations, which can be expensive and restrict how we do business.

Our manufacturing activities, and the manufacturing activities of our third-party suppliers and manufacturers, involve the controlled storage, use and disposal of hazardous materials. Further, our manufactured drug substance and drug products may be considered hazardous materials under applicable laws and regulations. Our manufacturing activities, whether conducted by us or our third-party suppliers and manufacturers, like all manufacturing processes that utilize hazardous materials, including those under high pressures, must be properly controlled to avoid unintended reactions or other accidents that could cause injury or damage to personnel, equipment or property. We and our manufacturers and suppliers are subject to laws and regulations governing the use, manufacture, storage, transportation, handling and disposal of these hazardous materials, and our failure to manage the use, manufacture, storage, transportation, handling or disposal of hazardous materials could subject us to significant costs or future liabilities. In some cases, these hazardous materials and various wastes resulting from their use are transported and stored at our suppliers' or manufacturers' facilities pending use and disposal. We and our suppliers and manufacturers cannot completely eliminate the risk of contamination, which could cause an interruption of our commercialization efforts, research and development efforts and business operations, injury to our service providers and others and environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although we believe that the manufacturing controls and safety procedures utilized by us and our third-party suppliers and manufacturers for handling, transporting and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk (i) that the laws and regulations will not restrict our or our third-party suppliers' or manufacturers' ability to use, manufacture, store, transport, handle or dispose of such materials or (ii) of accidental contamination or injury from these hazardous materials and processes. If these risks were to materialize, we could experience an interruption of our business operations and we may be held liable for any resulting damages and such liability could exceed our financial resources.

Our employees, independent contractors, principal investigators, CMOs, CROs, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could expose us to liability and hurt our reputation.

We are exposed to the risk that our employees, independent contractors, principal investigators, CMOs, CROs, consultants, commercial partners and vendors may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless or negligent conduct or disclosure of unauthorized activities to us that violates: (i) FDA laws and regulations, including those laws that require the reporting of true, complete and accurate information to the FDA, (ii) manufacturing standards, (iii) federal, state and foreign data privacy, security, fraud and abuse and other healthcare laws, or (iv) laws that require the true, complete and accurate reporting of financial information or data. Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of clinical trials, creating fraudulent data in our preclinical studies or clinical trials or illegal misappropriation of drug product, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, 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 us from governmental investigations or other actions or lawsuits stemming from a

failure to be in compliance with such laws or regulations. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. 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, without limitation, 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.

We may be adversely affected by the effects of inflation.

Inflation has the potential to adversely affect our liquidity, business, financial condition and results of operations by increasing our overall cost structure. The existence of inflation in the economy has resulted in, and may continue to result in, higher interest rates and capital costs, supply shortages, increased costs of labor, components, manufacturing and shipping, as well as weakening exchange rates and other similar effects. As a result of inflation, we have experienced and may continue to experience cost increases. Although we may take measures to mitigate the effects of inflation, if these measures are not effective and if the inflationary pressure is sustained, our business, financial condition, results of operations and liquidity could be negatively affected. Even if such measures are effective, there could be a difference between the timing of when these beneficial actions impact our results of operations and when the cost of inflation is incurred.

Risks Related to Government Regulation

We are subject to ongoing regulatory obligations and continued regulatory review of our products, which results in significant additional expense, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products.

The regulatory approvals for our products are and any regulatory approvals that we receive for our product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or the conditions of approval or contain requirements for potentially costly post-market testing and surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a REMS as a condition of approval of our product candidates, which could include requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our products is subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, and continued compliance with cGMP and GCP requirements for any clinical trials that we conduct post-approval. Later discovery of previously unknown problems with any of our products or our product candidates, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of our products or product candidates, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- fines, warning letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of approvals;
- product seizure or detention, or refusal to permit the import or export of our products or product candidates; and
- injunctions or the imposition of civil or criminal penalties.

The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates.

We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. 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 be subject to enforcement action and we may not achieve or sustain profitability.

The regulatory approvals for our products and any regulatory approvals for our product candidates in the United States are and will be limited to the specific indication authorized by the FDA. If we are found to be in violation of FDA and other regulations restricting the promotion of any approved products for unapproved uses, we could be subject to criminal penalties, substantial fines or other sanctions and damage awards.

The regulatory approvals we have obtained to market our products are limited by an indication statement for the treatment of one or more indications, and we are prohibited from marketing any approved products for uses outside of those for which we have received approval. Similarly, if we obtain regulatory approval for any of our product candidates, such approval will be limited to the specific indication(s) authorized by the FDA.

The regulations relating to the promotion of products for unapproved uses are complex and subject to substantial interpretation by the FDA and other government agencies. Products may not be promoted for uses that are not approved in the labeling by the FDA or EMA. Physicians may, following FDA approval, nevertheless prescribe our products off-label to their patients in a manner that is inconsistent with the approved label. We have implemented compliance and training programs designed to ensure that our sales and marketing practices comply with applicable regulations. Notwithstanding these programs, the FDA or other government agencies may allege or find that our practices constitute prohibited promotion of our products for unapproved uses. We also cannot be sure that our employees will comply with company policies and applicable regulations regarding the promotion of products for unapproved uses, but we may nevertheless be deemed responsible for their marketing activities.

In recent years, a significant number of pharmaceutical and biotechnology companies have been the target of inquiries and investigations by various federal and state regulatory, investigative, prosecutorial and administrative entities in connection with the promotion of products for unapproved uses and other sales practices, including the Department of Justice and various United States Attorneys' Offices, the Office of Inspector General of the Department of Health and Human Services, the FDA, the Federal Trade Commission and various state Attorneys General offices. These investigations have alleged violations of various federal and state laws and regulations, including claims asserting antitrust violations, violations of the Federal Food, Drug and Cosmetic Act, the False Claims Act, the Prescription Drug Marketing Act, anti-kickback laws and other alleged violations in connection with the promotion of products for unapproved uses, pricing and Medicare and/or Medicaid reimbursement. Many of these investigations originate as "*qui tam*" actions under the False Claims Act. Under the False Claims Act, any individual can bring a claim on behalf of the government alleging that a person or entity has presented a false claim, or caused a false claim to be submitted, to the government for payment. The person bringing a *qui tam* suit is entitled to a share of any recovery or settlement. *Qui tam* suits, also commonly referred to as "whistleblower suits," are often brought by current or former employees. In a *qui tam* suit, the government must decide whether to intervene and prosecute the case. If it declines, the individual may pursue the case alone.

If the FDA or any other governmental agency initiates an enforcement action against us or if we are the subject of a *qui tam* suit and it is determined that we violated prohibitions relating to the promotion of products for unapproved uses, we could be subject to warning letters, untitled letters, substantial civil or criminal fines or damage awards and other sanctions such as consent decrees and corporate integrity agreements pursuant to which our activities would be subject to ongoing scrutiny and monitoring to ensure compliance with applicable laws and regulations. Any such fines, awards or other sanctions would have an adverse effect on our revenue, business, financial prospects and reputation.

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

In the United States and some foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell our products and any product candidates for which we obtain marketing approval. In 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the ACA, was signed into law. Since its enactment, however, there have been significant ongoing efforts to modify or eliminate the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court's decision, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. On August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, resulted in reductions to Medicare payments to providers, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2032, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022, unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. In addition, on March 11, 2021, the American Rescue Plan Act of 2021 was signed into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, beginning January 1, 2024.

Further, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs. Such scrutiny has resulted in several recent congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement

methodologies for products. On August 16, 2022, the Inflation Reduction Act of 2022, or IRA, was into law. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023), and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Secretary of the Department of Health and Human Services to implement many of these provisions through guidance, as opposed to regulation, for the initial years. For that and other reasons, it is currently unclear how the IRA will be effectuated.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our product candidates, if approved, or put pressure on our product pricing, which could negatively affect our business, results of operations, financial condition and prospects.

We expect that other healthcare reform measures that may be adopted in the future, may, among other things, result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our product candidates, if approved. Adoption of government controls and measures, and tightening of restrictive policies in jurisdictions with existing controls and measures, could limit payments for pharmaceuticals.

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

We are subject to governmental economic sanctions and export and import controls that could impair our ability to compete in international markets or subject us to liability if we are not in compliance with applicable laws.

As a United States company, we are subject to United States import and export controls and economic sanctions laws and regulations, and we are required to import and export our API, products and product candidates, technology and services in compliance with those laws and regulations, including the United States Export Administration Regulations, the International Traffic in Arms Regulations, and economic embargo and trade sanction programs administered by the Treasury Department's Office of Foreign Assets Control. United States economic sanctions and export control laws and regulations prohibit the shipment of certain products and services to countries, governments and persons targeted by United States sanctions. While we are currently taking precautions to prevent doing any business, directly or indirectly, with countries, governments and persons targeted by United States sanctions and to ensure that our product candidates, if approved, are not exported or used by countries, governments and persons targeted by United States sanctions, such measures may be circumvented. Furthermore, if we export our API, products or product candidates, if approved, the exports may require authorizations, including a license, a license exception or other appropriate government authorization. Complying with export control and sanctions regulations for a particular sale may be time-consuming and may result in the delay or loss of sales opportunities. Failure to comply with export control and sanctions regulations for a particular sale may expose us to government investigations and penalties. If we are found to be in violation of United States sanctions or import or export control laws, it could result in civil and criminal, monetary and non-monetary penalties, including possible incarceration for those individuals responsible for the violations, the loss of export or import privileges and reputational harm.

We are subject to anti-corruption and anti-money laundering laws with respect to our operations and non-compliance with such laws can subject us to criminal or civil liability and harm our business.

We are subject to the United States Foreign Corrupt Practices Act of 1977, as amended, or the FCPA, the United States domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act and possibly other anti-bribery and anti-money laundering laws in countries in which we may conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees and third-party intermediaries from authorizing, offering or providing, directly or indirectly, improper payments or benefits to recipients in the public or private sector. As we commercialize our products and product candidates, if approved, and as we sell products internationally, whether directly or through our strategic

partners, we may engage with collaborators and third-party intermediaries to sell our products abroad and to obtain necessary permits, licenses and other regulatory approvals. We or our third-party intermediaries may have direct or indirect interactions with officials and employees of government agencies or state-owned or affiliated entities. We may be held liable for the corrupt or other illegal activities of these third-party intermediaries, our employees, representatives, contractors, partners and agents, even if we do not explicitly authorize such activities.

Noncompliance with anti-corruption and anti-money laundering laws could subject us to whistleblower complaints, investigations, sanctions, settlements, prosecution, other enforcement actions, disgorgement of profits, significant fines, damages, other civil and criminal penalties or injunctions, suspension or debarment from contracting with certain persons, the loss of export privileges, reputational harm, adverse media coverage and other collateral consequences. Responding to any action will likely result in a materially significant diversion of management's attention and resources and significant defense costs and other professional fees.

Changes in and failures to comply with United States and foreign privacy and data protection laws, regulations and standards may adversely affect our business, operations and financial performance.

We are subject to or affected by numerous federal, state and foreign laws and regulations, as well as regulatory guidance, governing the collection, use, disclosure, retention, and security of personal data, such as information that we collect about patients and healthcare providers in connection with clinical trials in the United States and abroad. The global data protection landscape is rapidly evolving, and implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future. This evolution may create uncertainty in our business, affect our or our collaborators', service providers' and contractors' ability to operate in certain jurisdictions or to collect, store, transfer use and share personal information, necessitate the acceptance of more onerous obligations in our contracts, result in liability or impose additional costs on us. The cost of compliance with these laws, regulations and standards is high and is likely to increase in the future. Any failure or perceived failure by us or our collaborators, service providers and contractors to comply with federal, state or foreign laws or regulation, our internal policies and procedures or our contracts governing processing of personal information could result in negative publicity, diversion of management time and effort and proceedings against us by governmental entities or others. In many jurisdictions, enforcement actions and consequences for noncompliance are rising.

In the United States, HIPAA imposes privacy, security and breach reporting obligations with respect to individually identifiable health information upon "covered entities" (health plans, health care clearinghouses and certain health care providers), and their respective business associates, individuals or entities that create, received, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. While we do not believe that we are currently acting as a covered entity or business associate under HIPAA and thus are not directly regulated under HIPAA, any person may be prosecuted under HIPAA's criminal provisions either directly or under aiding-and-abetting or conspiracy principles. Consequently, depending on the facts and circumstances, we could face substantial criminal penalties if we knowingly receive individually identifiable health information from a HIPAA-covered healthcare provider or research institution that has not satisfied HIPAA's requirements for disclosure of individually identifiable health information.

Further, even when HIPAA does not apply, according to the Federal Trade Commission or the FTC, failing to take appropriate steps to keep consumers' personal information secure constitutes unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act. The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities.

In addition, certain state laws govern the privacy and security of health-related and other personal information in certain circumstances, many of which may differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation. For example, the California Consumer Privacy Act, or the CCPA, went into effect on January 1, 2020. The CCPA gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that has increased the likelihood of, and risks associated with data breach litigation. Additionally, the California Privacy Rights Act, or the CPRA, generally went into effect in January 2023, and imposes additional data protection obligations on companies doing business in California, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data and opt outs for certain uses of sensitive data. It also creates a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. Similar laws have passed in Virginia, Colorado, Connecticut and Utah and have been proposed in other states and at the federal level, reflecting a trend toward more stringent privacy legislation in the United States. The enactment of such laws could have potentially conflicting requirements that would make compliance challenging. In the event that we are subject to or affected by HIPAA, the CCPA, the CPRA or other domestic privacy and data protection laws, any liability from failure to comply with the requirements of these laws could adversely affect our financial condition.

Our operations abroad may also be subject to increased scrutiny or attention from data protection authorities. Many countries in these regions have established or are in the process of establishing privacy and data security legal frameworks with which we, our collaborators, service providers, including our CROs, and contractors must comply. For example, the European Union, or EU, has adopted the EU General Data Protection Regulation, or GDPR, which went into effect in May 2018 and imposes strict requirements for processing the personal data of individuals within the EU and the European Economic Area, or EEA, including clinical trial data. The GDPR has and will continue to increase compliance burdens on us, including by mandating potentially burdensome documentation requirements and granting certain rights to individuals to control how we collect, use, disclose, retain and process personal data about them. Member states of the EEA may impose further obligations relating to the processing of genetic, biometric or health data, which could further add to our compliance costs and limit how we process this information. Further, the GDPR increases the scrutiny of transfers of personal data from clinical trial sites located in the EEA to the United States and other jurisdictions that the European Commission does not recognize as having "adequate" data protection laws; in July 2020, the CJEU, limited how organizations could lawfully transfer personal data from the EEA to the United States by invalidating the EU-US Privacy Shield and imposing further restrictions on use of the standard contractual clauses, which could increase our costs and our ability to efficiently process personal data from the EEA. In March 2022, the US and EU announced a new regulatory regime intended to replace the invalidated regulations; however, this new EU-US Data Privacy Framework has not been implemented beyond an executive order signed by President Biden on October 7, 2022 on Enhancing Safeguards for United States Signals Intelligence Activities. European court and regulatory decisions subsequent to the CJEU decision of July 16, 2020 have taken a restrictive approach to international data transfers. In addition, the GDPR provides for robust regulatory enforcement and fines of up to €20 million or 4% of the annual global revenue of the noncompliant company, whichever is greater. Further, from January 1, 2021, we have had to comply with the GDPR and the UK data protection regime, which imposes separate but similar obligations to those under the GDPR and comparable penalties, including fines of up to the greater of £17.5 million or 4% of global turnover.

Although we work to comply with applicable laws, regulations and standards, our contractual obligations and other legal obligations, these requirements are evolving and may be modified, interpreted and applied in an inconsistent manner from one jurisdiction to another, and may conflict with one another or other legal obligations with which we must comply. Any failure or perceived failure by us or our employees, representatives, contractors, consultants, collaborators, or other third parties to comply with such requirements or adequately address privacy and security concerns, even if unfounded, could result in additional cost and liability to us, damage our reputation, and adversely affect our business and results of operations. As we expand into other foreign countries and jurisdictions, we may be subject to additional laws and regulations that may affect how we conduct business.

We may be subject to confidential information theft or misuse, which could harm our business and results of operations. Our information technology systems, or those of any of our CROs, CMOs, other contractors or consultants or potential future collaborators, may fail or suffer security breaches, which could result in a material disruption of our commercial operations or product development programs, expose the Company to liability, affect our reputation and otherwise harm our business, which could materially affect our results.

We face attempts by others to gain unauthorized access to our information technology systems on which we maintain proprietary and other confidential information. Despite the implementation of security measures, our information technology systems and those of our current and any future CROs, CMOs and other contractors, consultants and collaborators are vulnerable to attack and damage from computer viruses and malware (e.g., ransomware), cybersecurity threats, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Attacks upon information technology systems are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives and expertise. As a result of the COVID-19 pandemic, and continued hybrid working environment, we may also face increased cybersecurity risks due to our reliance on internet technology and the number of our employees who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience security breaches that may remain undetected for an extended period. Even if identified, we may be unable to adequately investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence.

We and certain of our service providers are from time to time subject to cyberattacks and security incidents. While we do not believe that we have experienced any significant system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations or result in the unauthorized disclosure of or access to personally identifiable information or health-related information, it could result in a material disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other similar disruptions. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. We could also incur liability, our commercial operations could be disrupted, and the

further development and commercialization of our product candidates could be delayed. In addition, we also rely on third parties to manufacture our products and product candidates, so similar events relating to their computer systems could also have a material adverse effect on our business. Some of the federal, state and foreign government requirements under data privacy and security laws include obligations of companies to notify individuals of security breaches involving particular personally identifiable information, which could result from breaches experienced by us or by our service providers or organizations with which we have formed strategic relationships. Notifications and follow-up actions related to a security breach could impact our reputation, cause us to incur significant costs, including legal expenses, harm customer confidence, hurt our expansion into new markets, cause us to incur remediation costs, or cause us to lose existing customers. Further, our insurance coverage may not be sufficient to cover the financial, legal, business or reputational losses that may result from an interruption or breach of our systems. To the extent that any disruption or security breach were to result in violations of privacy and security laws, we could also be subject to significant fines, penalties or liabilities, which could adversely affect our business, financial condition, results of operations and prospects.

Risks Related to Our Intellectual Property

If we fail to comply with our obligations under any license, collaboration or other agreements, it could have a material adverse effect on our, or our potential future commercial partners', commercialization efforts for our product candidates.

Our current licenses impose, and any future licenses we enter into may impose, various development, commercialization, milestone, royalty, diligence, sublicensing, insurance, patent prosecution and enforcement, and other obligations on us. If we breach any of these obligations, or use the intellectual property licensed to us in an unauthorized manner, we may be required to pay damages and the licensor may have the right to terminate the license, which could result in us being unable to develop, manufacture and sell products that are covered by the licensed technology or enable a competitor to gain access to the licensed technology.

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

In addition to seeking patents for our technology (e.g., our Nitricil technology) and for our product candidates, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position.

We seek to protect our trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees (including through specific provisions in employment contracts), corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be materially impaired.

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.

Because we expect to rely on third parties to manufacture any of our current or future product candidates, we must, at times, share trade secrets with them. 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 adversely impact our business.

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

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain our competitive advantage, for reasons including but not limited to the following:

- others may be able to make compounds, formulations, or compositions that are the same as or similar to certain of our product candidates or Nitricil compounds but that are not covered by the claims of the patents that we own or license;

- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our trade secret or similar rights;
- issued patents that we own or license may not provide us with any competitive advantages, or may be held invalid or unenforceable as a result of legal challenges;
- our competitors might conduct research and development activities in the United States and other countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as 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; and
- we may not develop additional proprietary technologies that are patentable.

Risks Related to Our Common Stock

The market price and trading volume of our common stock has fluctuated substantially and may fluctuate widely in the future and the value of an investment in our common stock may decline.

Our stock price has experienced extreme volatility and could vary significantly as a result of many factors. Between December 31, 2021 and March 14, 2023, the last reported sales price of our common stock fluctuated between a high of $4.41 and a low of $0.82. The market price and trading volume of our common stock may continue to fluctuate from time to time as a result of factors outside of our control. There is a potential for rapid and substantial decreases in the price of our common stock, including decreases unrelated to our operating performance or prospects, which could result in substantial losses for our existing stockholders.

In addition, the stock market in general and smaller reporting companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. These broad market and industry fluctuations, including but not limited to those connected with the ongoing military conflict between Russia and Ukraine and trade and monetary sanctions in response to such developments, may negatively impact the price or liquidity of our common stock, regardless of our operating performance. Any actual or perceived negative operational developments or market or industry fluctuations may compound each other's negative impacts on the price of liquidity of our common stock.

If we fail to meet the requirements for continued listing on the Nasdaq Capital Market, our common stock could be delisted from trading, which would decrease the liquidity of our common stock and impact our ability to raise additional capital.

Although our common stock is currently listed on the Nasdaq Capital Market, an active trading market for our shares may not be sustained. We are required to meet specified requirements to maintain our listing on the Nasdaq Capital Market. If our common stock is delisted and there is no longer an active trading market for our shares, it may, among other things:

- cause difficulty in stockholders selling their shares without depressing the market price for the shares or in selling their shares at all;
- substantially impair our ability to raise additional funds;
- result in a loss of institutional investor interest and fewer financing opportunities for us; and/or
- result in potential breaches of representations or covenants of agreements pursuant to which we made representations or covenants relating to our compliance with applicable listing requirements. Claims related to any such breaches, with or without merit, could result in costly litigation, significant liabilities and diversion of our management's time and attention and could have a material adverse effect on our financial condition, business and results of operations.

A delisting would also reduce the value of our equity compensation plans, which could negatively impact our ability to retain key employees.

We, and certain of our directors and current and former officers, have in the past been named as parties to putative stockholder class action lawsuits and may be subject to litigation or other claims again in the future, and such litigation or other claims could adversely affect us, require significant management time and attention, result in significant legal expenses or damages, and cause our business and financial condition, results of operations to suffer.

Putative stockholder class action lawsuits were filed against us and certain of our current and former directors and officers in 2017. The court dismissed those putative stockholder class actions with prejudice, and we have concluded that these matters are closed. We currently have no other pending litigation against us, but we may face additional claims in the future. If we face similar litigation or other claims again in the future, it could result in substantial costs and a diversion of management's attention and resources and their ultimate outcomes could have a material adverse effect on our business, financial condition

and results of operations. While we expect insurance to cover certain costs associated with defending such litigation, insurance coverage may be insufficient and could require a diversion of our resources. There also may be adverse publicity associated with litigation or claims made against us and/or our directors and officers that could negatively affect perception of our business, regardless of whether the allegations are valid or whether we are ultimately found liable.

Provisions in our amended and restated certificate of incorporation and amended and restated bylaws under Delaware law could make an acquisition of our company, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our amended and restated certificate of incorporation and our amended and restated bylaws may discourage, delay or prevent a merger, acquisition or other change in control of our company that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, 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. Among other things, these provisions include those establishing (i) a classified board of directors with three-year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our board of directors, (ii) no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates and (iii) other provisions.

Our restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us and/or our directors, officers, or employees or agents.

Our restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for (i) any derivative action or proceeding brought on behalf of us; (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees or agents to us and/or our stockholders; (iii) any action asserting a claim against us arising pursuant to any provision of the Delaware General Corporation Law or our amended and restated certificate of incorporation or amended and restated bylaws; or (iv) any action asserting a claim against us governed by the internal affairs doctrine. These choice of forum provisions do not preclude or contract the scope of exclusive federal or concurrent jurisdiction for any actions brought under the Securities Act of 1933, as amended or the Exchange Act. Accordingly, our choice of forum provisions will not relieve us of our duties to comply with the federal securities laws and the rules and regulations thereunder, and our stockholders will not be deemed to have waived our compliance with these laws, rules and regulations. Any person or entity purchasing or otherwise acquiring any interest in any of our securities shall be deemed to have notice of and consented to these provisions. These choice of forum provisions may limit a stockholder's ability to bring a claim in a judicial forum of its choosing for disputes with us and/or our directors, officers or other employees or agents, which may discourage lawsuits against us and our directors, officers and other employees or agents.

If a court were to find the choice of forum provision contained in our restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, results of operations, and financial condition. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management and other employees.

Our ability to use net operating losses to offset future taxable income may be subject to certain limitations.

As of December 31, 2022, we had federal and state net operating loss carryforwards, or NOLs, of $104.7 million and $65.1 million, respectively. The NOLs begin to expire in 2029 and 2024 for federal and state tax purposes, respectively. As of December 31, 2022, we had government research and development tax credits of approximately $2.4 million to offset future federal taxes which begin to expire in 2041.

During the course of preparing our consolidated financial statements as of and for the year ended December 31, 2022, we completed an assessment of the available NOL and tax credit carryforwards under Sections 382 and 383, respectively, of the Internal Revenue Code, or the Code. In the past, we have determined that we underwent multiple ownership changes throughout our history as defined under Section 382, including most recently in 2015 and 2020, and we made corresponding adjustments to our financial statements within those periods. If an ownership change, as defined in Section 382, occurs, it results in a Section 382 limitation that applies to all NOLs and tax credits generated prior to the ownership change date that can be used to offset taxable income incurred after the ownership change date. The annual limitation is based on a company's stock value prior to the ownership change, multiplied by the applicable federal long-term, tax-exempt interest rate. The Company has not experienced a cumulative ownership change since 2020.

In addition, future changes in our stock ownership, as well as other changes that may be outside of our control, could result in additional ownership changes under Section 382. As a result, even if we achieve profitability, we may not be able to use a material portion of our NOLs or tax credit carryforwards. We have recorded a full valuation allowance related to our NOLs and tax credits due to the uncertainty of the ultimate realization of the future benefits of those assets.

If securities or industry analysts do not publish research or reports about our business, or if they issue an adverse or misleading opinion regarding our stock, our stock price and trading volume could decline.

The trading market for our common stock is influenced by the research and reports that industry or securities analysts publish about us and/or our business. If any of the analysts who cover us issue an adverse or misleading opinion regarding us, our business model, our intellectual property or our stock performance, or if our regulatory clearance timelines, clinical trial results or operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of these analysts ceases coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

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

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

General Risk Factors

We may be subject to confidential information theft or misuse, which could harm our business and results of operations. Our internal computer systems, or those of any of our existing or potential future collaborators, CROs, CMOs or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our product development programs or other operations, expose the Company to liability, affect our reputation and otherwise harm our business.

We face attempts by others to gain unauthorized access to our information technology systems on which we maintain proprietary and other confidential information. Despite the implementation of security measures, our internal computer systems and those of our current and any future CROs, CMOs, and other contractors, consultants and collaborators are vulnerable to damage from cyberattacks, "phishing" attacks, computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Attacks upon information technology systems are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives and expertise. The risk of a security breach or disruption, particularly through cyberattacks or cyber intrusion, including by computer hackers, foreign governments and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. We may also face increased cybersecurity risks due to our increased reliance on internet technology and hybrid work environments following the onset of the COVID-19 pandemic, which may create additional opportunities for cybercriminals to exploit vulnerabilities. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience security breaches that may remain undetected for an extended period.

If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other similar disruptions. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. In addition, the FDA and comparable foreign regulatory authorities regulate, among other things, the record keeping and storage of data pertaining to approved and potential pharmaceutical products, and we currently store most of our preclinical research data, our clinical data and our manufacturing data at our facilities. In addition, such a breach may require notification to governmental agencies, the media or individuals pursuant to applicable data privacy and security law and regulations. We would also be exposed to a risk of loss, including financial assets or litigation and potential liability, which could materially adversely affect our business, financial condition, results of operations and prospects. We also rely on third parties to manufacture our products and product candidates, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could be subject to material legal claims and incur liability or other negative consequences, including increased cybersecurity protection costs, damage to our reputation, disruption of our internal operations and delays in the further development of and potential commercialization of our product candidates.

We may be adversely affected by natural disasters, pandemics and other catastrophic events, and by man-made problems such as terrorism, that could disrupt our business operations and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Our corporate headquarters is located in Durham, North Carolina, near major hurricane and tornado zones. If a disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as enterprise financial systems, manufacturing, resource planning or enterprise quality systems, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. Our manufacturers' and suppliers' facilities are located in multiple locations, where other natural disasters, pandemics or similar events, such as blizzards, tornadoes, fires, explosions or large-scale accidents or power outages, could severely disrupt their operations. In addition, acts of terrorism, pandemic illness and other geo-political unrest could cause disruptions in our business or the businesses of our collaborators, manufacturers or the economy as a whole. All of the aforementioned risks may be further increased if we do not implement a disaster recovery plan or our collaborators' or manufacturers' disaster recovery plans prove to be inadequate. Any of the above could result in delays in the regulatory approval, manufacture, distribution or commercialization of our product candidates.

If we are unable to obtain and maintain patent protection for our product candidates or Nitricil compounds, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully commercialize our technology and product candidates may be impaired.

We rely upon a combination of patents, trade secret protection, and confidentiality agreements to protect the intellectual property related to our product candidates and Nitricil compounds. Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our product candidates and Nitricil compounds. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our product candidates and Nitricil compounds.

The patent prosecution process is expensive and time-consuming, however, 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 technology platform, Nitricil compounds, or product candidates before it is too late to obtain patent protection. We may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the rights to patents licensed to or from third parties. In particular, certain patents and patent applications covering our core technology platform are exclusively licensed from the University of North Carolina, or UNC, and under our license agreement with UNC, we rely on UNC to prosecute and maintain such patents and applications. Therefore, these patents and applications, and any other patents and applications that we may license from or to third parties, may not be prosecuted and enforced in a manner consistent with the best interests of our business.

If the patent applications we hold or have in-licensed with respect to our product candidates or Nitricil compounds fail to issue, if their breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for our current or any future product candidates or Nitricil compounds, it could have a materially adverse effect on our business. Even if our owned and/or licensed patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our owned and/or licensed patents by developing similar or alternative technologies, compounds, or products in a non-infringing manner.

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 or vice versa. For example, European patent law restricts the patentability of methods of treatment of the human body more than United States law does. Publications of discoveries in the 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 and/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 products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. 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 owned and/or licensed patents or narrow the scope of our patent protection while patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

Changes to patent laws in the United States or other countries could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. For example, changes to the United

States patent system have come into force under the Leahy-Smith America Invents Act, or the Leahy-Smith Act, which was signed into law in September 2011. The Leahy-Smith Act included a number of significant changes to United States patent law. Under the Leahy-Smith Act, the United States transitioned in March 2013 to a "first to file" system in which the first inventor to file a patent application will be entitled to the patent. Third parties are allowed to submit prior art before the issuance of a patent by the USPTO, and may invoke or participate in opposition, derivation, reexamination, *inter partes* review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, which could adversely affect our competitive position. While we cannot predict with certainty the impact the Leahy-Smith Act or any potential future changes to the United States or foreign patent systems will have on the operation of our business, the Leahy-Smith Act and such future changes 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 a material adverse effect on our business, results of operations, financial condition and prospects. Additionally, the first to file system under the Leahy-Smith Act may incentivize companies like us in the biopharmaceutical industry to file patent applications as soon as possible, and filing applications as soon as possible runs the risk that the application will not have the supporting data to claim the broadest protection possible in the United States or abroad.

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

In addition, the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and/or licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate or 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 products. 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, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Finally, certain of our activities and our licensors' activities have been funded, and may in the future be funded, by the United States federal government. When new technologies are developed with United States federal government funding, the government has certain rights in any resulting patents, including a nonexclusive license authorizing the government to use the invention for non-commercial purposes. These rights may permit the government to disclose our confidential information to third parties and to exercise "march-in" rights to use or allow third parties to use our patented technology. The government can exercise its march-in rights if it determines that action is necessary because we fail to achieve practical application of the United States government-funded technology, because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations or to give preference to United States industry. In addition, United States government-funded inventions must be reported to the government, United States government funding must be disclosed in any resulting patent applications, and our rights in such inventions may be subject to certain requirements to manufacture products in the United States.

We may be involved in lawsuits to protect or enforce our owned and/or licensed patents, which could be expensive, time-consuming and unsuccessful. Further, our issued patents could be found invalid or unenforceable if challenged in court.

If we were to initiate legal proceedings against a third-party to enforce a patent directed to our Nitricil technology, our products or product candidates, or one of our future product candidates, the defendant could counterclaim that our patent is 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, non-enablement or insufficient written description. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution. Third parties may also raise similar claims before the USPTO, even outside the context of litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our products or product candidates. Such a loss of patent protection would harm our business.

Interference proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our owned and/or licensed patents or patent applications. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms, or at all.

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.

Most of our competitors are larger than we are and have substantially greater resources than we do. They are, therefore, likely to be able to sustain the costs of complex patent or other intellectual property rights litigation longer than we could. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating our intellectual property. Litigation could result in substantial costs and diversion of management resources, which could harm our business. In addition, the uncertainties associated with litigation could compromise our ability to raise the funds necessary to continue our clinical trials, continue our internal research programs, or in-license needed technology or other product candidates. There could also be public announcements of the results of the hearing, motions, or other interim proceedings or developments. If securities analysts or investors perceive those results to be negative, it could cause the price of shares of our common stock to decline.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, 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 other foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign national or international patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse or assertion of entity size for payment of reduced fees 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, unenforceability, 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 patent rights include, but are not limited to, failure to timely file national and regional stage patent applications based on our international patent application, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. Non-compliance events that could result in the unenforceability of patent rights include, but are not limited to, improperly claiming or maintaining small entity or micro entity status. If we or our licensors fail to maintain the patents and patent applications covering our technology platform or product candidates, our competitors might be able to enter the market, which would have an adverse effect on our business.

Changes in United States patent laws could diminish the value of patents in general, thereby impairing our ability to protect our products.

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, modifying some legal standards applied by the USPTO in examination of patent applications 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 United States 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, increase the likelihood of challenges to patents we obtain or license or weaken our ability to enforce patents that we have licensed or that we might obtain in the future.

Changes in foreign patent laws could diminish the value of patents in general, thereby impairing our ability to protect our products.

In Europe, certain members of the European Union have executed an agreement (Agreement on a Unified Patent Court, or the UPCA) to create a European patent with unitary effect (a Unitary Patent) and to form a Unified Patent Court (UPC) system. Once the UPCA enters into force, which will occur on June 1, 2023, a patent owner may elect to receive a Unitary Patent, which will provide patent protection in all UPCA member countries, as an alternative to the current practice of registering and enforcing the patent in individual countries ("classic European patents"). This will be a significant change in European patent practice. In addition, the UPC system will also commence operations on June 1, 2023. The UPCA provides that the UPC system will eventually have sole jurisdiction over classic European patents and Unitary Patents in UPCA member states. However, the UPCA provides for a seven-year transitional period (which may be extended) in which owners of classic European patents will be subject to jurisdiction in both the UPC system and national courts, meaning that patent owners may bring a legal action, or be subject to a legal action, in either the UPC system or a national court. As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation. In addition, if a single litigation action

(e.g., an invalidity action) against a patent is successful under the UPC system, then the patent may be revoked in all UPCA member countries, whereas, for a classic European patent, a litigation action is separately brought, and the result effective in, each validated country. Thus, the UPC system, while potentially offering a cheaper streamlined process, has potential disadvantages to patent holders, such as making a European patent vulnerable in all UPCA member countries when challenged.

Geo-political actions in the United States and in foreign countries could increase the uncertainties and costs surrounding the prosecution, maintenance, enforcement, or defense of our owned and/or licensed patents or patent applications or those of any future owned and/or licensed patents or patent applications. For example, the United States and foreign government actions related to Russia's invasion of Ukraine may limit or prevent filing, prosecution, maintenance, and/or enforcement of patent applications and patents in Russia and/or Ukraine. These actions could result in abandonment or lapse of our owned and/or licensed patents or patent applications, resulting in partial or complete loss of patent rights in Russia. If such an event were to occur, it could have a material adverse effect on our business. In addition, a decree was adopted by the Russian government in March 2022, allowing Russian companies and individuals to exploit inventions owned by patentees from the United States without consent or compensation. Consequently, we may not be able to prevent third parties from practicing our inventions in Russia or from selling or importing products made using our inventions in and into Russia. Accordingly, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

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

Filing, prosecuting and defending patents on our product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our invention in such countries. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and may export otherwise infringing products to territories where we have patent protection, but enforcement rights are not as strong as those in the United States. These products may compete with our product candidates and our owned and/or licensed patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of some countries do not favor the enforcement of patents and other intellectual property protection, which could make it difficult for us to stop the infringement of our owned and/or licensed patents generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our owned and/or licensed patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful.

Many countries, including European countries, India, Japan and China, have compulsory licensing laws under which a patent owner may be compelled under specified circumstances to grant licenses to third parties. In those countries, we may have limited remedies if patents are infringed or if we are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

In Europe, expected by the end of 2023, European applications will soon have the option, upon grant of a patent, of becoming a Unitary Patent which will be subject to the jurisdiction of the Unitary Patent Court (UPC). This will be a significant change in European patent practice. As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation. It is our initial belief that the UPC, while offering a cheaper streamlined process, has potential disadvantages to patent holders, such as making a single European patent vulnerable in all jurisdictions when challenged in a single jurisdiction

Geo-political actions in the United States and in foreign countries could increase the uncertainties and costs surrounding the prosecution or maintenance of our patent applications or those of any current or future licensors and the maintenance, enforcement or defense of our issued patents or those of any current or future licensors. For example, the United States and foreign government actions related to Russia's invasion of Ukraine may limit or prevent filing, prosecution and maintenance of patent applications in Russia. Government actions may also prevent maintenance of issued patents in Russia. These actions could result in abandonment or lapse of our patents or patent applications, resulting in partial or complete loss of patent rights in Russia. If such an event were to occur, it could have a material adverse effect on our business. In addition, a decree was adopted by the Russian government in March 2022, allowing Russian companies and individuals to exploit inventions owned by patentees from the United States without consent or compensation. Consequently, we would not be able to prevent third parties from practicing our inventions in Russia or from selling or importing products made using our inventions in and into Russia.

Accordingly, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

We may not be able to obtain licenses to third-party intellectual property. Third parties may initiate legal proceedings alleging infringement of their intellectual property rights.

A third party may hold intellectual property, including patent rights that are important or necessary to the development or commercialization of our product candidates. However, we may not be able to obtain such licenses on commercially reasonable terms, or at all. In addition, our existing licenses may be terminated or may not be renewed, which could hurt our business.

In addition, our commercial success depends upon our ability to develop, manufacture, market and sell our products and product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. There is considerable intellectual property litigation in the biotechnology and pharmaceutical industries. We may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our products and technology, including interference or derivation proceedings before the USPTO. Numerous United States and foreign issued patents and pending patent applications owned by third parties exist in the fields in which we are developing our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, and as we gain greater visibility and market exposure as a public company, the risk increases that our products and product candidates or other business activities may be subject to claims of infringement of the patent and other proprietary rights of third parties. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future. We have conducted searches for information in support of efforts to obtain patent protection and have otherwise evaluated the patent landscape for nitric oxide releasing materials and products. Based on our knowledge of these searches and evaluations to date, we are not aware of any valid patents that contain granted claims that could be asserted with respect to our nitric oxide-based product candidates.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our products or product candidates or force us to cease some of our business operations. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. If we are found to infringe a third party's intellectual property rights, we could be required to redesign our infringing products or obtain a license from such third party to continue developing and marketing our products and technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. Moreover, we could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

We may be subject to claims by third parties asserting that we or our employees have misappropriated their intellectual property or claiming ownership of what we regard as our own intellectual property.

Many of our employees were previously employed at other biotechnology or pharmaceutical companies or universities. 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 these employees or we have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. Litigation may be necessary to defend against these claims. In addition, while it is our policy to require our employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. Our and their assignment agreements may not be self-executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property. If we fail in prosecuting or 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 prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to management.

Any trademarks we have obtained or may obtain may be infringed or successfully challenged, materially harming our business.

We expect to rely on trademarks as one means to distinguish our products and any of our product candidates that are approved for marketing from the products of our competitors. Once we select new trademarks and apply to register them, our trademark applications may not be approved. From time to time, third parties oppose or attempt to cancel our trademark applications and trademarks, or otherwise challenge our use of a trademark. In the event that our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. Further, our competitors may infringe our trademarks, including with respect to our Nitricil technology, and we may not have adequate resources to enforce our trademarks.

*Outside of the United States we cannot be certain that any country's patent or trademark office will not implement new rules that could seriously affect how we draft, file, prosecute and maintain patents, trademarks and patent and trademark applications***.**

We cannot be certain that the patent or trademark offices of countries outside the United States will not implement new rules that increase costs for drafting, filing, prosecuting and maintaining patents, trademarks and patent and trademark applications or that any such new rules will not restrict our ability to file for patent or trademark protection. For example, we may elect not to seek patent or trademark protection in some jurisdictions or for some product candidates or Nitricil compounds in order to save costs. We may be forced to abandon or return the rights to specific patents or trademark due to a lack of financial resources. In addition, changes in foreign patent or trademark laws along with geo-political actions involving the United States and/or a foreign country may limit or prevent filing, prosecution, maintenance, and/or enforcement of a patent application, patent, or trademark outside the United States.

Item 1B. Unresolved Staff Comments.

Not applicable.

Item 2. Properties.

On January 18, 2021, we entered into a lease with an initial term expiring in 2032, which has subsequently been amended, for 19,265 rentable square feet located in Durham, North Carolina. This site serves as our corporate headquarters and will support various cGMP activities, including research and development and small-scale manufacturing capabilities, used principally by our Research and Development Operations segment. These capabilities include the infrastructure necessary to support small-scale drug substance manufacturing and the ability to act as a primary, or secondary backup, component of a potential future commercial supply chain.

We have prepared our new location to support various cGMP activities, including research and development and small-scale manufacturing capabilities, as described in the section entitled "Business—Manufacturing and Supplies" in this Annual Report.

On March 3, 2022, EPI Health entered into a sublease agreement with EPG for office space at 174 Meeting Street in Charleston, South Carolina for approximately 6,000 rentable square feet (the "Meeting Street Lease"). The term of the Meeting Street Lease was initially through September 30, 2024, was used principally by our Commercial Operations segment, and we had the right to terminate the Meeting Street Lease with prior notice. On August 31, 2022, we notified EPG of our termination of the Meeting Street Lease effective February 28, 2023.

See "Note 6—"Leases" to the accompanying consolidated financial statements included in this Annual Report for additional information regarding facility lease transactions.

Item 3. Legal Proceedings.

We are not currently a party to any material legal proceedings and are not aware of any claims or actions pending against us that we believe could have a material adverse effect on our business, operating results, cash flows or financial statements. In the future, we may from time to time become involved in litigation relating to claims arising from our ordinary course of business.

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 Information

Our common stock trades on the Nasdaq Capital Market under the symbol "NOVN."

Holders

As of March 16, 2023, there were approximately 106 stockholders of record of our common stock. Holders of record are defined as those stockholders whose shares are registered in their names in our stock records and do not include beneficial owners of common stock whose shares are held in the names of brokers, dealers or clearing agencies.

Dividends

We have never paid cash dividends and do not anticipate paying cash dividends in the foreseeable future.

Recent Sales of Unregistered Securities

None.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

We did not purchase any of our equity securities during the fourth quarter of 2022.

Item 6. [Reserved]

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

This Management's Discussion and Analysis of Financial Condition and Results of Operations should be read with our consolidated financial statements and notes thereto included elsewhere in this Annual Report. In addition to historical information, the following discussion contains forward-looking statements that involve risks, uncertainties and assumptions. Where possible, we have tried to identify these forward-looking statements by using words such as "believe," "contemplate," "continue," "due," "goal," "objective," "plan," "seek," "target," "expect," "believe," "anticipate," "intend," "may," "will," "would," "could," "should," "potential," "predict," "project," or "estimate," and similar expressions or variations. These statements are based on the beliefs and assumptions of our management based on information currently available to management. Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Except as may be required by law, we undertake no obligation to update any forward-looking statements to reflect events or circumstances after the date of such statements. These forward-looking statements are subject to numerous risks including, but not limited to, those set forth in the "Risk Factors" in Part I, Item 1A of this Annual Report.

Overview

We are a medical dermatology company focused on developing and commercializing innovative therapeutic products for skin diseases. Our goal is to deliver safe and efficacious therapies to patients, including developing product candidates where there are unmet medical needs. We are developing SB206 (berdazimer gel, 10.3%) as a topical prescription gel for the treatment of viral skin infections, with a current focus on molluscum contagiosum, or molluscum.

In March 2022, we completed the EPI Health Acquisition. EPI Health equips us with a commercial infrastructure across sales, marketing, and communications, as well as a dedicated market access and pharmacy relations team, and positions us as a fully integrated dermatology company with a pipeline of development candidates focused primarily on dermatological indications, supported by a commercial platform to market and sell therapeutic products for skin diseases. We promote products for plaque psoriasis, rosacea and acne. We also have a pipeline of potential product candidates using our proprietary nitric oxide-based technology platform, Nitricil, to generate new treatments for multiple indications.

Further advancement of our molluscum program, including through the potential approval of SB206, advancement of any other early-stage or late-stage clinical program across our platform, and continuing our commercial operations until they are profitable, are all subject to our ability to secure additional capital. Sources of additional capital may potentially include (i) debt or equity financings, such as through sales of common stock, or (ii) other sources, such as partnerships, collaborations, licensing, grants or other strategic relationships. Any issuance of equity, or debt convertible into equity, would result in further significant dilution to our existing stockholders.

Please see additional details related to our "Commercial Portfolio" and "Research and Development Portfolio", as described in the section entitled "Business" in this Annual Report.

Business Updates

- In March 2023, we announced that the FDA completed its filing review of our NDA submitted in early January seeking marketing approval for berdazimer gel, 10.3% (SB206) for the topical treatment of molluscum contagiosum, or molluscum. The FDA determined our application was sufficiently complete, no filing review issues were identified, the substantive review process had commenced, and we were assigned a Prescription Drug User Fee Act goal date of January 5, 2024.
- For the year ended December 31, 2022, we demonstrated growth in total prescriptions for our actively marketed portfolio:
    - Rhofade (oxymetazoline hydrochloride) - 33% annual growth for the year ended December 31, 2022 with 156,664 total prescriptions.
    - Wynzora (calcipotriene and betamethasone dipropionate) - 41,023 total prescriptions for the year ended December 31, 2022, as the product was launched in the third quarter of 2021.
    - Minolira (minocycline hydrochloride) - 61% annual growth for the year ended December 31, 2022 with 40,641 total prescriptions.
- In late December 2022, we announced that we had entered into an exclusive license agreement with Sato granting Sato the right to develop, manufacture and market Rhofade (oxymetazoline hydrochloride 1% cream) for rosacea in the Japan territory. Under the exclusive license agreement, we received an upfront payment of $5.0 million in January 2023 and are entitled to receive a $2.5 million milestone payment at the time of marketing approval in Japan and royalty payments on net sales of the product in Japan. Sato will be responsible for obtaining regulatory approval in

Japan and will have the right to use our U.S. dossier for Rhofade held by EPI Health. Sato will also have a right of first negotiation related to Rhofade in certain other countries in the Asia Pacific region. A portion of the amounts of the upfront and milestone payments are payable by us to a third party under contractual obligations related to Rhofade.

- In early December 2022, we announced that we, through EPI Health, entered into an accounts receivable-backed factoring agreement with Bay View Funding, a wholly owned subsidiary of Heritage Bank of Commerce. The new $15.0 million factoring facility provides working capital in an amount that is up to 70% of our EPI Health subsidiary's gross eligible receivables.
- In July 2022, we announced the publication of positive efficacy and safety data from our completed B-SIMPLE 4 pivotal Phase 3 clinical study evaluating berdazimer gel, 10.3% for the treatment of molluscum in the peer-reviewed journal, *JAMA Dermatology*.
- In June 2022, we announced the closing of a $15.0 million registered direct offering priced at-the-market under Nasdaq rules with an institutional investor.
- In March 2022, we announced the acquisition of EPI Health, a specialty pharmaceutical company focused on the U.S. dermatology market. The acquisition provided the commercial infrastructure for us to become a fully-integrated specialty dermatology company with a solid pipeline of development candidates complemented by a commercial foundation. In July 2022, we announced that we had reached agreement with Evening Post Group, LLC, or EPG, regarding payment, satisfaction and termination of our $16.5 million secured promissory note and security agreement associated with the EPI Health Acquisition. We and EPG agreed that, upon EPG's receipt of $10.0 million, which we subsequently paid, all of our outstanding indebtedness and obligations under the promissory note were fully satisfied, and accordingly, the promissory note and related security agreements were terminated.

Working Capital and Additional Capital Needs

We will continue to need additional funding to support our planned and future operating activities, to support our commercial operations until they are profitable and make further advancements in our product development programs beyond what is currently included in our operating forecast and related cash projection. We do not currently have sufficient funds to complete commercialization of any of our product candidates that are under development, and our funding needs will largely be determined by our commercialization strategy for SB206 (berdazimer gel, 10.3%), subject to the regulatory approval process and outcome. We are pursuing a broad range of financing options that could be used to extend our cash runway and further prepare for commercialization of SB206 following approval.

Further advancement of our molluscum program, advancement of any other early-stage or late-stage clinical program across our platform, and supporting our commercial operations until they are profitable are subject to our ability to secure additional capital. Sources of additional capital may potentially include (i) debt or equity financings, such as through sales of common stock, or (ii) other sources, such as partnerships, collaborations, licensing, grants or other strategic relationships. Any issuance of equity, or debt convertible into equity, would result in further significant dilution to our existing stockholders.

In addition to the regulatory progression of SB206, including implementing prelaunch strategy and commercial preparation, subject to obtaining additional financing or strategic partnering, we may progress (a) SB204, a topical monotherapy for the treatment of acne, by commencing a pivotal Phase 3 study, or (b) SB019, as a potential intranasal treatment option for respiratory infections.

As of December 31, 2022, we had total cash and cash equivalents of $12.3 million and a working capital deficit of $4.0 million. As of December 31, 2022, we had $48.3 million in remaining availability for sales of our common stock under the Equity Distribution Agreement dated March 11, 2022, or the Equity Distribution Agreement, with Oppenheimer & Co., Inc., or Oppenheimer. Pursuant to the Equity Distribution Agreement, we may from time to time issue and sell our common stock to or through Oppenheimer, acting as our sales agent, in at-the-market transactions, subject to certain limitations. See Note 11 —"Stockholders' Equity" to the accompanying consolidated financial statements included in this Annual Report for more information on the Equity Distribution Agreement. In March 2023, we consummated a registered direct offering with an institutional investor for gross proceeds of approximately $6 million, or the March 2023 Registered Direct Offering. See Note 21—"Subsequent Events" to the accompanying consolidated financial statements included in this Annual Report for more information on the March 2023 offering.

Our inability to obtain significant additional funding on acceptable terms could have a material adverse effect on our business and cause us to alter or reduce our planned operating activities, including, but not limited to delaying, reducing, terminating or eliminating planned product candidate development activities or our preparations for potential commercial launch of SB206 (berdazimer gel, 10.3%), if approved, to conserve our cash and cash equivalents. We may pursue additional capital through equity or debt financings, including potential sales under the Equity Distribution Agreement, or from other sources, including partnerships, collaborations, licensing, grants or other strategic relationships. Alternatively, we may seek to engage in one or more potential transactions, which could include the sale of our company, or the sale, licensing or divestiture of some of our

assets, such as a sale of our dermatology platform assets, but there can be no assurance that we will be able to enter into such a transaction or transactions on a timely basis or at all on terms that are favorable to us.

If we are unable to obtain significant additional funding on acceptable terms or progress with a strategic transaction, we may instead determine to dissolve and liquidate our assets or seek protection under applicable bankruptcy laws. If we decide to dissolve and liquidate our assets or to seek protection under applicable bankruptcy laws, it is unclear to what extent we would be able to pay our obligations, and, accordingly, it is further unclear whether and to what extent any resources would be available for distributions to stockholders.

Please refer to "Liquidity and Capital Resources" for further discussion of our current liquidity and our future funding needs.

Supply Chain, Manufacturing and Supplies

We currently rely on third-party suppliers to provide the raw materials that are used by us and our third-party manufacturers in the manufacture of our product candidates and commercial products.

We have completed the commissioning of our new facility to support various research and development and cGMP activities, including small-scale manufacturing capabilities for API and drug product associated with our nitric oxide product candidates. We are in the process of, and proceeding with the related preparatory activities associated with, qualifying and validating the manufacturing equipment for use in API production in preparation for the FDA pre-approval inspection in connection with our pending NDA for SB206 (berdazimer gel, 10.3%) as a treatment for molluscum.

Please see additional details related to our "Supply Chain" and "Manufacturing and Supplies", as described in the section entitled "Business" in this Annual Report.

Financial Overview

Since our incorporation in 2006 through mid-March 2022, we devoted substantially all of our efforts to developing our nitric oxide platform technology and resulting product candidates, including conducting preclinical and clinical trials and providing general and administrative support for these operations. With the acquisition of a commercial entity, EPI Health, in March 2022, we have expanded our business into marketing and sales efforts with a portfolio of therapeutic products for skin diseases.

To date, we have focused our funding activities primarily on equity raises and strategic relationships. However, other historical forms of funding have included payments received from licensing and supply arrangements, as well as government research contracts.

As of December 31, 2022, we had an accumulated deficit of $310.3 million, and there is substantial doubt about our ability to continue as a going concern. We incurred net losses of $31.3 million and $29.7 million in the years ended December 31, 2022 and December 31, 2021, respectively. We expect to continue to incur substantial losses in the future as we conduct our planned operating activities.

Please refer to the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources" in this Annual Report for further discussion of our current liquidity and our future funding needs.

Components of our Results of Operations

Revenue

Net Product Revenues

The EPI Health Acquisition has provided our company with a commercial infrastructure to sell a marketed product portfolio of therapeutic products for skin diseases. Net product revenues represent the sales of medical dermatology products primarily for the treatment of rosacea, plaque psoriasis and acne, including Rhofade, Wynzora and Minolira.

For additional information regarding our accounting for net product revenues, see Note 1—"Organization and Significant Accounting Policies" and Note 13—"Net Product Revenues" to the accompanying consolidated financial statements.

License and Collaboration Revenues

License and collaboration revenues consist of (i) the amortization of certain fixed and variable consideration under the Sato license agreement that was entered into during the first quarter of 2017, as amended in October 2018, or the Sato Agreement, that either has been received to date in the form of upfront and milestone payments or non-contingent milestone payments that become payable upon the earlier occurrence of specified fixed dates or are contingent milestone payments that become payable upon the achievement of specified milestone events, (ii) amounts due under the Sato Rhofade Agreement in the form of upfront and milestone payments, and (iii) a distribution and supply agreement related to an out-license of an authorized generic, or AG, version of Cloderm, or Cloderm AG.

For additional information regarding our accounting for license and collaboration revenues, see Note 1—"Organization and Significant Accounting Policies" and Note 14—"License and Collaboration Revenues" to the accompanying consolidated financial statements.

Government Research Contracts and Grants Revenue

Government research contracts and grant revenue relates to the research and development of our nitric oxide platform for preclinical advancement of NCEs and formulations related to potential treatments for illnesses in the women's health field. Revenue related to conditional government contracts and grants is recognized when qualifying expenses are incurred.

Cost of Goods Sold

Cost of goods sold includes all costs directly incurred to produce net revenues from our marketed portfolio of medical dermatology products. Cost of goods sold primarily consist of (i) costs to procure, ship, handle and warehouse our marketed drug products, and (ii) royalty and milestone expenses incurred in connection with the various license, collaboration and asset purchase agreements underlying our marketed portfolio of medical dermatology products.

Research and Development Expenses

Research and development activities include conducting preclinical studies and clinical trials, manufacturing development efforts and activities related to regulatory filings for our product candidates. Research and development expenses, including those paid to third parties for which there is no alternative use, are expensed as they are incurred. Research and development expenses include:

- external research and development expenses incurred under agreements with clinical research organizations, or CROs, investigative sites and consultants to conduct our clinical trials and preclinical studies;
- costs to acquire, develop and manufacture supplies for clinical trials and preclinical studies at our facilities;
- costs to establish drug substance and drug product manufacturing capabilities with external contract manufacturing organizations, or CMOs, and to enhance drug delivery device technologies through partnerships with technology manufacturing vendors;
- legal and other professional fees related to compliance with FDA requirements;
- licensing fees and milestone payments incurred under license agreements;
- salaries and related costs, including stock-based compensation, for personnel in our research and development functions; and
- facilities, depreciation and other allocated expenses, which include direct and allocated expenses for rent, maintenance of facilities, utilities, equipment and other supplies.

We expect that for the foreseeable future, the substantial majority of our research and development efforts will be focused on (i) technical transfer and supportive manufacturing activities by our drug product CMO, (ii) operational testing and validation activities related to the NDA pre-inspection process, and (iii) regulatory and quality documentation compilation related to our CMC data, and our drug manufacturing and related processes.

We also expect to incur substantial costs in 2023 associated with our research and development personnel, and manufacturing capability costs related to the infrastructure necessary to support small-scale drug substance and drug product manufacturing operations at our corporate headquarters, including capital costs subject to depreciation and various ongoing operating costs. We may decide to revise our development and operating plans or the related timing, depending on information we learn through our research and development activities, including regulatory submission updates related to SB206, potential SB206 commercialization strategies, the impact of outside factors such as the COVID-19 pandemic, our ability to enter into strategic arrangements, our ability to access additional capital and our financial priorities.

The successful development and potential regulatory approval of our product candidates is highly uncertain. At this time, we cannot reasonably estimate the nature, timing or costs required to complete the remaining development of our current product candidates or any future product candidates. This is due to the numerous risks and uncertainties associated with the development of product candidates. See the "Risk Factors" section in this Annual Report for a discussion of the risks and uncertainties associated with our research and development projects.

Selling, General and Administrative Expenses

Our selling, general and administrative expenses consist primarily of salaries and related costs, including stock-based compensation expenses, for personnel in our commercial, field sales, marketing, market access, medical affairs, regulatory, finance, corporate development and other functions. Other selling, general and administrative expenses include advertising, promotion, travel, consulting, market research costs, prelaunch strategy costs, medical affairs, and commercial costs, including commercial preparation activities for our lead product candidate, SB206, allocated depreciation and facility-related costs, legal costs of pursuing patent protection of our intellectual property, insurance coverage and professional services fees for auditing, tax, general legal, business development, litigation defense and other corporate and administrative services.

We expect to continue to incur substantial selling, general and administrative expenses in 2023 in support of our commercial product portfolio and the prelaunch strategy and commercial preparation activities for SB206. We may decide to revise our plans or the related timing associated with our commercial product portfolio, and prelaunch strategy and commercial preparation activities for SB206, depending on information we learn through our regulatory submission updates and potential SB206 commercialization strategies.

We also expect to continue to incur substantial selling, general and administrative expenses in 2023 in support of our operating activities and as necessary to operate in a public company environment. These expenses include legal, accounting, regulatory and tax-related services associated with maintaining compliance with exchange listing and SEC requirements, directors' and officers' liability insurance premiums and investor relations activities.

Amortization of Intangible Assets

Amortization of intangible assets is associated with the amortization of definite lived intangible assets acquired as part of the EPI Health Acquisition.

For additional information regarding the recognition and amortization of our intangible assets, see Note 7—"Goodwill and Intangible Assets, net" to the accompanying consolidated financial statements.

Change in Fair Value of Contingent Consideration

Contingent consideration is recorded as a liability and is the estimate of the fair value of potential milestone payments related to the EPI Health Acquisition. The estimated fair value of contingent consideration was determined based on a probability-weighted valuation model that measures the present value of the probable cash payments based upon the future milestone events of EPI Health at a discount rate that captures the risk associated with the liability and also based on a Monte Carlo simulation, whereby EPI Health's forecasted net sales from the EPI Health legacy products were simulated over the measurement period to calculate the contingent consideration. Contingent consideration is remeasured at each reporting date and any changes in the liability are recorded within the consolidated statement of operations and comprehensive loss.

For additional information regarding the valuation of contingent consideration, see Note 19—"Fair Value" to the accompanying consolidated financial statements.

Impairment Loss on Long-lived Assets

During the second quarter of 2021, we assessed the carrying value of a disposal group classified as assets held for sale in the accompanying consolidated balance sheets. The disposal group and related assets consisted of certain manufacturing and laboratory equipment associated with our previous large scale drug manufacturing capability that was being sold over time through a consignment seller. Based on our assessment of the disposal group's recoverability, during the three months ended June 30, 2021, we recognized an impairment loss on long-lived assets that represented the full write off of its remaining carrying value.

Other Income (Expense), net

Other income (expense), net consists primarily of (i) foreign currency adjustments related to the contract asset and contract receivables related to the Sato Agreement, (ii) interest expense on outstanding notes payable, (iii) interest income earned on cash and cash equivalents, (iv) gain on extinguishment of debt related to the forgiveness of our PPP loan and extinguishment of our note payable related to the EPI Health Acquisition, and (v) other miscellaneous income and expenses.

Financial Information About Segments

Management evaluates performance of the Company based on operating segments. Segment performance for our two operating segments is based on segment net revenue and net loss. Our reportable segments consist of (i) research and development activities related to our nitric oxide-based technology to develop product candidates, or the Research and Development Operations segment, and (ii) the promotion of commercial products for the treatment of medical dermatological conditions, or the Commercial Operations segment. We do not currently evaluate certain items at the segment level, including certain selling, general and administrative expenses that result from shared infrastructure, certain expenses associated with litigation and other legal matters, public company costs (e.g. investor relations), board of directors and principal executive officers, and other like shared expenses.

See Note 20—"Segment Information" in the accompanying consolidated financial statements included in this Annual Report for more information about our reportable segments.

Results of Operations

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

The following table sets forth our results of operations for the periods indicated:

	Year Ended December 31,			
	2022	2021	$ Change	% Change
	(in thousands, except percentages)			
Net product revenues	$ 15,796	$ —	$ 15,796	*
License and collaboration revenue	7,813	2,822	4,991	177 %
Government research contracts and grants revenue	73	136	(63)	(46)%
Total revenue	23,682	2,958	20,724	701 %
Operating expenses:				
Cost of goods sold	7,379	—	7,379	*
Research and development	15,990	20,416	(4,426)	(22)%
Selling, general and administrative	34,103	12,343	21,760	176 %
Amortization of intangible assets	1,600	—	1,600	*
Change in fair value of contingent consideration	(1,160)	—	(1,160)	*
Impairment loss on long-lived assets	—	114	(114)	(100)%
Total operating expenses	57,912	32,873	25,039	76 %
Operating loss	(34,230)	(29,915)	(4,315)	14 %
Other income (expense), net:				
Interest income	53	13	40	308 %
Interest expense	(1,452)	—	(1,452)	*
Gain on debt extinguishment	4,340	956	3,384	354 %
Other expense	(22)	(746)	724	(97)%
Total other income (expense), net	2,919	223	2,696	1209 %
Net loss and comprehensive loss	$ (31,311)	$ (29,692)	$ (1,619)	5 %

** Not meaningful*

Net product revenues

The EPI Health Acquisition provided commercial infrastructure to sell a marketed product portfolio of therapeutic products for skin diseases. Net product revenues for the year ended December 31, 2022 were $15.8 million, which were all generated by our Commercial Operations segment.

Net product revenues represent the sales of medical dermatology products primarily for the treatment of rosacea, plaque psoriasis, acne and dermatoses, including Rhofade, Wynzora, Minolira and Cloderm. There were no such net product revenues in the comparative period in 2021.

For additional information regarding our accounting for net product revenues, see Note 1—"Organization and Significant Accounting Policies" and Note 13—"Net Product Revenues" to the accompanying consolidated financial statements included in this Annual Report.

License and collaboration revenues

License and collaboration revenues were $7.8 million and $2.8 million for the years ended December 31, 2022 and December 31, 2021, respectively. For the year ended December 31, 2022, license and collaboration revenue was comprised of amounts related to (i) the Amended Sato Agreement, related to the Japanese territory out-license of SB206 and SB204, of $2.6 million, recorded in the Research and Development Operations segment, (ii) $5.0 million related to the December 2022 Sato Rhofade Agreement and the related upfront payment, recorded in the Commercial Operations segment, and (iii) $0.2 million related to the distribution and supply agreement with Prasco, LLC related to the out-license of Cloderm AG (the "Prasco Agreement"), recorded in the Commercial Operations segment.

For the year ended December 31, 2021 license and collaboration revenue was comprised solely of amounts related to the Amended Sato Agreement.

The Amended Sato Agreement and the related revenue recognized is associated with our performance during the period and the related amortization of the non-refundable upfront and expected milestone payments under that agreement. A change in revenue recognized for the years ended December 31, 2022 and December 31, 2021 relates to a change in estimate related to the expected duration of the combined SB204 and SB206 development program timeline in July 2021. This most recent change in estimate resulted in a program timeline extension of the performance period estimate to 10 years, completing in the first quarter of 2027.

The material terms of the Amended Sato Agreement and the December 2022 Sato Rhofade Agreement and related revenue recognition are described in Note 14—"License and Collaboration Revenues" to the accompanying consolidated financial statements included in this Annual Report.

Government Research Contracts and Grants Revenue

Government research contracts and grants revenue totaled $0.1 million and $0.1 million for the years ended December 31, 2022 and December 31, 2021, respectively. These amounts relate to (i) a federal grant from the U.S. Department of Defense's Congressionally Directed Medical Research Programs, and (ii) a federal grant from the National Institute of Health for certain nitric oxide based anti-viral therapies and their related development.

Cost of goods sold

Cost of goods sold of $7.4 million for the year ended December 31, 2022 is recorded by our Commercial Operations segment and includes all costs directly incurred to produce net product revenues from our marketed portfolio of medical dermatology products. Cost of goods sold primarily consist of (i) costs to procure, ship, handle and warehouse our marketed drug products, and (ii) royalty and milestone expenses incurred in connection with the various license, collaboration and asset purchase agreements underlying our marketed portfolio of medical dermatology products.

As part of the Sato Rhofade Agreement and third-party obligations related to our Rhofade agreements, we accrued 25% of the upfront payment due to us, resulting in an accrued milestone expense of $1.25 million within cost of goods sold as of December 31, 2022.

For additional information regarding our accounting for cost of goods sold, see Note 1—"Organization and Significant Accounting Policies", Note 12—"License and Collaboration Agreements", Note 13—"Net Product Revenues" and Note 14—"License and Collaboration Revenues" to the accompanying consolidated financial statements included in this Annual Report.

Research and development expenses

Our Research and Development Operations segment incurred the substantial majority of our research and development expenses, which were $16.0 million for the year ended December 31, 2022, compared to $20.4 million for the year ended December 31, 2021. The net decrease of $4.4 million, or 22%, was primarily related to a $4.6 million net decrease in the SB206 program, partially offset by a $0.2 million increase in other research and development expenses.

In the SB206 program, we experienced (i) a $6.8 million decrease in gross clinical trial costs primarily due to the B-SIMPLE4 Phase 3 trial execution activities that occurred during the prior year comparative period, and (ii) a $0.9 million increase in contra-research and development expense from the ratable amortization of the Ligand Funding Agreement liability, which represents Ligand's contribution to specified clinical development and regulatory activities for SB206 as a treatment for molluscum, partly offset by (iii) a $3.1 million increase in regulatory consulting services, stability and other analytical testing services, and CMC consulting services and materials in support of our SB206 NDA submission.

The $0.2 million increase in other research and development expenses was primarily driven by (i) a $0.8 million net increase in research and development personnel costs, and (ii) a $0.4 million net increase in research and development facility operating expenses, partly offset by a $1.0 million net decrease in preclinical development activity costs, including the SB019 program, and research and development facility operating expenses.

The $0.8 million net increase in research and development personnel costs is primarily due to (i) a $0.7 million increase in non-cash compensation expense, including stock based compensation, and (ii) a $0.1 million increase in recurring salary and benefits costs.

Selling, general and administrative expenses

Selling, general and administrative expenses were $34.1 million for the year ended December 31, 2022, compared to $12.3 million during the year ended December 31, 2021.

The table below sets forth our total selling, general and administrative expenses incurred for the year ended December 31, 2022 and December 31, 2021 and the primary drivers of the fluctuations from the prior period:

	Selling, general and administrative expenses	
Year Ended December 31, 2021	$	12,343
Year Ended December 31, 2022		34,103
Change from prior period	**$**	**21,760**

	Prior Period Variance Detail Increase / (Decrease)	
EPI Health Acquisition Transaction-related costs	$	4,691
EPI Health commercial sales operations		13,733
SB206 prelaunch and commercial preparation		1,103
Tax and insurance costs		291
Facility and depreciation costs		295
Professional services and other administrative costs		598
Personnel and related benefits		1,049
Change from prior period	**$**	**21,760**

The $4.7 million of transaction- and integration-related expenditures incurred in connection with the EPI Health Acquisition included transaction-related fees paid to banking advisors, insurance brokers, due diligence costs, and legal, regulatory, intellectual property, information technology, valuation and accounting consultants and specialists, and integration-related expenditures associated with transition services, information technology systems, integration project management and continued valuation and accounting consultants and specialists.

The $13.7 million of selling, general and administrative expenses incurred to support the conduct of EPI Health's commercial sales operations included (i) $6.9 million of recurring salary, incentive compensation and benefits costs, (ii) $1.4 million of advertising and promotion costs, (iii) $3.8 million of administrative costs related to third-party consultants for regulatory services, external third-party data services and other service providers that support the commercial sales and operations teams, and (iv) $1.6 million of travel and expense related costs.

The $1.0 million increase in general and administrative personnel and related costs includes (i) a $0.9 million increase in non-cash compensation expense associated with stock based compensation, and (ii) a $0.1 million increase in recurring salary and benefits costs between the two comparative periods.

Amortization of intangible assets

Amortization of intangible assets of $1.6 million for the year ended December 31, 2022 is associated with the amortization of definite lived intangible assets acquired as part of the EPI Health Acquisition.

For additional information regarding the recognition and amortization of our intangible assets, see Note 7—"Goodwill and Intangible Assets, net" to the accompanying consolidated financial statements included in this Annual Report.

Change in fair value of contingent consideration

For the year ended December 31, 2022, the changes in fair value related to contingent consideration related to the EPI Health Acquisition related primarily to changes in market assumptions, management forecasts and discount rates since the transaction date. For additional information regarding contingent consideration valuation, see Note 19—"Fair Value" to the accompanying consolidated financial statements included in this Annual Report.

Impairment loss on long-lived assets

During the second quarter of 2021, we assessed the carrying value of a disposal group classified as assets held for sale in our condensed consolidated balance sheets. The disposal group and related assets consisted of certain manufacturing and laboratory equipment associated with our previous large scale drug manufacturing capability that was being sold over time through a consignment seller. Based on our assessment of the disposal group's recoverability, during the year ended December 31, 2021, we recognized a $0.1 million non-cash impairment loss on long-lived assets that represented the full write off of its remaining carrying value.

Other income (expense), net

Other income, net was $2.9 million for the year ended December 31, 2022, compared to $0.2 million for the year ended December 31, 2021. This change was primarily due to a $4.3 million gain on debt extinguishment recognized in connection with the termination of the Seller Note during the third quarter of 2022, partially offset by $1.4 million of interest expense related to the Seller Note issued in March 2022 in connection with the EPI Health Acquisition.

Total other income, net in the comparative 2021 period is primarily comprised of a $1.0 million gain on extinguishment of debt related to the forgiveness of our PPP loan in 2021, partially offset by $0.7 million of other expense related to the impact of foreign currency exchange rate fluctuations for certain time-based milestones related to the Amended Sato Agreement.

For additional information regarding the Seller Note and the accounting for its termination, see Note 10—"Notes Payable" to the accompanying consolidated financial statements included in this Annual Report.

Liquidity and Capital Resources

As of December 31, 2022, we had an accumulated deficit of $310.3 million. We incurred net losses of $31.3 million and $29.7 million for the years ended December 31, 2022 and December 31, 2021, respectively, and there is substantial doubt about our ability to continue as a going concern. Despite revenues generated from the sales of commercial products acquired during the EPI Health Acquisition, we anticipate that we will continue to generate losses for the foreseeable future, and we expect the losses to increase as we further commercialize our existing commercial products and continue the development of, and seek regulatory approvals for, our product candidates and potentially begin commercialization activities for our product candidates that are currently under development. We are subject to all of the risks inherent in the commercialization of drug products, such as risks related to competition, supply issues or issues that may impact use of our commercial drug products, and in the development of new pharmaceutical products, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The sales of our commercial products will decrease over time if and when they face generic competition or if other risks materialize, and we do not expect to generate revenue from product sales for our clinical-stage product candidates unless and until we obtain regulatory approval from the FDA for such product candidates. We will continue to incur significant expenses related to the commercialization of our commercial products, and if we obtain regulatory approval for any of our product candidates, we and/or our commercial partners and commercial solutions providers would expect to incur significant expenses related to product sales, marketing, manufacturing and distribution.

As of December 31, 2022, we had total cash and cash equivalents of $12.3 million and a working capital deficit of $4.0 million. As discussed below, we used a portion of our cash and cash equivalents to pay off and terminate the Seller Note issued in connection with the EPI Health Acquisition, as well as to fund the EPI Health Acquisition. With the payment and termination of the Seller Note for a reduced amount of principal, we have removed certain previously existing liabilities and eliminated the need to make cash payments to service the interest on the Seller Note going forward. This allows us to use our cash for development of our product candidates and to support the commercialization of our products. The payment and termination of the Seller Note removed encumbrances from the assets of EPI Health and allows us to pursue a broader range of financing options that could be used to extend our cash runway and to further prepare for commercialization of SB206 following approval.

From January 1, 2021 through December 31, 2022, we have raised total equity and debt proceeds of $70.1 million to fund our operations, including (i) $14.0 million in net proceeds from the sale of common stock (or pre-funded warrants in lieu thereof) and accompanying common warrants in the June 2022 Registered Direct Offering, (ii) $37.2 million in net proceeds from the sale of common stock in the June 2021 public offering, (iii) $6.3 million in proceeds from the sale of common stock under our common stock purchase agreements with Aspire Capital, (iv) $1.7 million from our Equity Distribution Agreement, (v) a net of $10.3 million from our accounts receivable factoring facility, (vi) an additional $0.5 million of proceeds associated with exercises of common stock warrants issued as part of the March 2020 public offering and March 2020 registered direct offering and (vii) less than $0.1 million of proceeds from the exercise of stock options.

To date, we have focused our funding activities primarily on equity financings, while generating additional liquidity and capital through other sources, including (i) governmental research contracts and grants totaling $12.9 million, (ii) our licensing and

supply arrangements with Sato, totaling $38.1 million, and (iii) $25.0 million and $12.0 million in proceeds from two funding transactions during the second quarter of 2019 with Reedy Creek Investments LLC, or Reedy Creek, and Ligand, respectively.

Going forward, we plan to finance our needs principally from the following:

- equity and/or debt financing, including but not limited to sales under the Equity Distribution Agreement, with certain limitations as described in "Management's Discussion and Analysis of Financial Condition and Results of Operations —Capital Requirements";
- revenues from product sales;
- payments under existing out-license and distribution arrangements for our product candidates and commercial products; and
- payments under current or future collaboration and licensing agreements with strategic partners.

We believe that our existing cash and cash equivalents as of December 31, 2022, plus expected receipts associated with product sales from our commercial product portfolio and the proceeds of the March 2023 Registered Direct Offering, will provide us with adequate liquidity to fund our planned operating needs into the latter part of the second quarter of 2023. Variability in our operating forecast, driven primarily by (i) commercial product sales, (ii) timing of operating expenditures, and (iii) unanticipated changes in net working capital, will impact our cash runway. This operating forecast and related cash projection includes (i) costs associated with preparing for and seeking U.S. regulatory approval of SB206 as a treatment for molluscum (ii) costs associated with the readiness and operation of our new manufacturing capability necessary to support small-scale drug substance and drug product manufacturing, (iii) conducting drug manufacturing activities with external third-party CMOs, (iv) ongoing commercial operations, including sales, marketing, inventory procurement and distribution, and supportive activities, related to our portfolio of therapeutic products for skin diseases acquired with the EPI Health Acquisition, and (v) initial efforts to support potential commercialization of SB206, but excludes additional operating costs that could occur between the NDA submission for SB206 through NDA approval, including, but not limited to, marketing and commercialization efforts to achieve potential launch of SB206. We may decide to revise our development and operating plans or the related timing, depending on information we learn through our research and development activities, including regulatory efforts related to SB206, potential commercialization strategies, the impact of outside factors such as the COVID-19 pandemic, our ability to enter into strategic arrangements, our ability to access additional capital and our financial priorities.

We will need significant additional funding to continue our operating activities, make further advancements in our product development programs and potentially commercialize any of our product candidates beyond those activities currently included in our operating forecast and related cash projection. Therefore, we will need to secure additional capital or financing and/or delay, defer or reduce our cash expenditures before the end of the second quarter of 2023. There can be no assurance that we will be able to obtain additional capital or financing on terms acceptable to us, on a timely basis or at all.

Our inability to obtain significant additional funding on acceptable terms could have a material adverse effect on our business and cause us to alter or reduce our planned operating activities, including, but not limited to delaying, reducing, terminating or eliminating planned product candidate development activities, furloughing employees or reducing the size of the workforce, to conserve our cash and cash equivalents. We may pursue additional capital through equity or debt financings, including potential sales under the Equity Distribution Agreement, or from other sources, including partnerships, collaborations, licensing, grants or other strategic relationships. Alternatively, we may seek to engage in one or more potential transactions, which could include the sale of our company, or the sale, licensing or divestiture of some of our assets, such as a sale of our dermatology platform assets, but there can be no assurance that we will be able to enter into such a transaction or transactions on a timely basis or at all on terms that are favorable to us.

If we are unable to obtain significant additional funding on acceptable terms or progress with a strategic transaction, we may instead determine to dissolve and liquidate our assets or seek protection under applicable bankruptcy laws. If we decide to dissolve and liquidate our assets or to seek protection under applicable bankruptcy laws, it is unclear to what extent we would be able to pay our obligations, and, accordingly, it is further unclear whether and to what extent any resources would be available for distributions to stockholders.

Our cash and cash equivalents are held in a variety of interest-bearing instruments, including money market accounts. Cash in excess of immediate requirements is invested with a view toward liquidity and capital preservation, and we seek to minimize the potential effects of concentration and degrees of risk.

Factoring Arrangement

As discussed further in Note 9—"Commitments and Contingencies" to the accompanying consolidated financial statements included in this Annual Report, EPI Health entered into an accounts receivable-backed factoring agreement with Bay View. Pursuant to the Factoring Agreement, EPI Health may sell certain trade accounts receivable to Bay View from time to time, with recourse. The factoring facility provides for EPI Health to have access to the lesser of (i) $15.0 million, or the Maximum Credit, or (ii) the sum of all undisputed receivables purchased by Bay View multiplied by 70% (which percentages may be adjusted by Bay View in its sole discretion), less any reserved funds. Upon receipt of any advance, EPI Health will have sold and assigned all of its rights in such receivables and all proceeds thereof. EPI Health factors the accounts receivable on a recourse basis. Therefore, if Bay View cannot collect the factored accounts receivable from the customer, EPI Health must refund the advance amount remitted to it for any uncollected accounts receivable from the customer.

As of December 31, 2022, $10.3 million of advances were outstanding under the factoring facility. The proceeds of the factoring will be used to fund general working capital needs. We have been and will be charged a financing and factoring fee in connection with the Factoring Agreement, and the extent to which we can utilize the Factoring Agreement is limited to the Maximum Credit and dependent on the extent to which we generate qualifying accounts receivable.

March 2022 Equity Distribution Agreement – At-the-Market Facility

On March 11, 2022, we entered into an Equity Distribution Agreement, or the Equity Distribution Agreement, with Oppenheimer & Co. Inc., or Oppenheimer. Pursuant to the Equity Distribution Agreement, we may from time to time issue and sell to or through Oppenheimer, acting as our sales agent, shares of our common stock, par value $0.0001 per share having an aggregate offering price of up to $50.0 million. Sales of the shares, if any, will be made by any method permitted by law deemed to be an "at the market offering" as defined in Rule 415(a)(4) promulgated under the Securities Act, or, if expressly authorized by us, in privately negotiated transactions. As sales agent, Oppenheimer will offer the shares at prevailing market prices and will use its commercially reasonable efforts, consistent with its sales and trading practices, to sell on our behalf all of the shares requested to be sold by us, subject to the terms and conditions of the Equity Distribution Agreement. We or Oppenheimer may suspend the offering of the shares upon proper notice to the other party. The offering of the shares pursuant to the Equity Distribution Agreement will terminate upon the sale of shares in an aggregate offering amount equal to $50.0 million, or sooner if either we or Oppenheimer terminate the Equity Distribution Agreement as permitted by its terms. We will pay Oppenheimer a commission in connection with sales under the Equity Distribution Agreement, and the extent to which we can utilize the Equity Distribution Agreement is limited by factors such as market conditions and the terms of the Equity Distribution Agreement.

During the year ended December 31, 2022, we sold 645,105 shares of our common stock at an average price of approximately $2.66 per share for total net proceeds of $1.7 million under the Equity Distribution Agreement.

See Note 11—"Stockholders' Equity" to the accompanying consolidated financial statements included in this Annual Report for additional information regarding Equity Distribution Agreement.

June 2022 Registered Direct Offering

On June 9, 2022, we entered into a securities purchase agreement with an institutional investor, or the Purchaser, pursuant to which we agreed to issue and sell to the Purchaser, in a registered direct offering priced at-the-market under Nasdaq rules, or the June 2022 Registered Direct Offering (i) 2,080,696 shares, or the June 2022 Shares of our common stock, and accompanying common stock warrants, or the June 2022 Common Warrants, to purchase an aggregate of 2,080,696 shares of common stock, for a combined price of $2.851 per share and accompanying common warrant, and (ii) pre-funded warrants to purchase 3,180,615 shares of our common stock, or the June 2022 Pre-funded Warrants, and accompanying common warrants to purchase 3,180,615 shares of common stock, for a combined price of $2.841 per pre-funded warrant and accompanying common warrant. The June 2022 Registered Direct Offering closed on June 13, 2022. Net proceeds from the offering were approximately $14.0 million after deducting fees and commissions and offering expenses of approximately $0.9 million. Offering costs were netted against the offering proceeds and recorded to additional paid-in capital.

As of December 31, 2022, no June 2022 Pre-funded Warrants and 5,261,311 June 2022 Common Warrants are outstanding.

We entered into a placement agent agreement, or the "Placement Agent Agreement, dated as of June 9, 2022, engaging Oppenheimer to act as the sole placement agent in connection with the June 2022 Registered Direct Offering. Pursuant to the Placement Agent Agreement, we agreed to pay Oppenheimer a placement agent fee in cash equal to 5.0% of the gross proceeds from the sale of the June 2022 Shares, the June 2022 Pre-funded Warrants and the June 2022 Common Warrants, and to reimburse certain expenses of Oppenheimer in connection with the June 2022 Registered Direct Offering. Each June 2022 Pre-funded Warrant had an exercise price of $0.01 per share. The June 2022 Pre-funded Warrants were exercisable immediately upon issuance until all of the June 2022 Pre-funded Warrants were exercised in full. Each June 2022 Common Warrant is immediately exercisable and has an exercise price of $2.851 per share and will expire five years from the date of issuance.

The exercise price and the number of shares of common stock purchasable upon the exercise of the June 2022 Pre-funded Warrants and June 2022 Common Warrants are subject to adjustment upon the occurrence of specific events, including stock dividends, stock splits, reclassifications and combinations of the Company's common stock.

See Note 11—"Stockholders' Equity" to the accompanying consolidated financial statements included in this Annual Report for additional information regarding the June 2022 Registered Direct Offering.

EPI Health

Acquisition

On March 11, 2022, we completed the acquisition of EPI Health, a commercial-stage pharmaceutical company founded in 2017 that focuses on the commercialization of medical dermatology pharmaceutical products for the treatment of skin conditions. Following the EPI Health Acquisition, our current portfolio includes six branded prescription drugs, and we actively promote three medical dermatological products in the U.S. and derive revenue from the sale of these branded products through pharmaceutical wholesalers as well as direct to pharmacies. These prescription dermatology therapies are targeted to patients with plaque psoriasis, rosacea and acne. The branded and promoted product portfolio currently includes Wynzora, Rhofade and Minolira.

At closing, we paid or committed to pay non-contingent consideration totaling $27.5 million, as adjusted for cash, indebtedness, net working capital estimates and other contractually defined adjustments. The purchase price consisted of (i) $11.0 million paid in cash, (ii) a secured promissory note issued to EPG in the principal amount of $16.5 million, or the Seller Note, and (iii) a $1.0 million payment representing an adjustment for estimated net working capital.

The purchase agreement entered into in connection with the EPI Health Acquisition, or the EPI Heath Purchase Agreement, included the potential payment of additional contingent consideration totaling up to $23.0 million upon achievement of certain milestones.

See Note 2—"Acquisition of EPI Health" to the accompanying consolidated financial statements included in this Annual Report for additional information regarding the acquisition of EPI Health.

Seller Note Payment and Termination

On July 13, 2022, we reached agreement with EPG regarding payment and termination of the outstanding $16.5 million Seller Note related to the EPI Health Acquisition. We achieved this termination by a payment of $10.0 million, or an approximate 39% discount on the original principal amount of the Seller Note. In addition to saving $6.5 million of principal with this termination, we also avoided paying interest over the previous term of the Seller Note of approximately $4.6 million.

Pursuant to the terms of the Seller Note, there was no penalty for repaying the Seller Note prior to the end of the term. In connection with the repayment of the Seller Note, the guaranty agreement between EPG and EPI Health, dated March 11, 2022, was terminated as of July 13, 2022. Accordingly, the liens on the membership interests and assets of EPI Health were also terminated such that no obligations with respect to the Seller Note and related securities agreement or the underlying loan remain outstanding.

See Note 2—"Acquisition of EPI Health" and Note 10—"Notes Payable" to the accompanying consolidated financial statements included in this Annual Report for additional information regarding the acquisition of EPI Health and the Seller Note.

Working Capital Adjustment Payment

On July 7, 2022, we and EPG agreed to the final net working capital adjustment amount as part of the post-closing adjustment to the estimated purchase price for the EPI Health Acquisition. The total adjustment amount was positive and in the amount of $3.1 million, which was paid to EPG on July 7, 2022.

See Note 2—"Acquisition of EPI Health" to the accompanying consolidated financial statements included in this Annual Report for additional information regarding the acquisition of EPI Health.

Licensing Arrangements

Sato Rhofade Agreement

In December 2022, we entered into a license agreement with Sato in which they were granted an exclusive, royalty-bearing, non-transferable right and license under certain of EPI Health's intellectual property rights to develop, manufacture and market Rhofade (oxymetazoline hydrochloride cream, 1%) for the treatment of rosacea in Japan, or the Sato Rhofade Agreement. In addition, per the Sato Rhofade Agreement, during a specified time period, Sato has an exclusive option to negotiate the terms under which its license would be expanded to include certain other countries in the Asia-Pacific region.

In exchange for the license granted to Sato, Sato agreed to pay us the following: (i) an upfront payment of $5.0 million; and (ii) a milestone payment of $2.5 million upon receipt of marketing approval of Rhofade for rosacea in the Japan territory. Sato also agreed to pay tiered royalty payments on net sales of the licensed product ranging over time from a percentage of net sales in the mid-teens to a percentage of net sales in the low single digits.

In addition, we are required to pay 25% of the upfront and milestone payment amounts to a third party under existing contractual obligations related to Rhofade and will also be required to pay a portion of the royalty amounts received under the Sato Rhofade Agreement to third parties, after which we will retain net royalties in the low single digits.

For additional information about the Sato Rhofade Agreement, please refer to Note 14—"License and Collaboration Revenues" to the accompanying consolidated financial statements included in this Annual Report.

Wynzora Agreement

Effective as of January 1, 2022, EPI Health entered into an amended and restated promotion and collaboration agreement with MC2 Therapeutics Limited, or MC2, relating to the commercialization of Wynzora for treatment of plaque psoriasis in adults in the United States, or the MC2 Agreement. Pursuant to the MC2 Agreement, which sets forth the collaborative efforts between EPI Health and MC2 to commercialize and promote Wynzora with MC2 in the United States, MC2 granted EPI Health an exclusive right and license under MC2's intellectual property rights to sell, or detail (as defined in the MC2 Agreement), and engage in certain commercialization activities with respect to Wynzora in the United States.

In exchange for the provision of promotional and commercialization activities, under the terms of the MC2 Agreement, we are entitled to receive:

- Reimbursement for all incremental costs incurred by us for the promotion and commercialization of Wynzora, including the incremental portion of our personnel and commercial operating costs. The supply price of Wynzora product inventory is also considered to be an incremental cost that is reimbursed by MC2.
- A commercialization fee equivalent to a percentage of net sales ranging from the mid-teens for net sales less than or equal to $65.0 million to the upper single digits for annual net sales greater than $105.0 million. We collect this commercialization fee by retaining our portion of the Wynzora product net sales we collect from our customers, with the remainder of the net sales being remitted by us to MC2 periodically in the form of a royalty payment, pursuant to the MC2 Agreement.
- A contingent incentive fee equal to 5% of the first $30.0 million in net sales of Wynzora sold in the United States by EPI Health in each of the 2022 and 2023 calendar years; provided that such incentive fee shall not exceed $1.5 million each year and such incentive fee shall not be credited to us until the royalty payments paid to MC2 surpass the amount of certain commercialization payments made previously by MC2.

The term of the MC2 Agreement runs until the seventh anniversary of the first commercial sale of Wynzora (as defined in the MC2 Agreement) or June 30, 2028, whichever is earlier. Either party may terminate the MC2 Agreement for the other party's material uncured breach or the bankruptcy or insolvency of the other party. MC2 may terminate the MC2 Agreement under certain scenarios, including for convenience with twelve months' advance notice to us, provided that the termination is not effective unless MC2 pays any unpaid historical liabilities related to commercialization of Wynzora owed by MC2. In the case of such termination, MC2 is also required to make an additional sunset payment to us, paid in installments over the 24 month period following termination. We may terminate the MC2 Agreement for convenience with twelve months' advance notice to MC2 provided that the termination is not effective unless we provide MC2 with a guarantee of the payment of any outstanding royalty payments, to the extent such royalty payments owed by us exceeds any unpaid historical liabilities related to commercialization of Wynzora owed by MC2.

For additional information about the Wynzora and MC2 Agreement, please refer to Note 13—"Net Product Revenues" to the accompanying consolidated financial statements included in this Annual Report.

Rhofade Agreements

As described in Note 9—"Commitments and Contingencies" to the accompanying consolidated financial statements included in this Annual Report, EPI Health acquired rights to that certain Assignment and License Agreement, whereby EPI Health licenses certain intellectual property from Aspect Pharmaceuticals, LLC, or Aspect and such agreement, the Aspect Agreement. Under the terms of the Aspect Agreement, EPI Health, as successor-in-interest, has exclusive rights to, and is required to use commercially reasonable efforts to, commercialize the Rhofade product. EPI Health also has a duty to certain other parties to use commercially reasonable efforts to commercialize the Rhofade product based on historical acquisition agreements for Rhofade that were assumed by EPI Health.

The material terms of the Rhofade Agreements and related revenue recognition are described in Note 12—"License and Collaboration Agreements" to the accompanying consolidated financial statements included in this Annual Report.

Cash Flows

The following table sets forth our cash flows for the periods indicated:

	Year Ended December 31,	
	2022	2021
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	$ (30,882)	$ (24,777)
Investing activities	(18,859)	(7,527)
Financing activities	16,019	44,093
Net increase in cash, cash equivalents and restricted cash	$ (33,722)	$ 11,789

Net Cash Used in Operating Activities

During the year ended December 31, 2022, net cash used in operating activities was $30.9 million and consisted primarily of a net loss of $31.3 million, with adjustments for non-cash amounts related primarily to (i) stock-based compensation expense of $1.9 million, (ii) amortization of definite lived intangible assets acquired in the EPI Health Acquisition of $1.6 million, (iii) $1.2 million of depreciation and amortization of property and equipment expense, (iv) a $1.2 million change in fair value of contingent consideration, (v) $4.3 million related to a gain on the extinguishment of the Seller Note, (vi) $0.6 million accretion of debt discount, (vii) a $0.1 million loss on disposal of equipment and (viii) a $0.6 million change in cash related to changes in other operating assets and liabilities. The favorable impacts to cash related to changes in assets and liabilities was primarily due to (i) a $2.3 million change in accounts receivable, (ii) a change in accounts payable of $11.0 million, and (iii) a change in prepaid expenses and other current assets of $0.5 million. The unfavorable impacts to cash related to changes in (i) deferred revenue of $2.6 million, (ii) research and development service obligation of $1.0 million, (iii) accrued expenses of $9.4 million, and (iv) a change in other long-term assets and liabilities of $0.2 million. The change in operating assets and liabilities and related changes from the prior period partially relate to the continued operations of the Research and Development Operations segment as it incurs expenditures to progress SB206, but primarily relate to the recently acquired EPI Health business, which comprises the Commercial Operations segment. See Note 2—"Acquisition of EPI Health" to the accompanying consolidated financial statements for additional detail regarding the EPI Acquisition Health and the related impacts of the opening balances related to the EPI Health Acquisition.

During the year ended December 31, 2021, net cash used in operating activities was $24.8 million and consisted primarily of a net loss of $29.7 million, with adjustments for non-cash amounts related primarily to (i) depreciation expense of $0.3 million, (ii) impairment of long-lived assets of $0.1 million, (iii) a foreign currency transaction loss of $0.8 million related to fair value adjustments for payments received and to be received under the Amended Sato Agreement, (iv) stock-based compensation expense of $0.3 million, (v) a $1.0 million gain on debt extinguishment related to forgiveness of the PPP loan, and (vii) a $4.3 million favorable change in cash related to changes in other operating assets and liabilities. The favorable net change in cash related to changes in assets and liabilities was primarily due to a $1.5 million increase in deferred revenue associated with (i) the recognition of license and collaboration revenue of $2.8 million associated with the Company's performance during the period and (ii) a time-based developmental milestone payment that became due and payable as of December 31, 2021 of $4.3 million, a $0.7 million decrease in prepaid insurance, prepaid expenses and other current assets primarily related to a decrease in certain prepaid service contracts, a $1.3 million increase in accrued expenses, which included a $0.7 million increase related to goods and services associated with the planning, design and build-out of our new facility, a $0.5 million increase in accounts payable, and a $0.3 million net change in other long-term assets and liabilities.

Net Cash Used in Investing Activities

During the year ended December 31, 2022, the $18.9 million of net cash used in investing activities was primarily related to (i) cash used in connection with the EPI Health Acquisition of $15.1 million, and (ii) $4.3 million in cash used for purchases of property, equipment and services associated with the build-out of our corporate headquarters and small-scale manufacturing facility in Durham, North Carolina, offset by $0.5 million of payments received related to the landlord funded tenant improvement allowance. See Note 2—"Acquisition of EPI Health" to the accompanying consolidated financial statements for additional detail regarding the EPI Health Acquisition.

During the year ended December 31, 2021, the $7.5 million of net cash used in investing activities included purchases of property, equipment and services associated with the planning, design and build-out of our new corporate headquarters and small-scale manufacturing facility in Durham, North Carolina, offset by payments received related to the landlord funded tenant improvement allowance. As of December 31, 2021, we also had goods and services associated with the planning, design and

build-out of our new facility of $1.5 million included in accounts payable and other accrued expenses in the accompanying balance sheets, which we settled through cash payments during the first half of 2022.

Net Cash Provided by Financing Activities

During the year ended December 31, 2022, net cash provided by financing activities was $16.0 million and consisted primarily of (i) net proceeds from the June 2022 Registered Direct Offering of $14.1 million, (ii) net proceeds from our factoring arrangement of $10.3 million and (iii) proceeds from the sale of our common stock pursuant to the Equity Distribution Agreement entered into in March 2022 of $1.7 million, offset by the repayment and termination of the Seller Note for $10.0 million.

During the year ended December 31, 2021, net cash provided by financing activities was $44.1 million and consisted primarily of (i) $37.6 million of proceeds from the sale of our common stock pursuant to the June 2021 Public Offering, (ii) $6.3 million of proceeds from the sale of our common stock pursuant to the July 2020 Aspire CSPA, (iii) $0.5 million of proceeds from the exercise of common warrants associated with the March 2020 Public Offering and March 2020 Registered Direct Offering, (iv) $0.1 million of proceeds from the exercise of stock options, partially offset by $0.4 million of payments of costs related to the June 2021 Public Offering.

Capital Requirements

As of December 31, 2022, we had a total cash and cash equivalents balance of $12.3 million and a working capital deficit of $4.0 million. While we currently generate revenue from our commercial portfolio of products, we do not believe that such revenues will be sufficient to fund the operating expenses of our business. To date, we have not generated any revenue from product sales of our product candidates, and we do not know when, or if, we will generate any such revenue from our product candidates. We do not expect to generate revenue from product sales of our product candidates unless, and until, we obtain regulatory approval of one of our current or future product candidates and achieve successful commercialization of such product candidate. As of December 31, 2022, we had an accumulated deficit of $310.3 million.

We will need significant additional funding to support our planned and future operating activities and make further advancements in our product development programs beyond what is currently included in our operating forecast and related cash projection. We do not currently have sufficient funds to complete commercialization of any of our product candidates, and our funding needs will largely be determined by our commercialization strategy for SB206, subject to the NDA regulatory approval process and outcome.

Our ability to continue to operate our business, including our ability to advance development programs unrelated to SB206, as well as our ability to progress SB206 for molluscum, if approved, is dependent upon future sales of our commercial products along with our ability to access additional sources of capital, including, but not limited to (i) equity or debt financings, including but not limited to potential sales using the remaining availability under the Equity Distribution Agreement, or (ii) other sources, such as partnerships, collaborations, licensing, grants or other strategic relationships. There can be no assurance that we will be able to obtain new funding on terms acceptable to us, on a timely basis, or at all. In addition, we agreed to certain limitations on our ability to raise funds in the short-term through equity financings in connection with the March 2023 Registered Direct Offering. In particular, we agreed not to issue any additional securities for 45 days after closing of the March 2023 Registered Direct Offering and not to make any sales under the Equity Distribution Agreement for 60 days after closing of the March 2023 Registered Direct Offering.

Our inability to obtain significant additional funding on acceptable terms could have a material adverse effect on our business and cause us to alter or reduce our planned operating activities, including, but not limited to delaying, reducing, terminating or eliminating planned product candidate development activities, furloughing employees or reducing the size of the workforce, to conserve our cash and cash equivalents. Our anticipated expenditure levels may change if we adjust our current operating plan. Such actions could delay development or commercialization-related timelines and have a material adverse effect on our business, results of operations, financial condition and market valuation. We are also exploring the potential for alternative transactions, such as strategic acquisitions or in-licenses, sales, out-licenses or divestitures of some of our assets, or other potential strategic transactions, which could include a sale of the company. If we were to pursue such a transaction, we may not be able to complete the transaction on a timely basis or at all or on terms that are favorable to us.

Our equity issuances during the years ended December 31, 2022 and December 31, 2021, as well as the March 2023 Registered Direct Offering, have resulted in significant dilution to our existing stockholders. Any future additional issuances of equity, or debt that could be convertible into equity, would result in further significant dilution to our existing stockholders.

As of December 31, 2022, we had 24,722,308 shares of common stock outstanding. In addition, as of December 31, 2022, we had reserved 7,327,414 shares of common stock for future issuance related to (i) outstanding warrants to purchase common stock, (ii) outstanding stock options and stock appreciation rights, (iii) nonvested restricted stock units, and (iv) future issuances under the 2016 Incentive Award Plan. Our common stock consists of 200,000,000 authorized shares as of December 31, 2022.

We have based our projections of operating capital requirements on assumptions that may prove to be incorrect, and we may use all of our available capital resources sooner than we expect. Because of the numerous risks and uncertainties associated with research, development and commercialization of pharmaceutical products, we are unable to estimate the exact amount or timing of our operating capital requirements. Our future funding requirements will depend on many factors, including, but not limited to:

- market acceptance of approved products and successful commercialization of such products by either us or our partners;
- our decision to expand our internal commercialization capabilities;
- the initiation, progress, timing, costs, results, and evaluation of results of trials for our clinical-stage product candidates, including trials conducted by us or potential future partners;
- the progress, timing, costs and results of development and preclinical study activities relating to other potential applications of our nitric oxide platform;
- the number and characteristics of product candidates that we pursue;
- the achievement of milestones that would require payment and whether such milestone payments are paid in cash or shares of our common stock, including those set forth in "Note 10—Commitments and Contingencies" to the accompanying condensed consolidated financial statements;
- our ability to enter into strategic relationships to support the continued development of certain product candidates and the success of those arrangements;
- our success in optimizing the size and capability of our new manufacturing facility and related processes to meet our strategic objectives;
- our success in the technical transfer of methods and processes related to our drug substance and drug product manufacturing with our current and/or potential future contract manufacturing partners;
- the outcome, timing and costs of seeking regulatory approvals;
- the occurrence and timing of potential development and regulatory milestones achieved by Sato, our licensee for SB204, SB206 and Rhofade in Japan;
- the terms and timing of any future collaborations, licensing, consulting, financing or other arrangements that we may enter into;
- the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights;
- the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights;
- defending against intellectual property related claims;
- the costs associated with any potential future securities litigation, and the outcome of that litigation;
- the extent to which we in-license or acquire other products and technologies;
- subject to receipt of marketing approval, revenue received from commercial sales or out licensing of our product candidates; and
- revenue received from commercial sales of our existing medical dermatology products.

Contractual Obligations and Contingent Liabilities

Factoring Arrangement

As discussed in Note 9—"Commitments and Contingencies" to the accompanying consolidated financial statements included in this Annual Report, EPI Health entered into the Factoring Agreement with Bay View on December 1, 2022.

In connection with the factoring facility, EPI Health will be charged a finance fee, defined as a floating rate per annum on outstanding advances under the Factoring Agreement, equal to the prime rate plus 2.00%, due on the first day of each month. EPI Health will also be charged a factoring fee of 0.35% of the gross face value of any trade accounts receivable for each 30 day period after the trade accounts receivable is purchased. Bay View has the right to demand repayment of any purchased receivables that remain unpaid for 90 days after purchase (or 100 days in the case of certain wholesale customers) or with respect to which any account debtor asserts a dispute.

The factoring facility is for an initial term of 12 months and will renew on a year to year basis thereafter, unless terminated in accordance with the Factoring Agreement. EPI Health may terminate the facility at any time upon 60 days prior written notice and payment to Bay View of an early termination fee equal to 0.25% of the Maximum Credit multiplied by the number of months remaining in the term.

Compensatory Obligations

The Company enters into employment agreements with certain officers and employees. These agreements are in the normal course of business and contain certain customary Company controlled termination provisions which, if triggered, could result in future severance payments.

See Note 16—"Stock Based Compensation" regarding Stock Appreciation Rights, Restricted Stock Units and Stock Options.

Contingent Payment Obligations Related to the Purchase of EPI Health

See Note 2—"Acquisition of EPI Health" for certain contingent payments related to consideration due to EPG upon achievement of certain milestones by EPI Health.

Contingent Payment Obligations from Historical Acquisitions by EPI Health

EPI Health has in the past acquired certain rights to pharmaceutical products and such arrangements have typically included requirements that EPI Health make certain contingent payments to the applicable seller as discussed below.

Rhofade. On October 10, 2019, EPI Health entered into an agreement whereby it acquired certain assets related to Rhofade, or the Rhofade Acquisition Agreement. In connection with the Rhofade Acquisition Agreement, we are required to make the following milestone payments to the seller upon reaching the following net sales thresholds during any calendar year following the closing date, as defined in the Rhofade Acquisition Agreement:

Calendar Year Net Sales Threshold	Milestone Payment
$ 50,000,000	$ 5,000,000
$ 75,000,000	$ 5,000,000
$ 100,000,000	$ 10,000,000

Under the terms of the Rhofade Acquisition Agreement, EPI Health assumed certain liabilities of the prior licensees of the product Rhofade. In particular, we are required to pay certain earnout payments pursuant to historic acquisition agreements for Rhofade upon the achievement of net sales thresholds higher than those set forth above. However, we have not recognized a liability for such Rhofade milestones based on current and historical sales figures and management's estimates of future sales.

Cloderm. On September 28, 2018, EPI Health entered into an agreement pursuant to which it acquired assets related to the product Cloderm. We are required to pay a low double-digit royalty once cumulative net sales of Cloderm reach $20.8 million, until we have made $6.5 million of royalty payments.

Minolira. On August 20, 2018, EPI Health entered into an agreement pursuant to which it acquired assets related to the product Minolira. In connection with the agreement, we are required to make the following milestone payments to the seller upon reaching cumulative net sales thresholds as defined in the acquisition agreement:

Cumulative Net Sales Threshold		Milestone Payment
$ 10,000,000		$ 1,000,000
$ 20,000,000		$ 1,000,000
Each additional	$ 20,000,000	$ 1,500,000

See Note 12—"License and Collaboration Agreements", Note 13—"Net Product Revenues" and Note 14—"License and Collaboration Revenues" for certain obligations and contingent payments related to license agreements, including those related to our commercial product portfolio.

Facility Leasing Transactions

In January 2021 we entered into a new lease agreement, pursuant to which we leased space located in Durham, North Carolina to serve as the Company's new corporate headquarters and support various cGMP activities, as described in the section entitled "Business—Manufacturing and Supplies" in this Annual Report.

See the section entitled "Properties" in this Annual Report and Note 6—"Leases" to the accompanying consolidated financial statements included in this Annual Report for additional information regarding our facility lease.

Amended Sato Agreement

Pursuant to the Amended Sato Agreement, we are obligated to supply Sato with all quantities of licensed products required by Sato for their development activities in Japan. As part of the Amended Sato Agreement, we and Sato also agreed to negotiate a commercial supply agreement pursuant to which we or a third-party contract manufacturer would be the exclusive supplier to Sato of the API of licensed products for the commercial manufacture of licensed products in the licensed territory. Additionally, we have agreed to perform certain oversight, review and supporting activities for Sato, including: (i) using commercially reasonable efforts to obtain marketing approval of SB204 and SB206 in the U.S, (ii) sharing all future scientific information we may obtain during the term of the Amended Sato Agreement pertaining to SB204 and SB206, (iii) performing certain additional preclinical studies if such studies are deemed necessary by the Japanese regulatory authority, up to and not to exceed a total cost of $1.0 million, and (iv) participating in a joint committee that oversees, reviews, and approves Sato's development and commercialization activities under the Amended Sato Agreement. Additionally, we have granted Sato the option to use our trademarks in connection with the commercialization of licensed products in the licensed territory for no additional consideration, subject to our approval of such use. We cannot estimate if, when or in what amounts such payments will become due under the Amended Sato Agreement.

The intellectual property rights granted to Sato under the Amended Sato Agreement include certain intellectual property rights which we have licensed from UNC. Under our license agreement with UNC described in Note 12—"License and Collaboration Agreements" to the accompanying consolidated financial statements included in this Annual Report, we are obligated to pay UNC a running royalty percentage in the low single digits on net sales of licensed products, including net sales that may be generated by Sato. Additionally, we are obligated to make payments to UNC that represent the portion of the Sato upfront and milestone payments that were estimated to be directly attributable to the UNC intellectual property rights included in the license to Sato.

We had also previously entered into an agreement with a third party to assist us in exploring the licensing opportunity which led to the execution of the Sato Agreement. We are obligated to pay the third party a low-single-digit percentage of all upfront and milestone payments the Company receives from Sato under the Amended Sato Agreement.

See Note 12—"License and Collaboration Agreements" to the accompanying consolidated financial statements included in this Annual Report for additional information on the Amended Sato Agreement.

Amendments to Sublicense Agreements with KNOW Bio

Pursuant to the terms of the amendments to the KNOW Bio Agreements that we entered into in October 2017, we re-acquired from KNOW Bio exclusive, worldwide rights under certain United States and foreign patents and patent applications controlled by us as of the execution date of the KNOW Bio Agreements, and patents and patent applications which became controlled by us during the three years immediately following the execution date of the KNOW Bio Agreements, directed towards nitric oxide-releasing compositions and methods of manufacturing thereof, including methods of manufacturing Nitricil compounds, and other nitric oxide-based therapeutics, to develop and commercialize products for all diagnostic, therapeutic, prophylactic and palliative uses for any disease, condition or disorder caused by certain oncoviruses, or the Oncovirus Field. KNOW Bio also granted to us an exclusive license, with the right to sublicense, under any patents and patent applications which became controlled by KNOW Bio during the three years immediately following the execution date of the KNOW Bio Agreements and directed towards nitric oxide-releasing compositions and methods of manufacturing thereof, including methods of manufacturing Nitricil compounds, and other nitric oxide-based therapeutics, but not towards medical devices, to develop and commercialize products for use in the Oncovirus Field. Additionally, KNOW Bio agreed that KNOW Bio would not commercialize any products in the Oncovirus Field during the first three years following the execution date of the KNOW Bio Agreements. The three-year period in which new patents and patent applications are added to the exclusive license and the three-year term of the commercialization non-compete both expired on December 29, 2018.

In addition to the $0.3 million non-refundable upfront payment we made upon execution of the KNOW Bio Amendments, we are obligated to make the following contingent payments in exchange for the rights granted to us in the Oncovirus Field:

For products that incorporate a certain nitric oxide-releasing composition specified in the KNOW Bio Amendments and (i) are covered by KNOW Bio patents or (ii) materially use or incorporate know-how of KNOW Bio or us related to such composition that is created during the three years immediately following the execution date of the KNOW Bio Agreements, or the Covered Products, we must make the following payments to KNOW Bio:

- A milestone payment upon the first time each Covered Product is approved by the FDA for marketing in the Oncovirus Field;
- A royalty in the low single digits on net sales of Covered Products in the Oncovirus Field until the later of the expiration of the KNOW Bio patents covering the applicable Covered Product or the expiration of regulatory exclusivity on the applicable Covered Product; and

- In the event we sublicense the rights to a Covered Product to a third party in the Oncovirus Field, the Company must pay KNOW Bio a low double-digit percentage of any clinical development or NDA approval milestones we receive from the sublicensee for the Covered Product in the Oncovirus Field.

Nitricil is not the nitric oxide-releasing composition specified in the KNOW Bio Amendments as the subject of the foregoing payments. As such, products based on Nitricil are not subject to the foregoing milestone, royalty and sublicensing payment obligations.

The rights granted to us in the Oncovirus Field in the KNOW Bio Amendments continue for so long as there is a valid patent claim under the KNOW Bio Agreements, and upon expiration continue on a perpetual non-exclusive basis, and are subject to the termination rights of KNOW Bio and us that are set forth in the KNOW Bio Agreements. In addition, under the KNOW Bio Amendments, KNOW Bio may terminate the rights granted to the Company in the Oncovirus Field without terminating the Original KNOW Bio Agreements.

See Note 12—"License and Collaboration Agreements" to the accompanying consolidated financial statements included in this Annual Report for additional information on the sublicense agreement with KNOW Bio.

Royalty and Milestone Payments Purchase Agreement with Reedy Creek Investments LLC

In April 2019, we entered into the Purchase Agreement with Reedy Creek pursuant to which Reedy Creek provided us funding and we are obligated to pay Reedy Creek certain ongoing quarterly payments. See the section entitled "Management's Discussion & Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources" in this Annual Report and Note 15—"Research and Development Agreements" to the accompanying consolidated financial statements included in this Annual Report for additional information related to the Purchase Agreement.

Development Funding and Royalties Agreement with Ligand Pharmaceuticals Incorporated

In 2019, we entered into the Funding Agreement with Ligand, pursuant to which Ligand provided us funding and we are obligated to pay Ligand up to $20.0 million in milestone payments. See the section entitled "Management's Discussion & Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources" in this Annual Report and Note 15—"Research and Development Agreements" to the accompanying consolidated financial statements included in this Annual Report for additional information related to the Funding Agreement.

Warrants

In our June 2022 Registered Direct Offering, March 2020 Public Offering, and March 2020 Registered Direct Offering, we issued warrants to purchase shares of our common stock. The warrants provide each warrant holder with the right to require net cash settlement of the warrants upon the occurrence of certain fundamental transactions, provided that such transactions are within our control. For any fundamental transaction that is not within our control, including a fundamental transaction not approved by our board of directors, the warrant holder will only be entitled to receive from us or any successor entity the same type or form of consideration (and in the same proportion) that is being offered and paid to our common stockholders in connection with the fundamental transaction, whether that consideration be in the form of cash, stock or any combination thereof. In the event of any fundamental transaction, and regardless of whether it is within our control, the settlement amount of the warrants (whether in cash, stock or a combination thereof) is determined based upon a Black-Scholes value that is calculated using inputs as specified in the warrants, including a defined volatility input equal to the greater of our 100-day historical volatility or 100%.

See the section entitled "Management's Discussion and Analysis—Critical Accounting Policies and Use of Estimates—Classification of Warrants and Pre-Funded Warrants Issued in Connection with Offerings of Common Stock" in this Annual Report and Note 11—"Stockholders' Equity" to the accompanying consolidated financial statements included in this Annual Report for additional discussion regarding the terms of the warrants.

Drug Product Manufacturing

We have established a strategic alliance with Orion, a Finnish full-scale pharmaceutical company with broad experience in drug manufacturing. The alliance enables Orion to manufacture our topical nitric oxide-releasing product candidates on our behalf and on the behalf of our global strategic partners. We have executed a master contract manufacturing agreement to enable technology transfer and manufacturing of clinical trial materials for future clinical trials with our topical product candidates.

We enter into various statements of work, under the master contract manufacturing agreement, that govern certain workflows and deliverables, including production of drug product and other manufacturing related services. These statements of work

generally provide for termination on notice, and, therefore, we believe that our non-cancelable obligations under these statements of work are not material.

Other

We enter into contracts in the normal course of business, including, but not limited to, with clinical research organizations for clinical trials, clinical supply manufacturing, and preclinical research studies, and with manufacturing related vendors for raw materials, production related equipment, drug product and drug substance stability testing, supportive consultative services, and other products and services for operating purposes. These contracts generally provide for termination on notice, and, therefore, we believe that our non-cancelable obligations under these agreements are not material.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under SEC rules.

Net Operating Loss and Research and Development Tax Credit Carryforwards

As of December 31, 2022, we had federal and state NOLs of approximately $104.7 million and $65.1 million, respectively. The NOLs begin to expire in 2029 and 2024 for federal and state tax purposes, respectively. Certain of our federal and state net operating losses have an indefinite carryforward. We have research and development tax credits of approximately $2.4 million to offset future federal taxes. These credits begin to expire in 2041.

We record a valuation allowance to offset any net deferred tax assets if, based upon the available evidence, it is more likely than not that we will not recognize some or all of the deferred tax assets. We have had a history of net losses since inception, and, as a result, we have established a 100% valuation allowance of $39.8 million for our net deferred tax assets as of December 31, 2022. If circumstances change and we determine that we will be able to realize some or all of these net deferred tax assets in the future, we will record an adjustment to the valuation allowance.

The Tax Reform Act of 1986 contains provisions which limit the ability to utilize the net operating loss carryforwards and general business credits, including the research and development credit in the case of certain events including significant changes in ownership interests. In accordance with Section 382 of the Code, a change in equity ownership of greater than 50% within a three-year period results in an annual limitation on our ability to utilize our NOL carryforwards created during the tax periods prior to the change in ownership.

During the course of preparing the Company's consolidated financial statements as of and for the year ended December 31 2021, the Company completed an analysis under Sections 382 and 383 of the Code of its historical NOL and tax credit carryforward amounts. If an ownership change, as defined in Section 382, occurs, it results in a Section 382 limitation that applies to all NOLs and tax credits generated prior to the ownership change date that can be used to offset taxable income incurred after the ownership change date. The annual limitation is based on a company's stock value prior to the ownership change, multiplied by the applicable federal long-term, tax-exempt interest rate. As a result, a portion of the prior year net operating loss and tax credit carryforwards were determined to be limited. The Company did not experience a cumulative ownership change that would result in a Section 382 limitation during the year ended December 31, 2022.

See Note 17—"Income Taxes" to the accompanying consolidated financial statements included in this Annual Report for further details. If an additional change in equity ownership occurs in the future which exceeds the Section 382 threshold, our NOL carryforwards and research and development credits may be subject to additional limitations. Since our net operating loss carryforwards are limited, if we have taxable income which exceeds the permissible yearly net operating loss carryforwards, we would incur a federal income tax liability even though net operating loss carryforwards would be available in future years.

Recent Accounting Pronouncements

Recently issued accounting pronouncements that we have adopted or are currently evaluating are described in detail within "Note 1—"Organization and Significant Accounting Policies"" to the accompanying consolidated financial statements included in this Annual Report.

Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

There were no changes in or disagreements with accountants on accounting and financial disclosures.

Critical Accounting Policies and Use of Estimates

Our management's discussion and analysis of financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with United States generally accepted accounting principles. The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements, as well as the reported revenue and expenses during the reporting periods. These items are monitored and analyzed by us for changes in facts and circumstances, and material changes in these estimates could occur in the future. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources.

Significant estimates made by us include provisions for product returns, coupons, rebates, chargebacks, trade and cash discounts, allowances and distribution fees paid to certain wholesalers, inventory net realizable value, useful lives of amortizable intangible assets, stock-based compensation, accrued expenses, valuation of assets and liabilities in business combinations, developmental timelines related to licensed products, valuation of contingent consideration and contingencies. Actual results may differ materially and adversely from these estimates.

Changes in estimates are reflected in reported results for the period in which they become known. Actual results may differ materially from these estimates under different assumptions or conditions. To the extent there are material differences between the estimates and actual results, our future results of operations will be affected.

While our significant accounting policies are more fully described in the notes to our consolidated financial statements included elsewhere in this Annual Report, we believe that the following accounting policies are critical to the process of making significant judgments and estimates in the preparation of our consolidated financial statements and understanding and evaluating our reported financial results.

Business Acquisitions

Business acquisitions are accounted for using the acquisition method of accounting in accordance with Accounting Standards Codification, or ASC, 805, *Business Combinations,* or ASC 805. ASC 805 requires, among other things, that assets acquired and liabilities assumed be recognized at their fair values, as determined in accordance with ASC 820, *Fair Value Measurements*, as of the acquisition date. For certain assets and liabilities, book value approximates fair value. In addition, ASC 805 establishes that consideration transferred be measured at the closing date of the acquisition at the then-current market price. Under ASC 805, acquisition-related costs (i.e., advisory, legal, valuation and other professional fees) are expensed in the period in which the costs are incurred. The application of the acquisition method of accounting requires us to make estimates and assumptions related to the estimated fair values of net assets acquired.

Significant judgments are used during this process, particularly with respect to intangible assets. Generally, intangible assets are amortized over their estimated useful lives. Goodwill and other indefinite-lived intangibles are not amortized, but are annually assessed for impairment. Therefore, the purchase price allocation to intangible assets and goodwill has a significant impact on future operating results.

See "Note 2—"Acquisition of EPI Health" to the accompanying consolidated financial statements included in this Annual Report for additional discussion, in addition to Note 19—"Fair Value", related to the EPI Health Acquisition.

Revenue Recognition

We account for revenue in accordance with ASC 606, *Revenue from Contracts with Customers,* or ASC 606. To determine revenue recognition for arrangements that we determine are within the scope of ASC 606, we (i) identify the contract with a customer, (ii) identify the performance obligations within the contract, (iii) determine the transaction price, (iv) allocate the transaction price to the performance obligations within the contract, and (v) recognize revenue when (or as) we satisfy a performance obligation. We only apply the five-step model to contracts when it is probable that we will collect the consideration we are entitled to in exchange for the goods or services we transfer to the customer.

Net Product Revenues

Net product revenues encompass sales resulting from transferring control of products to customers, excluding amounts collected on behalf of other third parties. The amount of revenue recognized is the amount allocated to the satisfied performance obligation taking into account variable consideration. The estimated amount of variable consideration is included in the transaction price only to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved.

Product sales are recognized at the point in time when a product is delivered and legal transfer of title has occurred. We record a reduction of the transaction price for estimated chargebacks, rebates, coupons, discounts and returns. A liability is recognized

for expected sales returns, rebates, coupons, trade and cash discounts, chargebacks or other reimbursements to customers in relation to sales made in the reporting period. Payment terms can differ from contract to contract, but no element of financing is deemed present based on the fact that typical payment terms are less than 100 days. Therefore, the transaction price is not adjusted for the effects of a significant financing component. A receivable is recognized as soon as control over the products is transferred to the customer as this is the point in time that the consideration is unconditional because only the passage of time is required before the payment is due.

Variable consideration relates to sales returns, rebates, coupons, trade and cash discounts, and chargebacks granted to various direct and indirect customers. We recognize provisions at the time of sale and adjust them if the actual amounts differ from the estimated provisions.

There can be a significant lag between our establishment of an estimate and the timing of the invoicing or claim. We believe we have made reasonable estimates for future rebates and claims, however, these estimates involve assumptions pertaining to contractual utilization and performance, and payor mix. If the performance or mix across third-party payors is different from our estimates, we may be required to pay higher or lower total price adjustments and/or chargebacks than we had estimated.

See Note 1—"Organization and Significant Accounting Policies" and Note 13—"Net Product Revenues" to the accompanying consolidated financial statements included in this Annual Report for additional discussion.

License and Collaboration Revenues

We have entered into various types of agreements that either license our intellectual property to a third party, acquire license rights to intellectual property of a third party, or both.

Agreements where we license our intellectual property to a third party for development and commercialization in a licensed territory. If the applicable license is determined to be distinct from the other performance obligations identified in the arrangement, we recognize revenues from non-refundable, upfront 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 estimated performance period and the appropriate method of measuring progress during the performance period for purposes of recognizing revenue. We re-evaluate the estimated performance period and measure of progress each reporting period and, if necessary, adjust related revenue recognition accordingly. These arrangements often include milestone as well as royalty or profit-share payments, contingent upon the occurrence of certain future events linked to the success of the asset in development, as well as expense reimbursements from or payments to the collaboration partner. Because of the risk that products in development will not receive regulatory approval, we do not recognize any contingent payments until regulatory approval becomes probable. Future sales-based royalties are not recorded until the subsequent sale occurs.

Agreements where we acquire license rights to, or otherwise access, a third party's intellectual property for commercialization of the third party's product in a licensed territory. We also enter into various types of arrangements to commercialize products. Our services provided to the third party under such arrangements, in exchange for compensation that may take the form of cost reimbursements, may include promoting, marketing, selling and distributing the third party's developed drugs, and may also involve certain license rights granted to the parties for use of the other party's intellectual property while providing defined services under the arrangements. We assess the nature of each such arrangement and the various rights granted and services performed thereunder.

Royalty revenue from licenses provided to our collaboration partners, which is based on sales to third parties of licensed products and technology, is based on the later of when the third-party sale occurs or the performance obligation to which some or all of the royalty has been allocated has been satisfied.

When we perform and incur marketing and promotional services expense under an arrangement that is determined to be within the scope of ASC 808, and where such services are on behalf of a collaboration partner that is not considered a customer under ASC 606, we recognize a contra-expense that reflects the value of the cost reimbursement to which we are expected to be entitled in exchange for those services. Such contractually required reimbursements are reported as a liability or an asset within the accompanying consolidated balance sheets based upon the timing of cash receipt from the collaboration partner.

See Note 14—"License and Collaboration Revenues" to the accompanying consolidated financial statements included in this Annual Report for additional discussion.

Intangible Assets and Goodwill

Intangible assets represent identifiable intangible assets including product rights consisting of pharmaceutical product licenses and patents. Amortization for pharmaceutical products licenses is computed using the straight-line method based on the lesser of the term or the useful life of the license. Amortization for pharmaceutical patents is computed using the straight-line method based on the useful life of the patent.

Definite-lived intangible assets are reviewed for impairment whenever events or circumstances indicate that carrying amounts may not be recoverable. In the event impairment indicators are present or if other circumstances indicate that an impairment might exist, we compare the future undiscounted cash flows directly associated with the asset or asset group to the carrying amount of the asset group being evaluated for impairment. If those estimated cash flows are less than the carrying amount of the asset group, an impairment loss is recognized. An impairment loss is recognized to the extent that the carrying amount exceeds the asset's fair value. Considerable judgment is necessary to estimate the fair value of these assets, accordingly, actual results may vary significantly from such estimates.

Indefinite-lived intangible assets, including goodwill, are not amortized. We test the carrying amounts of goodwill for recoverability on an annual basis at October 1 or when events or changes in circumstances indicate evidence that a potential impairment exists, using a fair value based test. Goodwill is assessed at the reporting unit level. We performed a qualitative assessment as of October 1, 2022 and concluded that it is not more likely than not that the fair value of our reporting unit was less than its carrying amount. A significant amount of judgment is involved in determining if an indicator of goodwill impairment has occurred. Such indicators may include, among others: a significant decline in expected future cash flows, a sustained, significant decline in our stock price and market capitalization, a significant adverse change in legal factors or in the business climate, adverse assessment or action by a regulator, and unanticipated competition. Any change in these indicators could have a significant negative impact on our financial condition, impact the goodwill impairment analysis or cause us to perform a goodwill impairment analysis more frequently than once per year.

See Note 7—"Goodwill and Intangible Assets, net" to the accompanying consolidated financial statements included in this Annual Report for additional discussion regarding intangible assets and goodwill related to the EPI Health Acquisition.

Contingent Consideration

Contingent consideration is recorded as a liability and is the estimate of the fair value of potential milestone payments related to business acquisitions. The estimated fair value of contingent consideration is determined based on a probability-weighted valuation model that measures the present value of the probable cash payments based upon the future milestone events of EPI Health at a discount rate that captures the risk associated with the liability and also based on a Monte Carlo simulation, whereby EPI Health's forecasted net sales from the EPI Health legacy products is simulated over the measurement period to calculate the contingent consideration.

Significant increases or decreases in any of the probabilities of success or changes in expected achievement of any of these milestones would result in a significantly higher or lower fair value of these milestones, respectively, and commensurate changes to the associated liability.

The contingent consideration is revalued at each reporting period and changes in fair value are recognized in the consolidated statements of operations and comprehensive loss until settlement.

See Note 2—"Acquisition of EPI Health" to the accompanying consolidated financial statements included in this Annual Report for additional discussion regarding purchase consideration, including contingent consideration related to the EPI Health Acquisition.

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

Not applicable.

Item 8. Financial Statements and Supplementary Data.

NOVAN, INC.
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

Stockholders and Board of Directors
Novan, Inc.
Durham, North Carolina

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Novan, Inc. (the "Company") as of December 31, 2022 and 2021, the related consolidated statements of operations and comprehensive loss, 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 1 to the consolidated financial statements, the Company has suffered recurring losses from operations and has not generated significant revenue or 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 1. 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 separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Acquisition of EPI Health – Intangible Assets related to Acquired Product Rights

As described in Notes 1 and 2 to the Company's consolidated financial statements, the Company acquired all of the issued and outstanding units of membership interest of EPI Health, LLC on March 11, 2022 for total consideration of approximately $32.0 million, which resulted in $29.0 million of intangible assets related to acquired product rights being recorded. Management applied significant judgment in estimating the fair value of the intangible assets acquired, which involved the use of significant estimates with respect to forecasted revenue and forecasted operating margin.

We have identified forecasted revenue and forecasted operating margin used in the valuation of the acquired product rights as a critical audit matter. The principal considerations of our determination were the inherent uncertainties of future revenue,

expected operating margin and the limited history of sales related to certain acquired product rights. Auditing management's forecasted revenue and forecasted operating margin involved a high degree of auditor judgment and specialized skills and knowledge was needed.

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

- Evaluating the reasonableness of forecasted revenue and forecasted operating margin used to determine the fair value of the acquired product rights by: 1) performing sensitivity analyses and evaluating potential effect of changes in certain estimates, 2) comparing forecasted revenue to historical sales for certain product rights and operating margins in aggregate, 3) comparing forecasts to guideline companies and industry information for certain product rights, and 4) evaluating the consistency of forecasts against the terms of agreements related to the acquired product rights.
- Utilizing professionals with specialized skills and knowledge to assist in: 1) evaluating the appropriateness of the valuation models used by management, and 2) testing the mathematical accuracy of the Company's calculation.

Variable Consideration Related to Net Product Revenues

As described in Note 1 to the Company's consolidated financial statements, the Company records product revenues net of variable consideration related to various items including sales returns, rebates, and coupons. Estimated provisions for these items as of December 31, 2022 are included in accrued rebates, discounts and chargebacks and accrued returns in Note 8. The Company's estimates of these provisions are based on considerations including historical sales, product shelf life, contractual arrangements with customers, and utilization rates.

We have identified management's estimates for sales returns, rebates and coupons as a critical audit matter. These estimates require a high degree of management judgment as they relate to estimates of future actions by customers and can have an extended period of time between accrual and settlement. Auditing these estimates involved especially challenging auditor judgment and a high degree of auditor subjectivity.

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

- Recalculating the accrual amounts based on historical return data and historical utilization of rebates and coupons and testing the completeness and accuracy of the historical data used in the recalculation.
- Testing sales that were subject to future potential returns and product quantities that were subject to future utilization of rebates and coupons.
- Performing sensitivity analyses related to the material components of the estimates to determine how sensitive the estimates were to potential fluctuations.
- Performing a review of subsequent activity that may impact these accruals, as applicable, to evaluate the reasonableness of management's estimates.

/s/ BDO USA, LLP

We have served as the Company's auditor since 2018.

Raleigh, North Carolina
March 30, 2023

NOVAN, INC.
Consolidated Balance Sheets
(in thousands, except share and per share amounts)

	Year Ended December 31,	
	2022	2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 12,316	$ 47,085
Restricted cash, current	1,047	—
Accounts receivable, net	22,002	4,473
Inventory, net	1,196	—
Prepaid expenses and other current assets	5,807	2,572
Total current assets	42,368	54,130
Restricted cash, net of current portion	583	583
Property and equipment, net	13,882	12,201
Intangible assets, net	27,475	75
Other assets	210	278
Right-of-use lease assets	1,756	1,693
Goodwill	4,056	—
Total assets	$ 90,330	$ 68,960
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 13,689	$ 2,170
Accrued expenses	18,624	4,988
Factoring arrangement payable	10,302	—
Deferred revenue, current portion	2,586	2,586
Research and development service obligation liability, current portion	555	1,406
Contingent consideration liability, current portion	451	—
Operating lease liabilities, current portion	191	—
Total current liabilities	46,398	11,150
Deferred revenue, net of current portion	8,079	10,665
Operating lease liabilities, net of current portion	3,739	3,613
Research and development service obligation liability, net of current portion	25	142
Research and development funding arrangement liability	25,000	25,000
Contingent consideration liability, net of current portion	2,037	—
Other long-term liabilities	447	71
Total liabilities	85,725	50,641
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Common stock $0.0001 par value; 200,000,000 shares authorized as of December 31, 2022 and 2021; 24,723,258 and 18,816,842 shares issued as of December 31, 2022 and 2021, respectively; 24,722,308 and 18,815,892 shares outstanding as of December 31, 2022 and 2021, respectively	2	2
Additional paid-in-capital	315,038	297,441
Treasury stock at cost, 950 shares as of December 31, 2022 and 2021	(155)	(155)
Accumulated deficit	(310,280)	(278,969)
Total stockholders' equity	4,605	18,319
Total liabilities and stockholders' equity	$ 90,330	$ 68,960

The accompanying notes are an integral part of these consolidated financial statements

NOVAN, INC.
Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share amounts)

	Year Ended December 31,	
	2022	2021
Net product revenues	$ 15,796	$ —
License and collaboration revenue	7,813	2,822
Government research contracts and grants revenue	73	136
Total revenue	23,682	2,958
Operating expenses:		
Cost of goods sold	7,379	—
Research and development	15,990	20,416
Selling, general and administrative	34,103	12,343
Amortization of intangible assets	1,600	—
Change in fair value of contingent consideration	(1,160)	—
Impairment loss on long-lived assets	—	114
Total operating expenses	57,912	32,873
Operating loss	(34,230)	(29,915)
Other income (expense), net:		
Interest income	53	13
Interest expense	(1,452)	—
Gain on debt extinguishment	4,340	956
Other expense	(22)	(746)
Total other income (expense), net	2,919	223
Net loss and comprehensive loss	$ (31,311)	$ (29,692)
Net loss per share, basic and diluted	$ (1.42)	$ (1.74)
Weighted-average common shares outstanding, basic and diluted	22,019,679	17,065,932

The accompanying notes are an integral part of these consolidated financial statements

NOVAN, INC.
Consolidated Statements of Stockholders' Equity
(in thousands, except share amounts)

	Common Stock		Additional Paid-In Capital	Treasury Stock	Accumulated Deficit	Total
	Shares	Amount				
Balance as of December 31, 2020	14,570,009	$ 1	$ 252,408	$ (155)	$ (249,277)	$ 2,977
Stock-based compensation	—	—	941	—	—	941
Extinguishment of fractional shares resulting from reverse stock split	(37)	—	—	—	—	—
Common stock issued pursuant to public offering, net	3,636,364	—	37,236	—	—	37,236
Exercise of common stock warrants	103,551	—	461	—	—	461
Common stock issued pursuant to common stock purchase agreements	493,163	1	6,333	—	—	6,334
Exercise of stock options	12,842	—	62	—	—	62
Net loss	—	—	—	—	(29,692)	(29,692)
Balance as of December 31, 2021	18,815,892	$ 2	$ 297,441	$ (155)	$ (278,969)	$ 18,319
Stock-based compensation	—	—	1,880	—	—	1,880
Common stock and pre-funded warrants issued pursuant to the June 2022 registered direct offering, net	2,080,696	—	14,020	—	—	14,020
Exercise of pre-funded warrants related to the June 2022 registered direct offering	3,180,615	—	32	—	—	32
Common stock issued pursuant to equity distribution agreement (at-the-market facility)	645,105	—	1,665	—	—	1,665
Net loss	—	—	—	—	(31,311)	(31,311)
Balance as of December 31, 2022	24,722,308	$ 2	$ 315,038	$ (155)	$ (310,280)	$ 4,605

The accompanying notes are an integral part of these consolidated financial statements

NOVAN, INC.
Consolidated Statements of Cash Flows
(in thousands)

	Year Ended December 31,	
	2022	2021
Cash flow from operating activities:		
Net loss	$ (31,311)	$ (29,692)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization of property and equipment	1,178	344
Impairment loss on long-lived assets	—	114
Amortization of intangible assets	1,600	—
Accretion of debt discount	635	—
Change in fair value of contingent consideration	(1,160)	—
Stock-based compensation	1,880	275
Foreign currency transaction loss	—	820
Gain on debt extinguishment	(4,340)	(956)
Loss on disposal and write-offs of property and equipment	70	—
Changes in operating assets and liabilities:		
Accounts receivable	2,275	47
Inventory	(17)	—
Prepaid insurance, prepaid expenses and other current assets	457	688
Accounts payable	10,997	544
Accrued expenses	(9,369)	1,289
Deferred revenue	(2,586)	1,525
Research and development service obligation liability	(968)	(88)
Other long-term assets and liabilities	(223)	313
Net cash used in operating activities	(30,882)	(24,777)
Cash flow from investing activities:		
Purchases of property and equipment	(4,274)	(9,050)
Landlord reimbursement of tenant improvement allowance	508	1,523
Payment for EPI Health Acquisition	(15,093)	—
Net cash used in investing activities	(18,859)	(7,527)
Cash flow from financing activities:		
Proceeds from issuance of common stock and pre-funded warrants, net of underwriting fees and commissions	14,252	37,600
Proceeds from common stock issued pursuant to equity distribution agreement (at-the-market facility)	1,665	—
Payment of note payable	(10,000)	—
Proceeds from exercise of common stock warrants	—	461
Proceeds from issuance of common stock under common stock purchase agreement	—	6,334
Proceeds from factoring arrangement	18,427	—
Repayments of factoring arrangement	(8,125)	—
Payments related to public offering costs	(200)	(364)
Proceeds from exercise of stock options	—	62
Net cash provided by financing activities	16,019	44,093
Net (decrease) increase in cash, cash equivalents and restricted cash	(33,722)	11,789
Cash, cash equivalents and restricted cash as of beginning of period	47,668	35,879
Cash, cash equivalents and restricted cash as of end of period	$ 13,946	$ 47,668
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 339	$ —
Supplemental disclosure of non-cash investing and financing activities:		
Non-cash gain on debt extinguishment	$ 4,340	$ —
Contingent consideration related to EPI Health Acquisition	3,648	—
Note payable issued for EPI Health Acquisition	13,305	—
Deferred offering costs reclassified to additional paid-in capital	—	364
Purchases of property and equipment with accounts payable and accrued expenses	26	1,471
Right-of-use assets obtained in exchange for lease liabilities	—	1,693
Non-cash gain on debt extinguishment from forgiveness of Paycheck Protection Program loan	—	956
Reconciliation to consolidated balance sheets:		
Cash and cash equivalents	$ 12,316	$ 47,085
Restricted cash	1,630	583
Total cash, cash equivalents and restricted cash shown in the statement of cash flows	$ 13,946	$ 47,668

The accompanying notes are an integral part of these consolidated financial statements

Note 1: Organization and Significant Accounting Policies

Business Description

Novan, Inc. ("Novan" and together with its subsidiaries, the "Company") is a medical dermatology company focused on developing and commercializing innovative therapeutic products for skin diseases. Its goal is to deliver safe and efficacious therapies to patients, including developing product candidates where there are unmet medical needs. The Company is developing SB206 (berdazimer gel, 10.3%) as a topical prescription gel for the treatment of viral skin infections, with a current focus on molluscum contagiosum. On March 11, 2022, the Company acquired EPI Health, LLC, a specialty pharmaceutical company focused on medical dermatology ("EPI Health"), from Evening Post Group, LLC, a South Carolina limited liability company ("EPG" or the "Seller"). The acquisition of EPI Health (the "EPI Health Acquisition") has provided the Company with a commercial infrastructure to sell a marketed portfolio of therapeutic products for skin diseases. Subsequent to the acquisition, the Company sells various medical dermatology products for the treatments of plaque psoriasis, rosacea and acne.

Novan was incorporated in January 2006 under the state laws of Delaware. In 2015, Novan Therapeutics, LLC, was organized as a wholly owned subsidiary under the state laws of North Carolina; in March 2019, the Company completed registration of a wholly owned Ireland-based subsidiary, Novan Therapeutics, Limited; and in March 2022, the Company acquired its wholly owned subsidiary, EPI Health, a South Carolina limited liability company. In August 2022, EPI Health, as sole equity member, formed and organized a new Delaware single member LLC which did not have any operating activity for the year ended December 31, 2022.

See Note 2—"Acquisition of EPI Health" for further information regarding the EPI Health Acquisition.

Basis of Presentation

The accompanying consolidated financial statements of the Company have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP"). Additionally, the report of the Company's independent registered public accounting firm on the Company's consolidated financial statements as of and for the year ended December 31, 2022, includes an explanatory paragraph indicating that there is substantial doubt about the Company's ability to continue as a going concern, as further discussed below.

Basis of Consolidation

The accompanying consolidated financial statements reflect the operations of the Company and its wholly owned subsidiaries. All intercompany accounts and transactions have been eliminated in consolidation.

The post-acquisition operating results of EPI Health are reflected within the Company's consolidated statement of operations and comprehensive loss for the year ended December 31, 2022, specifically from March 11, 2022 through December 31, 2022.

Liquidity and Ability to Continue as a Going Concern

The Company's consolidated financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. The accompanying consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from uncertainty related to the Company's ability to continue as a going concern.

The Company has evaluated principal conditions and events, in the aggregate, that may raise substantial doubt about its ability to continue as a going concern within one year from the date that these financial statements are issued. The Company identified the following conditions:

- The Company has reported a net loss in all fiscal periods since inception and, as of December 31, 2022, the Company had an accumulated deficit of $310,280.
- As of December 31, 2022, the Company had a total cash and cash equivalents balance of $12,316.
- The Company anticipates that it will continue to generate losses for the foreseeable future, and it expects the losses to increase as it continues the development of, and seeks regulatory approvals for, its product candidates and begins activities to prepare for potential commercialization of SB206, if approved.
- The Company has concluded that the prevailing conditions and ongoing liquidity risks faced by the Company, coupled with its current forecasts, including costs associated with implementing the SB206 prelaunch strategy and commercial preparation, raise substantial doubt about its ability to continue as a going concern.

This evaluation is also based on other relevant conditions that are known or reasonably knowable at the date that the financial statements are issued, including ongoing liquidity risks faced by the Company, the Company's conditional and unconditional obligations due or anticipated within one year, the funds necessary to maintain the Company's operations considering its current financial condition, obligations, and other expected cash flows, and other conditions and events that, when considered in conjunction with the above, may adversely affect the Company's ability to meet its obligations. The Company will continue to evaluate this going concern assessment in connection with the preparation of its quarterly and annual financial statements based upon relevant facts and circumstances, including, but not limited to, its cash and cash equivalents balance and its operating forecast and related cash projection.

The Company believes that its existing cash and cash equivalents as of December 31, 2022, plus expected receipts associated with product sales from its commercial product portfolio will not provide it with adequate liquidity to fund its planned operating needs for one year from the date of these financial statements. Variability in its operating forecast, driven primarily by (i) commercial product sales, (ii) timing of operating expenditures, and (iii) unanticipated changes in net working capital, will impact the Company's cash runway. This operating forecast and related cash projection includes (i) costs associated with preparing for potential U.S. regulatory approval of SB206 as a treatment for molluscum, (ii) costs associated with the readiness and operation of the Company's new manufacturing capability necessary to support small-scale drug substance and drug product manufacturing, (iii) conducting drug manufacturing activities with external third-party contract manufacturing organizations ("CMOs"), (iv) ongoing commercial operations, including sales, marketing, inventory procurement and distribution, and supportive activities, related to its portfolio of therapeutic products for skin diseases acquired with the EPI Health Acquisition, and (v) initial efforts to support potential commercialization of SB206, but excludes additional operating costs that could occur between the New Drug Application ("NDA") submission for SB206 through NDA approval, including, but not limited to, manufacturing, marketing and commercialization efforts to achieve potential launch of SB206. The Company does not currently have sufficient funds to complete commercialization of any of its product candidates that are under development, and its funding needs will largely be determined by its commercialization strategy for SB206, subject to the regulatory approval process and outcome, and the operating performance of its commercial product portfolio.

The inability of the Company to generate sufficient net revenues to fund its operations or obtain significant additional funding on acceptable terms in the near term, could have a material adverse effect on the Company's business and cause the Company to alter or reduce its planned operating activities, including, but not limited to, delaying, reducing, terminating or eliminating planned product candidate development activities, furloughing employees or reducing the size of the workforce, to conserve its cash and cash equivalents. The Company has pursued and may continue to pursue additional capital through equity or debt financings or from other sources, including partnerships, collaborations, licensing, grants or other strategic relationships. The Company's anticipated expenditure levels may change as it adjusts its current operating plan. Such actions could delay development timelines and have a material adverse effect on its business, results of operations, financial condition and market valuation.

The Company may also explore the potential for additional strategic transactions, such as strategic acquisitions or in-licenses, sales, out-licenses or divestitures of some of its assets, or other potential strategic transactions, which could include a sale of the Company. If the Company were to pursue such a transaction, it may not be able to complete the transaction on a timely basis or at all or on terms that are favorable to the Company. Alternatively, if the Company is unable to obtain significant additional funding on acceptable terms or progress with a strategic transaction, it could instead determine to dissolve and liquidate its assets or seek protection under the bankruptcy laws. If the Company decides to dissolve and liquidate its assets or to seek protection under the bankruptcy laws, it is unclear to what extent the Company would be able to pay its obligations, and, accordingly, it is further unclear whether and to what extent any resources would be available for distributions to stockholders.

Business Acquisitions

The Company accounts for business acquisitions using the acquisition method of accounting in accordance with Accounting Standards Codification ("ASC") 805, *Business Combinations* ("ASC 805"). ASC 805 requires, among other things, that assets acquired and liabilities assumed be recognized at their fair values, as determined in accordance with ASC 820, *Fair Value Measurements* ("ASC 820"), as of the acquisition date. For certain assets and liabilities, book value approximates fair value. In addition, ASC 805 establishes that consideration transferred be measured at the closing date of the acquisition at the then-current market price. Under ASC 805, acquisition-related costs (i.e., advisory, legal, valuation and other professional fees) are expensed in the period in which the costs are incurred. The application of the acquisition method of accounting requires the Company to make estimates and assumptions related to the estimated fair values of net assets acquired, which require significant management judgment.

COVID-19

The extent to which COVID-19, and its variant strains, and domestic and global efforts to contain its spread along with lingering effects of the foregoing will impact the Company's business, including its operations, preclinical studies, clinical trials, and financial condition, will depend on future developments, which are highly uncertain and cannot be predicted, and include the duration, severity and scope of the pandemic and its lingering impacts, the availability and effectiveness of vaccines in preventing the spread of COVID-19 (and its variants), and the actions taken by other parties, such as governmental authorities, to contain and treat COVID-19 and its variants.

During the pandemic, the timetable for development of the Company's product candidates has been impacted and may face further disruption and the Company's business could be further adversely affected by the outbreak of COVID-19 and its variants. In particular, COVID-19 impacted the timing of trial initiation of the Company's B-SIMPLE4 Phase 3 study and was a factor influencing the Company's previous adjustment of its targeted SB206 NDA submission timing.

In addition, certain factors from the COVID-19 pandemic may delay or otherwise adversely affect the Company's generation of product revenues from its portfolio of therapeutic products for skin diseases, as well as adversely impact the Company's business generally, including (i) changes in buying patterns caused by lack of normal access by patients to the healthcare system and concern about the supply of medications, (ii) adverse impacts on the Company's manufacturing operations, supply chain and distribution processes, which may impact its ability to procure, produce and distribute its products or product candidates, (iii) the inability of third parties to fulfill their obligations to the Company due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems, (iv) the risk of shutdown in countries where the Company relies on CMOs to provide commercial manufacture of its products or clinical batch manufacturing of its product candidates, (v) the ability to procure raw materials needed for the production of the Company's active pharmaceutical ingredient ("API") and other manufacturing components for the Company's product candidates, (vi) the possibility that third parties on which the Company may rely for certain functions and services, including CMOs, suppliers, distributors, logistics providers, and external business partners, may be adversely impacted by restrictions resulting from the COVID-19 pandemic, which could cause the Company to experience delays or to incur additional costs, and (vii) the risk that the COVID-19 pandemic may intensify other risks inherent in the Company's business.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amount of revenues and expenses during the reporting period. The Company reviews all significant estimates affecting the consolidated financial statements on a recurring basis and records the effects of any necessary adjustments prior to their issuance.

Significant estimates made by management include provisions for product returns, coupons, rebates, chargebacks, trade and cash discounts, allowances and distribution fees paid to certain wholesalers, inventory net realizable value, useful lives of amortizable intangible assets, stock-based compensation, accrued expenses, valuation of assets and liabilities in business combinations, developmental timelines related to licensed products, valuation of notes payable issued in conjunction with the acquisition, valuation of contingent consideration and contingencies. Actual results may differ materially and adversely from these estimates. To the extent there are material differences between the estimates and actual results, the Company's future results of operations will be affected.

Reclassifications

Certain amounts in the Company's consolidated balance sheet as of December 31, 2021 have been reclassified to conform to the current presentation. Prepaid insurance in the amount of $1,697 and other current assets related to leasing arrangement, net in the amount of $109 has been reclassified to prepaid expenses and other current assets. In addition, certain current liabilities totaling $2,164, which were previously classified as accrued compensation, accrued outside research and development services, and accrued legal and professional fees, have been reclassified to all be included in accrued expenses to conform with the current presentation.

These reclassifications had no impact on the Company's consolidated current assets, current liabilities or on the consolidated statements of operations and comprehensive loss or cash flows from operations as of and for the year ended December 31, 2021.

Cash and Cash Equivalents

The Company considers all highly liquid instruments with a maturity of three months or less when purchased to be cash equivalents. Cash and cash equivalents include deposits and money market accounts.

Restricted Cash

Restricted cash as of December 31, 2022 and December 31, 2021 includes both a current and non-current component. The current component relates to a factoring facility entered into in December 2022. See Note 9—"Commitments and Contingencies" for further information. The non-current component relates to funds maintained in a deposit account to secure a letter of credit for the benefit of the lessor of the Company's headquarters. See Note 6—"Leases" for further information regarding the letter of credit.

Accounts Receivable, net

Accounts receivable are carried at original invoice amount less an estimate made for doubtful receivables. An account receivable is considered to be past due if any portion of the receivable balance is outstanding beyond the agreed-upon due date.

The Company records an allowance for credit losses, which includes a provision for expected losses based on historical write-offs, adjusted for current conditions as deemed necessary, reasonable and supportable forecasts about future conditions that affect the expected collectability of the reported amount of the financial asset, as well as a specific reserve for accounts deemed at risk. The allowance is the Company's estimate for accounts receivable as of the balance sheet date that ultimately will not be collected. Any changes in the allowance are reflected in the results of operations in the period in which the change occurs. As of December 31, 2022, the Company had recorded a provision for expected losses of $141. No allowance for credit losses was recorded as of December 31, 2021 as all amounts included in accounts receivable were expected to be collected.

Account balances are written off against the allowance after all means of collection have been exhausted and the potential for recovery is considered remote. Recoveries of receivables previously written off are recorded when received. The Company does not charge interest on accounts receivable.

As part of the EPI Health Acquisition, accounts receivable, net, were marked to fair value as part of the Company's ASC 805 business combination accounting. See Note 2—"Acquisition of EPI Health" for additional detail.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to a concentration of credit risk consist principally of cash, cash equivalents and accounts receivable. The Company places its cash and cash equivalents with financial institutions and these deposits may at times be in excess of insured limits and the Company assesses the creditworthiness of its customers on an on-going basis.

As of December 31, 2022, three of the Company's wholesaler customers accounted for more than 10% of its total accounts receivable balance at 25%, 13% and 12%, respectively.

As of December 31, 2022, 23% of accounts receivable related to amounts due from Sato under the Rhofade agreement. As of December 31, 2021, 97% of accounts receivable related to amounts due from Sato under the SB206 and SB204 license agreement. See Note 14—"License and Collaboration Revenues" for additional detail.

Inventory, net

The Company maintains inventory consisting of for-sale pharmaceuticals related to its marketed product portfolio. The Company measures inventory using the first-in, first-out method and values inventory at the lower of cost or net realizable value. Net realizable value represents the estimated selling price for inventories less all estimated costs to sell.

The Company performs an analysis and records a provision for potentially obsolete inventory. The reserve for obsolescence is generally an estimate of the amount of inventory held at period end that is expected to expire in the future based on projected sales volume and expected product expiration or sell-by dates. These assumptions require the Company to analyze the aging of and forecasted demand for its inventory and make estimates regarding future product sales.

Property and Equipment

Property and equipment are recorded at cost and depreciated using the straight-line method over their estimated useful lives as follows:

Computer and office equipment	3 years
Furniture and fixtures	5-7 years
Laboratory equipment	7 years

Leasehold improvements are amortized over the shorter of the life of the lease or the useful life of the improvements. Expenditures for maintenance and repairs are expensed as incurred. Improvements and betterments that add new functionality or extend the useful life of an asset are capitalized. Leases for real estate often include tenant improvement allowances, which

the Company assesses according to applicable accounting guidance to determine the appropriate owner, and capitalizes such tenant improvement assets accordingly.

Intangible Assets, net and Goodwill

Intangible assets represent certain identifiable intangible assets, including product rights consisting of pharmaceutical product licenses and patents. Amortization for pharmaceutical products licenses is computed using the straight-line method based on the lesser of the term of the agreement and the useful life of the license. Amortization for pharmaceutical patents is computed using the straight-line method based on the useful life of the patent.

Definite-lived intangible assets are reviewed for impairment whenever events or circumstances indicate that carrying amounts may not be recoverable. In the event impairment indicators are present or if other circumstances indicate that an impairment might exist, then management compares the future undiscounted cash flows directly associated with the asset or asset group to the carrying amount of the asset group being determined for impairment. If those estimated cash flows are less than the carrying amount of the asset group, an impairment loss is recognized. An impairment loss is recognized to the extent that the carrying amount exceeds the asset's fair value. Considerable judgment is necessary to estimate the fair value of these assets, accordingly, actual results may vary significantly from such estimates.

Indefinite-lived intangible assets, including goodwill and the cost to obtain and register the Company's internet domain, are not amortized. The Company tests the carrying amounts of goodwill for recoverability on an annual basis at October 1 or when events or changes in circumstances indicate evidence that a potential impairment exists, using a fair value based test.

Goodwill is assessed at the reporting unit level. The Company performed a qualitative assessment as of October 1, 2022 and concluded that it is not more likely than not that the fair value of the Company's reporting unit was less than its carrying amount.

A significant amount of judgment is involved in determining if an indicator of goodwill impairment has occurred. Such indicators may include, among others: a significant decline in expected future cash flows, a sustained, significant decline in the Company's stock price and market capitalization, a significant adverse change in legal factors or in the business climate, adverse assessment or action by a regulator, and unanticipated competition. Any change in these indicators could have a significant negative impact on the Company's financial condition, impact the goodwill impairment analysis or cause the Company to perform a goodwill impairment analysis more frequently than once per year.

Intellectual Property

The Company's policy is to file patent applications to protect technology, inventions and improvements that are considered important to its business. Patent positions, including those of the Company, are uncertain and involve complex legal and factual questions for which important legal principles are largely unresolved. Due to the uncertainty of future value to be realized from the expenses incurred in developing the Company's intellectual property, the cost of filing, prosecuting and maintaining internally developed patents are expensed as general and administrative costs as incurred.

Leases

The Company leases office space and certain equipment under non-cancelable lease agreements. The Company applies the accounting guidance in ASC 842, *Leases.* As such, the Company assesses all arrangements, that convey the right to control the use of property, plant and equipment, at inception, to determine if it is, or contains, a lease based on the unique facts and circumstances present in that arrangement. For those leases identified, the Company determines the lease classification, recognition, and measurement at the lease commencement date. For arrangements that contain a lease the Company: (i) identifies lease and non-lease components; (ii) determines the consideration in the contract; (iii) determines whether the lease is an operating or financing lease; and (iv) recognizes lease Right of Use ("ROU") assets and corresponding lease liabilities. Lease liabilities are recorded based on the present value of lease payments over the expected lease term. The corresponding ROU asset is measured from the initial lease liability, adjusted by (i) accrued or prepaid rents; (ii) remaining unamortized initial direct costs and lease incentives; and (iii) any impairments of the ROU asset.

The Company elected the practical expedient to not separate non-lease components from the lease components. Fixed lease payments on operating leases are recognized over the expected term of the lease on a straight-line basis. Variable lease expenses that are not considered fixed are expensed as incurred. Fixed and variable lease expense on operating leases is recognized within operating expenses within the accompanying consolidated statements of operations and comprehensive loss. The Company has elected the short-term lease exemption and, therefore, does not recognize an ROU asset or corresponding liability for lease arrangements with an original term of 12 months or less.

The interest rate implicit in the Company's lease contracts is typically not readily determinable and as such, the Company uses its incremental borrowing rate based on the information available at the lease commencement date, which represents an internally developed rate that would be incurred to borrow, on a collateralized basis, over a similar term, an amount equal to the lease payments in a similar economic environment.

Impairment of Long-Lived Assets

Long-lived assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to estimated undiscounted future cash flows expected to be generated by the asset. If the carrying amount of an asset exceeds its estimated future cash flows, an impairment charge is recognized for an amount by which the carrying amount of the asset exceeds the fair value of the asset.

Revenue Recognition

The Company accounts for revenue in accordance with ASC 606, *Revenue from Contracts with Customers* ("ASC 606"). To determine revenue recognition for arrangements that are within the scope of ASC 606, the Company (i) identifies the contract with a customer, (ii) identifies the performance obligations within the contract, (iii) determines the transaction price, (iv) allocates the transaction price to the performance obligations in the contract, and (v) recognizes revenue when (or as) the Company satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that it will collect the consideration to which it is entitled in exchange for the goods or services it transfers to the customer.

At contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within the contract and determines those that are performance obligations and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

Upon occurrence of a contract modification, the Company conducts an evaluation pursuant to the modification framework in ASC 606 to determine the appropriate revenue recognition. The framework centers around key questions, including (i) whether the modification adds additional goods and services, (ii) whether those goods and services are distinct, and (iii) whether the contract price increases by an amount that reflects the standalone selling price for the new goods or services. The resulting conclusions will determine whether the modification is treated as a separate, standalone contract or if it is combined with the original contract and accounted for in that manner. In addition, some modifications are accounted for on a prospective basis and others on a cumulative catch-up basis.

The Company currently has the following types of revenue generating arrangements:

Net Product Revenues

Net product revenues encompass sales resulting from transferring control of products to the customer, excluding amounts collected on behalf of third parties. The amount of revenue recognized is the amount allocated to the satisfied performance obligation taking into account variable consideration. The estimated amount of variable consideration is included in the transaction price only to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved.

Product sales are recognized at the point in time when legal transfer of title has occurred, based on shipping terms. The Company records a reduction to the transaction price for estimated chargebacks, rebates, coupons, trade and cash discounts and sales returns. A liability is recognized for expected sales returns, rebates, coupons, trade and cash discounts, chargebacks or other reimbursements to customers in relation to sales made in the reporting period. Payment terms can differ from contract to contract, but no element of financing is deemed present as the typical payment terms are less than 100 days. Therefore, the transaction price is not adjusted for the effects of a significant financing component. A receivable is recognized as soon as control over the products is transferred to the customer as this is the point in time that the consideration is unconditional because only the passage of time is required before the payment is due.

Variable consideration relates to sales returns, rebates, coupons, trade and cash discounts, and chargebacks granted to various direct and indirect customers. The Company recognizes provisions at the time of sale and adjusts them if the actual amounts differ from the estimated provisions. The following describes the nature of each deduction and how provisions are estimated:

Chargebacks – The Company has arrangements with various third-party wholesalers that require the Company to issue a credit to the wholesaler for the difference between the invoice price to the wholesaler and the customer's contract price. Provisions for chargebacks involve estimates of the contract prices within multiple contracts with multiple wholesalers. The provisions for chargebacks vary in relation to changes in product mix, pricing and the level of inventory at the wholesalers and, in addition, fluctuate in proportion to an increase or decrease in sales. Provisions for estimated chargebacks are calculated using the historical chargeback experience and expected chargeback levels for new products and anticipated pricing changes, which involves significant estimates by management. Chargeback provisions are compared to externally obtained distribution channel reports for reasonableness. The Company regularly monitors the provisions for chargebacks and makes adjustments when the Company believes that actual chargebacks may differ from estimated provisions.

Rebates – Rebates include managed care services, fee for service and the Medicaid rebate programs. Rebates are primarily related to volume-based incentives and are offered to key customers to promote loyalty. Customers receive rebates upon the

attainment of a pre-established volume or the attainment of revenue milestones for a specified period. Since rebates are contractually agreed upon, provisions are estimated based on the specific terms in each agreement based on historical trends and expected sales.

Returns – Returns primarily relate to customer returns of expired products that the customer has the right to return up to one year following the product's expiration date. Such returned products are destroyed and credits and/or refunds are issued to the customer for the value of the returns. Accordingly, no returned assets are recorded in connection with those products. The returns provision is estimated by applying a historical return rate to the amounts of revenue estimated to be subject to returns. Revenue subject to returns is estimated based on the lag time from time of sale to date of return. The estimated lag time is developed by analyzing historical experience. Additionally, the Company considers specific factors, such as levels of inventory in the distribution channel, product dating and expiration, size and maturity of launch, entrance of new competitors, changes in formularies or packaging and any changes to customer terms, in determining the overall expected levels of returns, which involves significant estimates by management.

Prompt pay discounts – Prompt pay discounts are offered to most customers to encourage timely payment. Discounts are estimated at the time of invoice based on historical discounts in relation to sales. Prompt pay discounts are almost always utilized by customers. As a result, the actual discounts typically do not vary significantly from the estimated amount.

Coupons – The Company offers coupons to market participants in order to stimulate product sales. The redemption cost of consumer coupons is based on historical redemption experience by product and value.

Sales and other taxes the Company collects concurrent with revenue-producing activities are excluded from revenue. Shipping and handling costs are accounted for as a fulfillment cost and are recorded as cost of revenue. Incidental items that are immaterial in the context of the contract are recognized as expense. Costs incurred to obtain a contract will be expensed as incurred when the amortization period is less than a year.

There can be a lag between the Company's establishment of an estimate and the timing of the invoicing or claim. The Company believes it has made reasonable estimates for future rebates and claims, however, these estimates involve assumptions pertaining to contractual utilization and performance, and payor mix. If the performance or mix across third-party payors is different from the Company's estimates, the Company may be required to pay higher or lower total price adjustments and/or chargebacks than it had estimated.

License and Collaboration Revenues

The Company has entered into various types of agreements that either license the Company's intellectual property to a third party or acquire license rights to intellectual property of a third party, or both.

Agreements where the Company licenses its intellectual property to a third party for development and commercialization in a licensed territory. If the applicable license is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenues from non-refundable, upfront 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, the Company's management utilizes 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 estimated performance period and the appropriate method of measuring progress during the performance period for purposes of recognizing revenue. The Company re-evaluates the estimated performance period and measure of progress each reporting period and, if necessary, adjusts related revenue recognition accordingly. These arrangements often include milestone as well as royalty or profit-share payments, contingent upon the occurrence of certain future events linked to the success of the asset in development, as well as expense reimbursements from or payments to the collaboration partner. Because of the risk that products in development will not receive regulatory approval, the Company does not recognize any contingent payments until regulatory approval becomes probable. Future sales-based royalties are not recorded until the subsequent sale occurs.

Agreements where the Company acquires licensed rights to, or otherwise accesses, a third party's intellectual property for commercialization of the third party's product in a licensed territory. The Company also enters into various types of arrangements to commercialize products. The Company's services provided to the third party under such arrangements, in exchange for compensation that may take the form of cost reimbursements, may include promoting, marketing, selling and distributing the third party's developed drugs, and may also involve certain license rights granted to the parties for use of the other party's intellectual property while providing defined services under the arrangements. The Company assesses the nature of each such arrangement and the various rights granted and services performed thereunder, and determines the applicable accounting standard, which may include ASC 808*, Collaborative Arrangements* ("ASC 808") or ASC 606.

Royalty revenue from licenses provided to the Company's collaboration partners, which is based on sales to third parties of licensed products and technology, is recorded based on the later of when the third-party sale occurs or the performance obligation to which some or all of the royalty has been allocated has been satisfied. This royalty revenue is included in license and collaboration revenue in the accompanying consolidated statements of operations and comprehensive loss.

When the Company performs and incurs marketing and promotional services expense under an arrangement that is determined to be within the scope of ASC 808, and where such services are on behalf of a collaboration partner that is not considered a customer under ASC 606, the Company recognizes a contra-expense that reflects the value of the cost reimbursement to which the Company is expected to be entitled in exchange for those services.

Such contractually required reimbursements are reported as a liability or an asset within the accompanying consolidated balance sheets based upon the timing of cash receipt from the collaboration partner.

Government research contracts and grants revenue

Under the terms of the contracts and grants awarded, the Company is entitled to receive reimbursement of its allowable direct expenses, allocated overhead, general and administrative expenses and payment of other specified amounts. Revenues from development and support activities under government research contracts and grants are recorded in the period in which the related costs are incurred. Associated expenses are recognized when incurred as research and development expense. Revenue recognized in excess of amounts collected from funding sources is recorded as accounts receivable. Any of the funding sources may, at their discretion, request reimbursement for expenses or return of funds, or both, as a result of noncompliance by the Company with the terms of the grants. No reimbursement of expenses or return of funds has been requested or made since inception of the contracts and grants.

Cost of Goods Sold

Cost of goods sold includes the direct costs attributable to the Company's product revenue and any licenses of the Company's commercial products. It includes the cost of the purchased finished goods, shipping and storage costs related to the Company's marketed drug products, sales based royalty and milestone expenses, and certain third-party intellectual property licensing costs.

Advertising Costs

Promotion, marketing and advertising costs are expensed as incurred. Promotion, marketing and advertising costs for the year ended December 31, 2022, were approximately $1,434. There were no costs for the year ended December 31, 2021. The costs are included in selling, general and administrative expenses in the consolidated statement of operations and comprehensive loss.

Research and Development Expenses

Research and development expenses include all direct and indirect development costs incurred for the development of the Company's drug candidates. These expenses include salaries and related costs, including stock-based compensation and travel costs for research and development personnel, allocated facility costs, laboratory and manufacturing materials and supplies, consulting fees, product development, preclinical studies, clinical trial costs, licensing fees and milestone payments under license agreements and other fees and costs related to the development of drug candidates. The costs of tangible and intangible assets that are acquired for use on a particular research and development project, have no alternative future uses, and are not required to be capitalized in accordance with the Company's capitalization policy, are expensed as research and development costs as incurred.

Accrued Outside Research and Development Expenses

The Company is required to estimate its expenses resulting from its obligations under contracts with clinical research organizations, clinical site agreements, vendors, and consultants in connection with conducting clinical trials and preclinical development. The financial terms of these contracts are subject to negotiations which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided to the Company under such contracts. The Company's objective is to reflect the appropriate development and clinical trial expenses in its financial statements by matching those expenses with the period in which the services and efforts are expended.

For clinical trials, the Company accounts for these expenses according to the progress of the trial as measured by actual hours expended by contract research organization personnel, investigator performance or completion of specific tasks, patient progression, or timing of various aspects of the trial. During the course of a clinical trial, the Company adjusts its rate of clinical trial expense recognition if actual results differ from its estimates. The Company utilizes judgment and experience to estimate its accrued expenses as of each balance sheet date in its financial statements based on facts and circumstances known at that time. Although the Company does not expect its estimates to be materially different from amounts actually incurred, its understanding of status and timing of services performed relative to the actual status and timing of services performed may vary and may result in increases or decreases in research and development expenses in future periods when the actual results become known.

For preclinical development services performed by outside service providers, the Company determines accrual estimates through financial models, considering development progress data received from outside service providers and discussions with applicable Company and service provider personnel.

Contingent Consideration

Contingent consideration is recorded as a liability and is the estimate of the fair value of potential milestone payments related to the EPI Health Acquisition. The estimated fair value of contingent consideration was determined based on a probability-weighted valuation model that measures the present value of the probable cash payments based upon the future milestone events of EPI Health at a discount rate that captures the risk associated with the liability and also based on a Monte Carlo simulation, whereby EPI Health's forecasted net sales from the EPI Health legacy products were simulated over the measurement period to calculate the contingent consideration. See Note 2—"Acquisition of EPI Health" for further information regarding purchase consideration.

Contingent consideration is remeasured at each reporting date and any changes in the liability are recorded within the consolidated statement of operations and comprehensive loss. See Note 19—"Fair Value" for further information.

Classification of Warrants Issued in Connection with Offerings of Common Stock

The Company accounts for common stock warrants as either equity-classified or liability-classified instruments based on an assessment of the warrant's specific terms and applicable authoritative guidance in ASC 480, *Distinguishing Liabilities from Equity* ("ASC 480") and ASC 815, *Derivatives and Hedging* ("ASC 815"). The assessment considers whether the warrants are freestanding financial instruments pursuant to ASC 480, whether the warrants meet the definition of a liability pursuant to ASC 480, and whether the warrants meet all of the requirements for equity classification under ASC 815, including whether the warrants are indexed to the Company's own common stock and whether the warrant holders could potentially require "net cash settlement" in a circumstance outside of the Company's control, among other conditions for equity classification. This assessment, which requires the use of professional judgment, is conducted at the time of warrant issuance.

For issued or modified warrants that meet all of the criteria for equity classification, the warrants are required to be recorded as a component of additional paid-in capital at the time of issuance. For issued or modified warrants that do not meet all the criteria for equity classification, the warrants are required to be recorded at their initial fair value on the date of issuance, and remeasured each balance sheet date thereafter. Changes in the estimated fair value of the liability-classified warrants are recognized as a non-cash gain or loss in the accompanying consolidated statements of operations and comprehensive loss.

Fair Value of Financial Instruments

The carrying values of cash equivalents, accounts receivable, accounts payable and accrued liabilities as of December 31, 2022 and December 31, 2021 approximated their fair values due to the short-term nature of these items.

The Company has categorized its financial instruments, based on the priority of the inputs used to value the investments, into a three-level fair value hierarchy. The fair value hierarchy gives the highest priority to quoted prices in active markets for identical assets or liabilities (Level 1) and lowest priority to unobservable inputs (Level 3). If the inputs used to measure the investments fall within different levels of the hierarchy, the categorization is based on the lowest level input that is significant to the fair value measurement of the instrument. Financial instruments recorded in the accompanying consolidated balance sheets are categorized based on the inputs to valuation techniques as follows:

Level 1 - Observable inputs that reflect unadjusted quoted market prices for identical assets or liabilities in active markets.

Level 2 - Observable inputs other than Level 1 that are observable, either directly or indirectly, in the marketplace for identical or similar assets and liabilities.

Level 3 - Unobservable inputs that are supported by little or no market data, where values are derived from techniques in which one or more significant inputs are unobservable.

See Note 19—"Fair Value" for additional detail regarding the fair value of certain balances reflected within the accompanying consolidated financial statements.

Stock-Based Compensation

Equity-Based Awards

The Company applies the fair value method of accounting for stock-based compensation, which requires all such compensation to employees, including the grant of employee stock options and restricted stock units, to be recognized in the accompanying consolidated statements of operations and comprehensive loss based on its fair value at the measurement date (generally the grant date). The expense associated with stock-based compensation is recognized over the requisite service period of each award. For awards with only service conditions and graded-vesting features, the Company recognizes compensation cost on a straight-line basis over the requisite service period. Stock-based awards granted to non-employee directors as compensation for serving on the Company's board of directors are accounted for in the same manner as employee stock-based compensation awards.

The fair value of each option grant is estimated using a Black-Scholes option-pricing model on the grant date using expected volatility, risk-free interest rate, expected life of options and fair value per share assumptions. The Company uses the simplified method of estimating the expected life of options for all options granted given the Company's limited history of option exercises. The risk-free rate is based on the United States Treasury yield curve during the expected life of the option. The Company estimates forfeitures based on the historical experience of the Company and adjusts the estimated forfeiture rate based upon actual experience.

Liability-Based Awards

Stock appreciation rights ("SARs") that include cash settlement features are accounted for as liability-based awards pursuant to ASC 718 *Share Based Payments*. The fair value of such SARs is estimated using a Black-Scholes option-pricing model on each financial reporting date using expected volatility, risk-free interest rate, expected life and fair value per share assumptions.

The fair value of obligations under the Tangible Stockholder Return Plan were estimated using a Monte Carlo simulation approach. The Company's common stock price is simulated under the Geometric Brownian Motion framework under each simulation path. The other assumptions for the Monte Carlo simulation include the risk-free interest rate, estimated volatility and the expected term.

The fair value of each liability award is estimated with a valuation model that uses certain assumptions, such as the award date, expected volatility, risk-free interest rate, expected life of the award and fair value per share assumptions. The Company estimates stock price volatility based on the Company's actual historical volatility over a historical period equal to the expected remaining life of the award. The expected term for liability-based awards is the estimated contractual life. The risk-free rate is based on the United States Treasury yield curve during the expected life of the award.

Income Taxes

Deferred tax assets and liabilities are determined based on the temporary differences between the financial statement carrying amounts and the tax bases of assets and liabilities using the enacted tax rates in effect in the years in which the differences are expected to reverse. In estimating future tax consequences, all expected future events are considered other than enactment of changes in the tax law or rates.

The Company did not record a federal or state income tax benefit for the years ended December 31, 2022 and December 31, 2021 due to its conclusion that a full valuation allowance is required against the Company's deferred tax assets.

The determination of recording or releasing a tax valuation allowance is made, in part, pursuant to an assessment performed by management regarding the likelihood that the Company will generate future taxable income against which benefits of its deferred tax assets may or may not be realized. This assessment requires management to exercise judgment and make estimates with respect to its ability to generate taxable income in future periods.

The Company recognizes the tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained on examination by the taxing authorities based on the technical merits of the position.

The Company's policy for recording interest and penalties is to record them as a component of general and administrative expenses. As of December 31, 2022 and December 31, 2021, the Company accrued no interest and penalties related to uncertain tax positions.

Tax years 2019-2021 remain open to examination by the major taxing jurisdictions to which the Company is subject. Additionally, years prior to 2019 are also open to examination to the extent of loss and credit carryforwards from those years.

In accordance with Section 382 of the Internal Revenue Code of 1986, as amended, a change in equity ownership of greater than 50% within a three-year period results in an annual limitation on the Company's ability to utilize its net operating loss carryforwards and general business credits, including the research and development credits, created during the tax periods prior to the change in ownership.

Comprehensive Loss

Comprehensive loss is defined as the change in equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. For the years ended December 31, 2022 and December 31, 2021, comprehensive loss was equal to net loss.

Net Loss Per Share

Basic net loss per share attributable to common stockholders is computed by dividing the net loss attributable to common stockholders by the weighted average number of shares of common stock outstanding for the period.

Diluted net loss per share is calculated by adjusting weighted average shares outstanding for the dilutive effect of common stock equivalents outstanding for the period. Diluted net loss per share is the same as basic net loss per share, since the effects of potentially dilutive securities are anti-dilutive for all periods presented.

The following securities, presented on a common stock equivalent basis, have been excluded from the calculation of weighted average common shares outstanding for the years ended December 31, 2022 and December 31, 2021 because the effect is anti-dilutive due to the net loss reported in each of those periods. All share amounts presented in the table below represent the total number outstanding as of the end of each period.

	December 31,	
	2022	2021
Warrants to purchase common stock (Note 11)	5,535,637	1,274,176
Stock options outstanding under the 2008 and 2016 Plans (Note 16)	1,031,320	517,303
Nonvested restricted stock units (Note 16)	457,406	—
Stock appreciation rights outstanding under the 2016 Plan (Note 16)	60,000	60,000
Inducement stock options outstanding (Note 16)	1,250	1,250

Segment and Geographic Information

Operating segments are identified as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker. The Company's chief operating decision maker reviews financial information on a disaggregated basis for purposes of allocating resources and evaluating financial performance. See Note 20—"Segment Information" for further information on reportable segments.

Related Parties

Members of the Company's board of directors held 27,654 and 100,497 shares of the Company's common stock as of December 31, 2022 and December 31, 2021, respectively.

Recently Issued Accounting Standards

Accounting Pronouncements Adopted

In June 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2016-13, *Financial Instruments-Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*, which is designed to provide financial statement users with more information about the expected credit losses on financial instruments and other commitments to extend credit held by a reporting entity at each reporting date. When determining such expected credit losses, the guidance requires companies to apply a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information to inform credit loss estimates. The adoption of this new accounting guidance, as of January 1, 2022, did not have a material impact on the Company's consolidated financial statements.

Note 2: Acquisition of EPI Health

On March 11, 2022, the Company completed the EPI Health Acquisition, in which the Company acquired all of the issued and outstanding units of membership interest of EPI Health from EPG for an estimated fair value of purchase consideration of $32,046. EPI Health is an integrated medical dermatology company providing the Company with a commercial infrastructure to support the commercialization of products. Subsequent to the EPI Health Acquisition, the Company sells various dermatological products for the treatments of plaque psoriasis, rosacea and acne.

At closing, the Company paid or committed to pay non-contingent consideration totaling $27,500, as adjusted for cash, indebtedness, net working capital estimates and other contractually defined adjustments (the "Closing Purchase Price"). The Closing Purchase Price consisted of (i) $11,000 paid in cash and (ii) a secured promissory note issued to EPG in the principal amount of $16,500 (the "Seller Note"). See Note 10—"Notes Payable" for additional detail regarding the Seller Note and its related terms. The Company also paid a total working capital adjustment of $4,093, including (i) a $993 payment at closing and (ii) a $3,100 payment post-closing in July 2022 as the parties agreed the final net working capital adjustment amount.

The purchase agreement entered into in connection with the EPI Health Acquisition (the "EPI Heath Purchase Agreement") included the potential payment of additional contingent consideration totaling up to $23,000 upon achievement of certain milestones, as follows:

a. $500, as a one-time cash payment, upon EPG's performance of transition services and the successful completion of the transition provided under the transition services agreement between the Company and EPG;

b. $3,000, as a one-time payment, payable in cash or the Company's common stock, at the discretion of the Company, upon net sales of certain of EPI Health's legacy products exceeding $30,000 during the period from April 1, 2022 through March 31, 2023;

c. up to $2,500, paid in quarterly installments in cash or the Company's common stock at the discretion of the Company, upon net sales of Wynzora Cream ("Wynzora") exceeding certain quarterly thresholds or an annual threshold of $12,500 during the period from April 1, 2022 through March 31, 2023;

d. $5,000, as a one-time payment, payable in cash or the Company's common stock at the discretion of the Company, upon the first occurrence of post-closing net sales of certain of EPI Health's legacy products exceeding $35,000 during any twelve-month period from April 1, 2023 through March 31, 2026; and

e. up to $12,000 based on receipt by EPI Health of regulatory and net sales milestones related to Sitavig from EPI Health's over-the-counter ("OTC") Switch License Agreement with Bayer.

Certain of the above milestone payments will accelerate and become immediately payable upon certain specified events during the applicable milestone periods, including a sale of all or substantially all of the assets with respect to certain of EPI Health's legacy products. The EPI Health Purchase Agreement provides that payment of any additional consideration may be made in cash or in shares of the Company's common stock, so long as the number of shares that may be issued pursuant to the EPI Health Purchase Agreement or otherwise in connection with the EPI Health Acquisition is limited to no more than 19.99% of the Company's outstanding shares of common stock immediately prior to the closing, unless stockholder approval is obtained to issue more than 19.99%.

The EPI Health Acquisition is being accounted for as a business combination using the acquisition method in accordance with ASC 805. Under this method of accounting the fair value of the consideration transferred is allocated to the assets acquired and liabilities assumed based upon their estimated fair values on the date of the EPI Health Acquisition. Any excess of the purchase price over the fair value of identified assets acquired and liabilities assumed is recognized as goodwill.

For the year ended December 31, 2022 and December 31, 2021, the Company incurred costs related to the EPI Health Acquisition of $4,981 and $290, respectively, recognized in selling, general and administrative expenses within the consolidated statements of operations and comprehensive loss.

From the EPI Health Acquisition date through December 31, 2022, $21,023 of total net revenue and a net loss of $1,776 associated with EPI Health's operations are included in the consolidated statements of operations and comprehensive loss.

Purchase Consideration

The following table presents the estimated fair value of purchase consideration as of each interim reporting period end date since the EPI Health Acquisition date, including measurement period adjustments made during each interim period. The estimated fair value of purchase consideration is then allocated to the estimated fair values of the net assets acquired at the EPI Health Acquisition date, as described further following the table under the section entitled *Allocation of Purchase Consideration to Estimated Fair Values of Net Assets Acquired.*

	As of March 11, 2022	Measurement Period Adjustments	As of June 30, 2022	Measurement Period Adjustments	As of September 30, 2022	Measurement Period Adjustments	As of December 31, 2022
Initial cash consideration to Seller	$ 11,000	$ —	$ 11,000	$ —	$ 11,000	$ —	$ 11,000
Secured promissory note issued to Seller	16,500	—	16,500	(3,195) (B)	13,305	—	13,305
Closing date fair value of contingent consideration liability	3,773	—	3,773	(125) (C)	3,648	—	3,648
Remaining working capital adjustment to be paid	4,069	(969) (A)	3,100	—	3,100	—	3,100
Working capital adjustment paid at close	993	—	993	—	993	—	993
Total estimated purchase consideration	$ 36,335	$ (969)	$ 35,366	$ (3,320)	$ 32,046	$ —	$ 32,046

A. On July 7, 2022, the Company and EPG agreed to the final net working capital adjustment amount (the "Total Adjustment Amount"), as defined in the EPI Health Purchase Agreement, as part of the post-closing adjustment to the estimated purchase price for the EPI Health Acquisition. The Total Adjustment Amount was determined to be positive and in the amount of $3,100, which was paid to EPG on July 7, 2022. As of March 31, 2022, the Company had previously estimated that the Total Adjustment Amount would be $4,069. Therefore, the Company has reflected a

$969 measurement period adjustment to the estimated fair value of total purchase consideration. As this adjustment related to the estimated fair value of purchase consideration and did not affect the fair value of any assets acquired or liabilities assumed, it resulted in a reduction of goodwill.

B. During the third quarter of 2022, the Company continued to conduct a fair value assessment of the Seller Note as of the EPI Health Acquisition date of March 11, 2022. The Company completed the fair value assessment and updated the Seller Note fair value estimate as of March 11, 2022 to $13,305 via a downward measurement period adjustment of $3,195 during the interim quarterly period ended September 30, 2022. The Seller Note fair value assessment included both quantitative and qualitative analyses. The quantitative analysis utilized observable credit spreads for market debt transactions with credit ratings similar to the Company's credit ratings. The qualitative analysis took into consideration the fact pattern leading up to the Seller Note's original issuance in March 2022 as well as the subsequent period through July 2022 when the Seller Note was settled and terminated. These qualitative and quantitative analyses were used in conjunction with one another to determine the best estimate of the Seller Note's fair value as of March 11, 2022. See Note 10—"Notes Payable" to these consolidated financial statements for further discussion regarding the Seller Note, including its repayment and termination during the third quarter of 2022.

C. During the third quarter of 2022, the Company continued to conduct a fair value assessment of the contingent consideration liability as of the EPI Health Acquisition date of March 11, 2022. The Company updated the contingent consideration provisional fair value estimate as of March 11, 2022 to $3,648 via a downward measurement period adjustment of $125 during the interim quarterly period ended September 30, 2022, based on progression of the fair value assessment procedures conducted.

Allocation of Purchase Consideration to Estimated Fair Values of Net Assets Acquired

ASC 805 requires, among other things, that the assets acquired and liabilities assumed in a business combination be recognized at their fair values as of the acquisition date. Further, ASC 805 requires any consideration transferred or paid in a business combination in excess of the fair value of the assets acquired and liabilities assumed should be recognized as goodwill.

The total estimated purchase consideration was allocated to the estimated fair values of the assets acquired and liabilities assumed as of March 11, 2022 as follows:

	As of March 11, 2022	Measurement Period Adjustments	As of June 30, 2022	Measurement Period Adjustments	As of September 30, 2022	Measurement Period Adjustments	As of December 31, 2022
Assets acquired and liabilities assumed:							
Accounts receivable, net of $282 allowance	$ 20,083	$ —	$ 20,083	$ —	$ 20,083	$ (279) **(e)**	$ 19,804
Inventory	1,710	—	1,710	(410) **(b)**	1,300	(121) **(e)**	1,179
Prepaid expenses and other current assets	3,692	—	3,692	—	3,692	—	3,692
Property and equipment	100	—	100	—	100	—	100
Intangible assets	33,000	—	33,000	(4,000) **(c)**	29,000	—	29,000
Other assets	27	—	27	—	27	—	27
Right-of-use lease assets	400	—	400	—	400	—	400
Total assets	$ 59,012	$ —	$ 59,012	$ (4,410)	$ 54,602	$ (400)	$ 54,202
Accounts payable	$ 947	$ —	$ 947	$ —	$ 947	$ —	$ 947
Accrued expenses	24,892	—	24,892	—	24,892	(467) **(e)**	24,425
Operating lease liabilities, current portion	208	—	208	—	208	—	208
Operating lease liabilities, net of current portion	342	—	342	—	342	—	342
Other long-term liabilities	290	—	290	—	290	—	290
Total liabilities	$ 26,679	$ —	$ 26,679	$ —	$ 26,679	$ (467)	$ 26,212
Total identifiable net assets acquired	$ 32,333	$ —	$ 32,333	$ (4,410)	$ 27,923	$ 67	$ 27,990
Goodwill	4,002	(969) **(a)**	3,033	1,090 **(d)**	4,123	(67) **(e)**	4,056
Total estimated purchase consideration	$ 36,335	$ (969)	$ 35,366	$ (3,320)	$ 32,046	$ —	$ 32,046

a. On July 7, 2022, the Company and EPG agreed to the final net working capital adjustment amount (the "Total Adjustment Amount"), as defined in the EPI Health Purchase Agreement, as part of the post-closing adjustment to the estimated purchase price for the EPI Health Acquisition. The Total Adjustment Amount was determined to be positive and in the amount of $3,100, which was paid to EPG on July 7, 2022. As of March 31, 2022, the Company had previously estimated that the Total Adjustment Amount would be $4,069. Therefore, the Company has reflected a $969 measurement period downward adjustment to the estimated fair value of total purchase consideration. As this adjustment related to the estimated fair value of purchase consideration and did not affect the fair value of any assets acquired or liabilities assumed, it resulted in a reduction of goodwill.

b. During the third quarter of 2022, the Company continued to conduct a fair value assessment of the trade inventory on hand as of the EPI Health Acquisition date of March 11, 2022. The Company updated the trade inventory's provisional fair value estimate as of March 11, 2022 to $1,300 via a downward measurement period adjustment of $410 during the interim quarterly period ended September 30, 2022, based on progression of the fair value assessment procedures conducted.

c. During the third quarter of 2022, the Company continued to conduct a fair value assessment of the acquired definite-lived intangible product rights assets as of the EPI Health Acquisition date of March 11, 2022, which included further

analysis of the forecasts used in the initial preliminary valuation. This downward measurement period adjustment also resulted in the recognition of $192 of additional amortization expense during the interim quarterly period ended September 30, 2022.

d. The aforementioned measurement period adjustments made to the acquired assets and assumed liabilities, as well as the measurement period adjustments made to the estimated fair value of purchase consideration in the preceding section entitled *Purchase Consideration*, result in an updated goodwill balance of $4,123 as of September 30, 2022 based on a net upward adjustment of $1,090 during the interim quarterly period ended September 30, 2022.

e. During the fourth quarter of 2022, the Company continued and completed its fair value assessment of accounts receivable, trade inventory and accrued expenses as of the EPI Health Acquisition date of March 11, 2022, which included analysis based upon year to date activity of those related balances. The related measurement period downward adjustments related to (i) $141 associated with the collectability of certain trade accounts receivable, (ii) $121 related to both inventory and accrued expenses for finished goods purchases that should not have been included in the acquisition date balances, (iii) $138 related to amounts due from a collaboration partner that should not have been included in the acquisition date balances, and (iv) $346 of certain previously accrued legal costs that should not have been accrued. The net results of these adjustments resulted in a reduction to goodwill of $67 during the quarterly period ended December 31, 2022.

The Company determined the estimated fair value of the acquired intangible assets as of the closing date using the income approach. This is a valuation technique that is based on the market participant's expectations of the cash flows that the intangible assets are forecasted to generate. The projected cash flows from these intangible assets were based on various assumptions, including estimates of revenues, expenses, and operating profit, and risks related to the viability of and commercial potential for alternative treatments. The cash flows were discounted at a rate commensurate with the level of risk associated with the projected cash flows. The Company believes the assumptions are representative of those a market participant would use in estimating fair value.

Goodwill was determined on the basis of the fair values of the assets and liabilities identified at the time of the EPI Health Acquisition. Goodwill was calculated as the excess of the consideration paid consequent to completing the acquisition, compared to the net assets recognized. Goodwill represents the future economic benefits arising from the other acquired assets, which could not be individually identified and separately valued. Goodwill is primarily attributable to the acquired commercial platform and infrastructure, including personnel, and expected synergies related to the commercialization of product candidates and has therefore been allocated to the Research and Development Operations reporting unit.

Pro forma Information

The following pro forma information presents the combined results of operations for the year ended December 31, 2022 and December 31, 2021, as if the Company had completed the EPI Health Acquisition at the beginning of the periods presented. The pro forma financial information is provided for comparative purposes only and is not indicative of what actual results would have been had the EPI Health Acquisition occurred at the beginning of the periods presented, nor does it give effect to synergies, cost savings, fair market value adjustments, and other changes expected to result from the EPI Health Acquisition. Accordingly, the pro forma financial results do not purport to be indicative of consolidated results of operations as of the date hereof, for any period ended on the date hereof, or for any other future date or period. The pro forma financial information has been calculated after applying the Company's accounting policies and includes adjustments for transaction-related costs.

	Twelve Months Ended	
	December 31, 2022 (unaudited)	December 31, 2021 (unaudited)
Total revenue	$ 27,701	$ 19,047
Net loss and comprehensive loss	(32,365)	(59,748)
Net loss per share, basic and diluted	$ (1.47)	$ (3.50)

Note 3: Inventory, net

The major components of inventory, net, were as follows:

	December 31, 2022
Finished goods available for sale	$ 2,037
Reserve for obsolescence	(841)
Inventory, net	$ 1,196

As part of the EPI Health Acquisition, inventory, net, were marked to fair value as part of the Company's ASC 805 business combination accounting. See Note 2—"Acquisition of EPI Health" for additional detail.

Note 4: Prepaid Expenses and Other Current Assets

The following table represents the components of prepaid expenses and other current assets as of:

	December 31, 2022	December 31, 2021
Inventory and raw material deposits	$ 1,280	$ —
Prepaid service contracts	121	—
Prepaid insurance	1,341	1,697
Prepaid Prescription Drug User Fee Act (PDUFA) fees	1,182	—
Product samples	1,362	—
Other current assets related to leasing arrangement	—	109
Prepaid expenses and other current assets	521	766
Total prepaid expenses and other current assets	$ 5,807	$ 2,572

Note 5: Property and Equipment, Net

Property and equipment consisted of the following:

	December 31,	
	2022	2021
Computer equipment	$ 58	$ 58
Furniture and fixtures	43	23
Laboratory equipment	6,195	4,134
Office equipment	177	177
Leasehold improvements	10,117	9,391
Property and equipment, gross	16,590	13,783
Less: Accumulated depreciation and amortization	(2,708)	(1,582)
Total property and equipment, net	$ 13,882	$ 12,201

Depreciation and amortization expense was $1,178 and $344 for the years ended December 31, 2022 and 2021, respectively.

Corporate and Manufacturing Facility

For the years ended December 31, 2022 and December 31, 2021, the Company had construction in progress amounts related to leasehold improvements of $210 and $7,485, respectively.

Note 6: Leases

The Company leases office space and certain equipment under non-cancelable lease agreements.

In accordance with ASC 842, *Leases*, arrangements meeting the definition of a lease are classified as operating or finance leases and are recorded on the balance sheet as both a right-of-use asset and lease liability, calculated by discounting fixed lease payments over the lease term at the rate implicit in the lease, if available, or otherwise at the Company's incremental borrowing rate. For operating leases, interest on the lease liability and the amortization of the right-of-use asset result in straight-line rent expense over the lease term. Variable lease expenses, if any, are recorded when incurred.

In calculating the right-of-use asset and lease liability, the Company elected, and has in practice, historically combined lease and non-lease components. The Company excludes short-term leases having initial terms of 12 months or less from the guidance as an accounting policy election and recognizes rent expense on a straight-line basis over the lease term.

Office Lease at Triangle Business Center, Durham, North Carolina

On January 18, 2021, the Company entered into a lease with an initial term expiring in 2032, as amended for 19,265 rentable square feet, located in Durham, North Carolina. This lease dated as of January 18, 2021, as amended (the "TBC Lease"), is by and between the Company and Copper II 2020, LLC (the "TBC Landlord"), pursuant to which the Company is leasing space serving as its corporate headquarters and small-scale manufacturing site (the "Premises") located within the Triangle Business

Center. The lease executed on January 18, 2021, as amended, was further amended on November 23, 2021 to expand the Premises by approximately 3,642 additional rentable square feet from 15,623 rentable square feet.

The Premises serves as the Company's corporate headquarters and supports various cGMP activities, including research and development and small-scale manufacturing capabilities. These capabilities include the infrastructure necessary to support small-scale drug substance manufacturing and the ability to act as a primary, or secondary backup, component of a potential future commercial supply chain.

The TBC Lease commenced on January 18, 2021 (the "Lease Commencement Date"). Rent under the TBC Lease commenced in October 2021 (the "Rent Commencement Date"). The term of the TBC Lease expires on the last day of the one hundred twenty-third calendar month after the Rent Commencement Date. The TBC Lease provides the Company with one option to extend the term of the TBC Lease for a period of five years, which would commence upon the expiration of the original term of the TBC Lease, with base rent of a market rate determined according to the TBC Lease; however, the renewal period was not included in the calculation of the lease obligation as the Company determined it was not reasonably certain to exercise the renewal option.

The monthly base rent for the Premises is approximately $40 for months 1-10 and approximately $49 for months 11-12, per the second amendment to the primary lease. Beginning with month 13 and annually thereafter, the monthly base rent will be increased by 3%. Subject to certain terms, the TBC Lease provided that base rent was abated for three months following the Rent Commencement Date. The Company is obligated to pay its pro-rata portion of taxes and operating expenses for the building as well as maintenance and insurance for the Premises, all as provided for in the TBC Lease.

The TBC Landlord has agreed to provide the Company with a tenant improvement allowance in an amount not to exceed $130 per rentable square foot, totaling approximately $2,450, per the primary lease, inclusive of the first amendment, and $115 per rentable square foot, totaling $419, per the second amendment to the TBC Lease. The tenant improvement allowance was to be paid over four equal installments corresponding with work performed by the Company. Pursuant to the terms of the TBC Lease, the Company delivered to the TBC Landlord a letter of credit in the amount of $583, as amended, as collateral for the full performance by the Company of all of its obligations under the TBC Lease and for all losses and damages the TBC Landlord may suffer as a result of any default by the Company under the TBC Lease. Cash funds maintained in a separate deposit account at the Company's financial institution to fully secure the letter of credit are presented as restricted cash in non-current assets on the accompanying consolidated balance sheets.

Office Lease at Meeting Street, Charleston, South Carolina

On March 3, 2022 EPI Health entered into a sublease agreement with EPG (the "Meeting Street Lease") for office space at 174 Meeting Street in Charleston, South Carolina for approximately 6,000 rentable square feet.

The term of the Meeting Street Lease was initially through September 30, 2024, and EPI Health had the right to terminate the Meeting Street Lease with prior notice. On August 31, 2022, EPI Health notified EPG of its termination of the sublease effective February 28, 2023. The monthly base rent for the Meeting Street Lease is $20 for months 1-12, inclusive of taxes and operating expenses such as maintenance and insurance.

TBC Lease and Meeting Street Lease

Rent expense, including both short-term and variable lease components associated with the TBC Lease and the Meeting Street Lease, as applicable, was $562 for the year ended December 31, 2022. Rent expense was $467 for the year ended December 31, 2021.

The remaining lease term for the TBC Lease and the Meeting Street Lease are 9.17 years and 0.17 years, respectively, as of December 31, 2022. The weighted average discount rate for both leases was 8.35% as of December 31, 2022.

Rent expense for leases less than one year in duration was $245 and $539 for the years ended December 31, 2022 and December 31, 2021, respectively.

Future minimum lease payments, net of amounts expected to be received related to the tenant improvement allowance, as of December 31, 2022 were as follows:

Maturity of Lease Liabilities	Operating Leases
2023	$ 229
2024	626
2025	645
2026	665
2027	685
2028 and beyond	3,016
Total future undiscounted lease payments	$ 5,866
Less: imputed interest	(1,936)
Total reported lease liability	$ 3,930

The table above reflects payments for an operating lease with a remaining term of one year or more, but does not include obligations for short-term leases. In addition, the net cash flow related to the 2023 fiscal year presented above includes the expected timing of the remaining tenant improvement allowance being funded by the TBC Landlord, which the Company reasonably expects to receive within the next twelve months, offset by expected lease payments for the corresponding period. During the year ended December 31, 2022 and December 31, 2021 the Company received $508 and $1,523, respectively, related to payments as part of the total TBC Landlord funded tenant improvement allowance.

Components of lease assets and liabilities as of December 31, 2022 were as follows:

	As of December 31, 2022
Assets	
Right-of-use lease assets	$ 1,756
Total lease assets	$ 1,756
Liabilities	
Operating lease liabilities, current portion	$ 191
Operating lease liabilities, net of current portion	3,739
Total lease liabilities	$ 3,930

Note 7: Goodwill and Intangible Assets, net

Goodwill

The Company's goodwill balance as of December 31, 2022 was $4,056. The entire goodwill balance relates to the EPI Health Acquisition during the year ended December 31, 2022. None of the goodwill is expected to be deductible for income tax purposes. All of the goodwill has been allocated to the Research and Development Operations reporting unit and operating segment, which has a negative carrying amount.

Intangible Assets

The following table presents both definite and indefinite lived intangible assets as of December 31, 2022, comprised primarily of acquired product rights related to the EPI Health Acquisition:

	Initial Carrying Value	Accumulated Amortization	Net Book Value	Remaining Useful Life (Years)
Rhofade	$ 15,500	$ 835	$ 14,665	14.25
Wynzora	2,000	108	1,892	14.25
Minolira	8,500	458	8,042	14.25
Cloderm	1,000	54	946	14.25
Sitavig	2,000	145	1,855	13.94
Website domain	75	—	75	
Total intangible assets	$ 29,075	$ 1,600	$ 27,475	

The Company amortizes the product rights related to its commercial product portfolio over their estimated useful lives. As part of the EPI Health Acquisition, product rights were recorded at fair value as part of the Company's ASC 805 business combination accounting. See Note 2—"Acquisition of EPI Health" for additional detail.

The following table represents annual amortization of definite lived intangible assets for the next five fiscal years, and thereafter:

2023	$	1,935
2024		1,941
2025		1,935
2026		1,935
2027		1,935
Thereafter		17,719
Total amortization	$	27,400

Note 8: Accounts Payable and Accrued Expenses

The following table represents the components of accounts payable as of December 31, 2022 and December 31, 2021:

	December 31, 2022	December 31, 2021
Rebates, coupons, discounts and chargebacks	$ 9,509	$ —
Finished goods inventory	721	—
Construction in process	—	451
Outside research and development services	721	140
Facility service providers	—	87
Legal and professional fees	530	193
SB206 regulatory activities	422	417
SB206 pre-commercial and marketing	153	682
Other payables	1,633	200
Total accounts payable	$ 13,689	$ 2,170

The following table represents the components of accrued expenses as of December 31, 2022 and December 31, 2021:

	December 31, 2022	December 31, 2021
Accrued rebates, coupons, discounts and chargebacks	$ 8,671	$ —
Accrued returns	3,011	—
Accrued compensation	937	1,543
Accrued outside research and development services	410	194
Accrued legal and professional fees	542	427
Accrued royalties	675	—
Accrued milestones	1,250	—
Accrued construction in process	—	1,020
Accrued insurance	747	—
Accrued SB206 regulatory activities	165	—
Accrued Wynzora payments due to collaborator	532	—
Accrued MC2 collaboration deposit	1,149	—
Accrued other expenses	535	1,804
Total accrued expenses	$ 18,624	$ 4,988

See Note 9—"Commitments and Contingencies", Note 12—"License and Collaboration Agreements", Note 13—"Net Product Revenues" and Note 14—"License and Collaboration Revenues" for certain obligations and contingent payments related to license agreements, including those related to the Company's commercial product portfolio.

Note 9: Commitments and Contingencies

Commitments

Factoring Arrangement

On December 1, 2022, EPI Health entered into an accounts receivable-backed factoring agreement (the "Factoring Agreement") with CSNK Working Capital Finance Corp. d/b/a Bay View Funding ("Bay View"), a subsidiary of Heritage Bank of Commerce. Pursuant to the Factoring Agreement, EPI Health may sell certain trade accounts receivable to Bay View from time to time, with recourse. The factoring facility provides for EPI Health to have access to the lesser of (i) $15,000 (the "Maximum Credit") or (ii) the sum of all undisputed receivables purchased by Bay View multiplied by 70% (which percentages may be adjusted by Bay View in its sole discretion), less any reserved funds. Upon receipt of any advance, EPI Health will have sold and assigned all of its rights in such receivables and all proceeds thereof.

In connection with the factoring facility, EPI Health will be charged a finance fee, defined as a floating rate per annum on outstanding advances under the Factoring Agreement, equal to the prime rate plus 2.00%, due on the first day of each month. EPI Health will also be charged a factoring fee of 0.35% of the gross face value of any trade accounts receivable for each 30 day period after the trade accounts receivable is purchased. Bay View has the right to demand repayment of any purchased receivables that remain unpaid for 90 days after purchase (or 100 days in the case of certain wholesale customers) or with respect to which any account debtor asserts a dispute.

The factoring facility is for an initial term of twelve months and will renew on a year to year basis thereafter, unless terminated in accordance with the Factoring Agreement. EPI Health may terminate the facility at any time upon 60 days prior written notice and payment to Bay View of an early termination fee equal to 0.25% of the Maximum Credit multiplied by the number of months remaining in the term.

All collections of purchased receivables will go directly to a controlled lockbox and Bay View shall apply these collections to EPI Health's obligations. At the end of each reconciliation period, the collection amount, net of the advanced amount, factoring and financing fees, and other payment obligations, as applicable, will be refunded to EPI Health. Bay View has a full recourse right as stated above. If Bay View cannot collect the factored receivables from debtors, EPI Health must refund the advanced amount for any uncollected receivables from debtors.

The Company has evaluated the Factoring Agreement under guidance in ASC 860, *Transfers and Servicing* ("ASC 860"). Based upon that evaluation, the Company has concluded that this agreement does not meet the criteria for sales accounting, and therefore is accounting for the Factoring Agreement as a secured borrowing. Accordingly, the Company records the advanced amount outstanding as a short-term liability and amounts in the controlled lockbox, which represent funds in transit to be applied against outstanding borrowings, as current restricted cash on its consolidated balance sheet. As of December 31, 2022, $10,302 of advances were outstanding under the Factoring Agreement.

During the year ended December 31, 2022, the Company incurred total costs of factoring, including the factoring fees, financing fees and administrative fees of $185, with $73 included as interest expense and the reminder included in selling, general and administrative expense in the consolidated statement of operations.

Contingencies

From time to time, the Company may have certain contingent liabilities that arise in the ordinary course of business activities. 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. See *Legal Proceedings* below for further discussion of pending legal claims.

The Company has entered into, and expects to continue to enter into, contracts in the normal course of business with various third parties who support its clinical trials, preclinical research studies and other services related to its development activities, including drug substance and drug product manufacturing technical transfer capabilities, production and supportive costs. The scope of the services under these agreements can generally be modified at any time, and these agreements can generally be terminated by either party after a period of notice and receipt of written notice.

In connection with entering into the Equity Distribution Agreement with Oppenheimer discussed in Note 11—"Stockholders' Equity", the Company terminated its common stock purchase agreement with Aspire Capital on March 10, 2022. Other than such termination and the repayment and termination of the Seller Note discussed in Note 10—"Notes Payable", there have been no material contract terminations as of December 31, 2022.

See Note 11—"Stockholders' Equity" regarding outstanding common stock warrants.

See Note 12—"License and Collaboration Agreements", Note 13—"Net Product Revenues" and Note 14—"License and Collaboration Revenues" regarding the Company's license agreements.

See Note 15—"Research and Development Agreements" regarding the Purchase Agreement with Reedy Creek and the Funding Agreement with Ligand.

Legal Proceedings

The Company is not currently a party to any material legal proceedings and is not aware of any claims or actions pending against the Company that the Company believes could have a material adverse effect on the Company's business, operating results, cash flows or financial statements. In the future, the Company might from time to time become involved in litigation relating to claims arising from its ordinary course of business.

Compensatory Obligations

The Company enters into employment agreements with certain officers and employees. These agreements are in the normal course of business and contain certain customary Company controlled termination provisions which, if triggered, could result in future severance payments.

See Note 16—"Stock Based Compensation" regarding Stock Appreciation Rights, Restricted Stock Units and Stock Options.

Contingent Payment Obligations Related to the Purchase of EPI Health

See Note 2—"Acquisition of EPI Health" for certain contingent payments related to consideration due to EPG upon achievement of certain milestones by EPI Health.

Contingent Payment Obligations from Historical Acquisitions by EPI Health

EPI Health has in the past acquired certain rights to pharmaceutical products and such arrangements have typically included requirements that EPI Health make certain contingent payments to the applicable seller as discussed below.

Rhofade. On October 10, 2019, EPI Health entered into an agreement whereby it acquired certain assets related to Rhofade (the "Rhofade Acquisition Agreement"). In connection with the Rhofade Acquisition Agreement, EPI Health is required to make the following milestone payments to the seller upon reaching the following net sales thresholds during any calendar year following the closing date, as defined in the Rhofade Acquisition Agreement:

Calendar Year Net Sales Threshold	Milestone Payment
$ 50,000	$ 5,000
$ 75,000	$ 5,000
$ 100,000	$ 10,000

Under the terms of the Rhofade Acquisition Agreement, EPI Health assumed certain liabilities of the prior licensees of the product Rhofade. In particular, EPI Health is required to pay certain earnout payments pursuant to historic acquisition agreements for Rhofade upon the achievement of net sales thresholds higher than those set forth above. However, the Company has not recognized a liability for such Rhofade milestones based on current and historical sales figures and management's estimates of future sales.

Cloderm. On September 28, 2018, EPI Health entered into an agreement pursuant to which it acquired assets related to the product Cloderm. EPI Health is required to pay a low double-digit royalty once cumulative net sales of Cloderm reach $20,833, until $6,500 of royalty payments have been made by EPI Health.

Minolira. On August 20, 2018, EPI Health entered into an agreement pursuant to which it acquired assets related to the product Minolira. In connection with the agreement, EPI Health is required to make the following milestone payments to the seller upon reaching cumulative net sales thresholds as defined in the acquisition agreement:

Cumulative Net Sales Threshold	Milestone Payment
$ 10,000	$ 1,000
$ 20,000	$ 1,000
Each additional $ 20,000	$ 1,500

See Note 12—"License and Collaboration Agreements", Note 13—"Net Product Revenues" and Note 14—"License and Collaboration Revenues" for certain obligations and contingent payments related to license agreements, including those related to the Company's commercial product portfolio.

Note 10: Notes Payable

Seller Note with Evening Post Group

On March 11, 2022, at the closing of the EPI Health Acquisition, the Company entered into a secured promissory note and security agreement with EPG. The Company entered into the Seller Note with EPG to finance a portion of the Closing Purchase Price related to the EPI Health Acquisition.

The Seller Note had a principal amount of $16,500 with interest-only payments due over the course of the 24-month term of the Seller Note. The Seller Note bore interest at the rate of 5.0% per annum for the first 90 days after the closing date, 15.0% per annum for the following 12 months, and 18.0% per annum for the remainder of the term. The non-amortizing principal of the Seller Note was to be paid in full at maturity and was secured by the membership interests of EPI Health held by the Company. EPI Health was a guarantor of the Seller Note. There was no penalty for repaying the Seller Note prior to the end of the term. Based on the escalating interest rate over the term of the Seller Note, the Company recorded interest expense using the effective interest method.

During the year ended December 31, 2022, the Company recorded interest expense of $1,375, related to the Seller Note, of which $635 related to accretion of the debt discount which was recorded related to the Seller Note's fair value estimate as of the date of the EPI Health Acquisition.

On July 13, 2022, the Company reached agreement with EPG regarding payment and termination of the Seller Note. Upon the Company's payment to EPG of $10,000, or an approximate 39% discount on the original principal amount of the Seller Note, the Seller Note and all related security agreements were terminated.

Pursuant to the terms of the Seller Note, there was no penalty for repaying the Seller Note prior to the end of the term. In connection with the repayment of the Seller Note, the guaranty agreement between EPG and EPI Health, dated March 11, 2022, was terminated as of July 13, 2022. Accordingly, the liens on the membership interests and assets of EPI Health were also terminated such that no obligations with respect to the Seller Note and related securities agreement or the underlying loan remain outstanding.

Upon repayment and termination of the Seller Note, the Company recognized a $4,340 gain on debt extinguishment within the consolidated statements of operations and comprehensive loss. This gain represents (i) the $3,939 difference between the Seller Note's $10,000 termination and settlement value and its $13,939 carrying value at the date of termination; and (ii) a $401 write-off of accrued interest outstanding upon termination of the Seller Note.

See Note 2—"Acquisition of EPI Health" for additional detail regarding the Seller Note as it relates to the EPI Health purchase consideration and its estimated fair value and measurement period adjustments.

Paycheck Protection Program

On April 22, 2020, the Company entered into a promissory note, which was subsequently amended (the "Note"), evidencing an unsecured loan in the amount of approximately $956 made to the Company (the "Loan") under the Paycheck Protection Program (the "PPP"). The PPP was established under the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act") and is administered by the United States Small Business Administration (the "SBA"). The Loan was made through PNC Bank, National Association. Subject to the terms of the Note, the Loan's interest rate was fixed at one percent (1%) per annum.

Under the terms of the CARES Act, PPP loan recipients could apply for and be granted forgiveness for all or a portion of loans granted under the PPP, with such forgiveness to be determined, subject to limitations, based on the use of loan proceeds for payment of permitted and program-eligible expenses. Interest payable on the Note could be forgiven only if the SBA agrees to pay such interest on the forgiven principal amount of the Note.

The Company previously applied for and during the second quarter of 2021 received notification of forgiveness of the entire loan balance, including any accrued interest. Based upon the Notice of Paycheck Protection Program Forgiveness Payment received by the Company from the SBA, as of June 14, 2021, the forgiveness of the principal balance of $956 is presented within the consolidated statements of operations and comprehensive loss as a gain on debt extinguishment.

Note 11: Stockholders' Equity

Capital Structure

In conjunction with the completion of the Company's initial public offering in September 2016, the Company amended its restated certificate of incorporation and amended and restated its bylaws. The amendment provided for 210,000,000 authorized shares of capital stock, of which 200,000,000 shares are designated as $0.0001 par value common stock and 10,000,000 shares are designated as $0.0001 par value preferred stock.

At the Company's Annual Meeting of Stockholders held on July 28, 2020 (the "2020 Annual Meeting"), the Company's stockholders approved an amendment to the Company's restated certificate of incorporation of the Company to effect a reverse stock split of the Company's common stock at a ratio of not less than one-for-two and not more than one-for-fifteen, with such ratio and the implementation and timing of such reverse stock split to be determined by the Company's board of directors in its sole discretion. On May 18, 2021, the Company's board of directors approved a one-for-ten reverse stock split of the Company's issued and outstanding common stock. On May 24, 2021, the Company filed with the Secretary of State of the State of Delaware a Certificate of Amendment to the Restated Certification of Incorporation of the Company in order to effect the Reverse Stock Split. The Reverse Stock Split became effective as of 5:00 p.m. Eastern Time on May 25, 2021, and the Company's common stock began trading on a split-adjusted basis on May 26, 2021. As a result of the Reverse Stock Split, on the effective date thereof, each outstanding ten (10) shares of common stock combined into and became one (1) share of common stock, and the number of the Company's issued and outstanding shares of common stock was reduced to 15,170,678. The accompanying consolidated financial statements and related notes give retroactive effect to the Reverse Stock Split.

March 2022 Equity Distribution Agreement – At-the-Market Facility

On March 11, 2022, the Company entered into an Equity Distribution Agreement (the "Equity Distribution Agreement") with Oppenheimer & Co. Inc. ("Oppenheimer"). Pursuant to the Equity Distribution Agreement, the Company may from time to time issue and sell to or through Oppenheimer, acting as the Company's sales agent, shares of the Company's common stock, par value $0.0001 per share having an aggregate offering price of up to $50,000. Sales of the shares, if any, will be made by any method permitted by law deemed to be an "at the market offering" as defined in Rule 415(a)(4) promulgated under the Securities Act of 1933 ("Securities Act"), or, if expressly authorized by the Company, in privately negotiated transactions. As sales agent, Oppenheimer will offer the shares at prevailing market prices and will use its commercially reasonable efforts, consistent with its sales and trading practices, to sell on the Company's behalf all of the shares requested to be sold by the Company, subject to the terms and conditions of the Equity Distribution Agreement. The Company or Oppenheimer may suspend the offering of the shares upon proper notice to the other party. The offering of the shares pursuant to the Equity Distribution Agreement will terminate upon the sale of shares in an aggregate offering amount equal to $50,000, or sooner if either the Company or Oppenheimer terminates the Equity Distribution Agreement as permitted by its terms.

The Company will pay Oppenheimer a commission equal to 3.0% of the aggregate gross proceeds from the sale of the shares sold pursuant to the Equity Distribution Agreement and will reimburse Oppenheimer for certain expenses incurred in connection with its services under the Equity Distribution Agreement. The foregoing rate of compensation will not apply when Oppenheimer acts as principal, in which case the Company may sell the shares to Oppenheimer as principal at a price agreed upon among the parties.

During the year ended December 31, 2022, the Company sold 645,105 shares of its common stock at an average price of approximately $2.66 per share for total net proceeds of $1,665 under the Equity Distribution Agreement.

In relation to the June 2022 Registered Direct Offering (as defined and described below), the Company agreed not to issue any additional securities in any variable rate transaction (as defined in the related securities purchase agreement), including under the Equity Distribution Agreement, until December 13, 2022, unless, on or after September 11, 2022, the VWAP (as defined in the related securities purchase agreement) for the trading day prior to the date of the transaction was greater than 50% above the exercise price for the June 2022 Common Warrants.

Equity Offerings and Outstanding Common Stock Warrants

The Company has historically entered into equity offerings with underwriters and placement agents. Certain of these offerings, such as the June 2022 Registered Direct Offering, the March 2020 Public Offering, the March 2020 Registered Direct Offering and the January 2018 Offering, included certain common stock warrant and pre-funded warrant issuances.

The following table presents the Company's outstanding warrants to purchase common stock for the periods indicated.

	December 31,		Exercise Price Per Share
	2022	2021	
Warrants to purchase common stock issued in the January 2018 Offering	—	999,850	$ 46.60
Warrants to purchase common stock issued in the June 2022 Registered Direct Offering	5,261,311	—	2.851
Warrants to purchase common stock issued in the March 2020 Public Offering	252,417	252,417	3.00
Underwriter warrants to purchase common stock associated with the March 2020 Public Offering	11,304	11,304	3.75
Placement agent warrants to purchase common stock issued in the March 2020 Registered Direct Offering	10,605	10,605	5.375
	5,535,637	1,274,176	

The weighted average exercise price per share for warrants outstanding as of December 31, 2022 and December 31, 2021 was $2.86 and $37.24, respectively. For the years ended December 31, 2022 and December 31, 2021, total proceeds from the exercise of common stock warrants was zero and $461, respectively.

June 2022 Registered Direct Offering

On June 9, 2022, the Company entered into a securities purchase agreement with an institutional investor (the "Purchaser"), pursuant to which the Company agreed to issue and sell to the Purchaser, in a registered direct offering priced at-the-market under Nasdaq rules (the "June 2022 Registered Direct Offering") (i) 2,080,696 shares (the "June 2022 Shares") of the Company's common stock, and accompanying common stock warrants (the "June 2022 Common Warrants") to purchase an aggregate of 2,080,696 shares of common stock, for a combined price of $2.851 per share and accompanying common warrant, and (ii) pre-funded warrants to purchase 3,180,615 shares of the Company's common stock (the "June 2022 Pre-funded Warrants") and accompanying common warrants to purchase 3,180,615 shares of common stock, for a combined price of $2.841 per pre-funded warrant and accompanying common warrant. The June 2022 Registered Direct Offering closed on June 13, 2022. Net proceeds from the offering were approximately $14,020 after deducting fees and commissions and offering expenses of approximately $948. Offering costs were netted against the offering proceeds and recorded to additional paid-in capital.

As of December 31, 2022, no June 2022 Pre-funded Warrants and 5,261,311 June 2022 Common Warrants are outstanding.

The Company entered into a placement agent agreement (the "Placement Agent Agreement") dated as of June 9, 2022, engaging Oppenheimer to act as the sole placement agent in connection with the June 2022 Registered Direct Offering. Pursuant to the Placement Agent Agreement, the Company agreed to pay Oppenheimer a placement agent fee in cash equal to 5.0% of the gross proceeds from the sale of the June 2022 Shares, the June 2022 Pre-funded Warrants and the June 2022 Common Warrants, and to reimburse certain expenses of Oppenheimer in connection with the June 2022 Registered Direct Offering. Each June 2022 Pre-funded Warrant had an exercise price of $0.01 per share. The June 2022 Pre-funded Warrants were exercisable immediately upon issuance until all of the June 2022 Pre-funded Warrants were exercised in full. Each June 2022 Common Warrant is immediately exercisable and has an exercise price of $2.851 per share and will expire five years from the date of issuance.

The exercise price and the number of shares of common stock purchasable upon the exercise of the June 2022 Pre-funded Warrants and June 2022 Common Warrants are subject to adjustment upon the occurrence of specific events, including stock dividends, stock splits, reclassifications and combinations of the Company's common stock.

Common warrants. The June 2022 Common Warrants include certain provisions that establish warrant holder settlement rights that take effect upon the occurrence of certain fundamental transactions. The June 2022 Common Warrants define a fundamental transaction to generally include any consolidation, merger or other transaction whereby another entity acquires more than 50% of the Company's outstanding common stock or the sale of all or substantially all of the Company's assets. The fundamental transaction provision provides the warrant holders with the option to settle any unexercised warrants for cash in the event of certain fundamental transactions that are within the control of the Company. For any fundamental transaction that is not within the control of the Company, including a fundamental transaction not approved by the Company's board of directors, the warrant holder will only be entitled to receive from the Company or any successor entity the same type or form of consideration (and in the same proportion) that is being offered and paid to the stockholders of the Company in connection with the fundamental transaction, whether that consideration be in the form of cash, stock or any combination thereof. In the event of any fundamental transaction, and regardless of whether it is within the control of the Company, the settlement amount of the June 2022 Common Warrants (whether in cash, stock or a combination thereof) is determined based upon a Black-Scholes value that is calculated using inputs as specified in the June 2022 Common Warrants, including a defined volatility input equal to the greater of the Company's 100-day historical volatility or 100%.

The June 2022 Common Warrants also include a separate provision whereby the exercisability of such warrants may be limited if, upon exercise, the warrant holder or any of its affiliates would beneficially own more than 4.99% (or an amount up to 9.99% if the holder so elects) of the Company's common stock.

The Company assessed the June 2022 Common Warrants for appropriate equity or liability classification pursuant to the Company's accounting policy described in Note 1—"Organization and Significant Accounting Policies". During this assessment, the Company determined (i) the June 2022 Common Warrants did not constitute a liability under ASC 480; (ii) the June 2022 Common Warrants met the definition of a derivative under ASC 815; (iii) the warrant holder's option to receive a net cash settlement payment under the June 2022 Common Warrants only becomes exercisable upon the occurrence of certain specified fundamental transactions that are within the control of the Company; (iv) upon the occurrence of a fundamental transaction that is not within the control of the Company, the warrant holder would receive the same type or form of consideration offered and paid to common stockholders; (v) the June 2022 Common Warrants are indexed to the Company's common stock; and (vi) the June 2022 Common Warrants met all other conditions for equity classification under ASC 480 and ASC 815. Based on the results of this assessment, the Company concluded that the June 2022 Common Warrants are

freestanding equity-linked derivative instruments that met the criteria for equity classification. Accordingly, the June 2022 Common Warrants were classified as equity and were accounted for as a component of additional paid-in capital at the time of issuance.

Pre-funded warrants. The June 2022 Pre-funded Warrants' fundamental transaction provision did not provide the warrant holders with the option to settle any unexercised warrants for cash in the event of any fundamental transactions; rather, in all fundamental transaction scenarios, the warrant holder was only entitled to receive from the Company or any successor entity the same type or form of consideration (and in the same proportion) that was being offered and paid to the stockholders of the Company in connection with the fundamental transaction, whether that consideration be in the form of cash, stock or any combination thereof. The June 2022 Pre-funded Warrants also included a separate provision whereby the exercisability of the warrants could be limited if, upon exercise, the warrant holder or any of its affiliates would beneficially own more than 4.99% (or an amount up to 9.99% if the holder so elects) of the Company's common stock.

The Company assessed the June 2022 Pre-funded Warrants for appropriate equity or liability classification pursuant to the Company's accounting policy described in Note 1—"Organization and Significant Accounting Policies". During this assessment, the Company determined the June 2022 Pre-funded Warrants were freestanding instruments that did not meet the definition of a liability pursuant to ASC 480 and did not meet the definition of a derivative pursuant to ASC 815. The June 2022 Pre-funded Warrants were indexed to the Company's common stock and met all other conditions for equity classification under ASC 480 and ASC 815. Based on the results of this assessment, the Company concluded that the June 2022 Pre-funded Warrants were freestanding equity-linked financial instruments that met the criteria for equity classification under ASC 480 and ASC 815. Accordingly, the June 2022 Pre-funded Warrants were classified as equity and were accounted for as a component of additional paid-in capital at the time of issuance.

June 2021 Public Offering

On June 17, 2021, the Company entered into an underwriting agreement with Cantor Fitzgerald & Co., as underwriter, pursuant to which the Company agreed to issue and sell an aggregate of 3,636,364 shares of the Company's common stock at a price to the public of $11.00 per share, less underwriting discounts and commissions. The Company also granted the underwriter a 30-day option (the "Underwriter Option") to purchase up to an additional 545,454 shares of common stock at the public offering price, less underwriting discounts and commissions. The June 2021 Public Offering closed on June 21, 2021, and the Underwriter Option expired unexercised in July 2021.

Net proceeds from the June 2021 Public Offering were approximately $37,236 after deducting underwriting discounts and commissions and offering expenses of approximately $2,764. Offering costs were netted against the offering proceeds and recorded to additional paid-in capital.

The June 2021 Public Offering was made pursuant to the Company's effective shelf registration statement on Form S-3 (No. 333-236583), filed with the Securities and Exchange Commission ("SEC") and declared effective by the SEC on April 10, 2020, including a prospectus contained therein dated as of April 10, 2020, as supplemented by a prospectus supplement, dated June 17, 2021.

March 2020 Public Offering

On February 27, 2020, the Company entered into an underwriting agreement with H.C. Wainwright, as underwriter, relating to the offering, issuance and sale of common stock, pre-funded warrants, and accompanying common warrants (the "CMPO Common Warrants"), in a public offering (the "March 2020 Public Offering"). The number of CMPO Common Warrants, excluding pre-funded warrants, issued in connection with the March 2020 Public Offering totaled 2,108,333. At closing, the Company also issued to designees of H.C. Wainwright, as underwriter, warrants to purchase an aggregate of up to 59,496 shares of common stock (the "CMPO UW Warrants") representing 3.0% of the aggregate number of shares of common stock sold and shares of common stock underlying the pre-funded warrants sold in the March 2020 Public Offering.

The CMPO Common Warrants have an exercise price of $3.00 per share and expire five years from the date of issuance. During the year ended December 31, 2022, there were no exercises of CMPO Common Warrants. During the year ended December 31, 2021, warrant holders exercised 10,000 of the CMPO Common Warrants for total proceeds of approximately $30. There were 252,417 of the CMPO Common Warrants outstanding as of December 31, 2022.

The CMPO UW Warrants have an exercise price of $3.75 per share and expire five years from the date of issuance. During the year ended December 31, 2022, there were no exercises of CMPO UW Warrants. During the year ended December 31, 2021, warrant holders exercised 48,192 of the CMPO UW Warrants for total proceeds of approximately $181. There were 11,304 of the CMPO UW Warrants outstanding as of December 31, 2022.

March 2020 Registered Direct Offering

On March 24, 2020, the Company entered into a securities purchase agreement with several institutional and accredited investors, pursuant to which the Company agreed to sell and issue shares of the Company's common stock and pre-funded

warrants in a registered direct offering priced at the market (the "March 2020 Registered Direct Offering"). The March 2020 Registered Direct Offering closed on March 26, 2020. At closing, the Company issued to designees of H.C. Wainwright, as placement agent, warrants to purchase an aggregate of up to 55,814 shares of common stock (the "RDO PA Warrants") representing 3.0% of the aggregate number of shares of common stock sold and shares of common stock underlying pre-funded warrants sold in the March 2020 Registered Direct Offering.

The RDO PA Warrants have an exercise price of $5.375 per share and expire five years from the date of issuance. During the year ended December 31, 2022, there were no exercises of RDO PA Warrants. During the year ended December 31, 2021, warrant holders exercised 45,209 of the RDO PA Warrants for total proceeds of approximately $243. There were 10,605 of the RDO PA Warrants outstanding as of December 31, 2022.

January 2018 Offering

There were no exercises of warrants issued in the Company's public offering that closed on January 9, 2018 (the "January 2018 Offering") during the year ended December 31, 2022. During the year ended December 31, 2021, warrant holders exercised 150 of the warrants issued in the January 2018 Offering. On January 9, 2022, the remaining 999,850 outstanding warrants related to the January 2018 Offering expired without being exercised.

Aspire Common Stock Purchase Agreement

On July 21, 2020, the Company entered into the Common Stock Purchase Agreement (the "July 2020 CSPA") with Aspire Capital Fund, LLC ("Aspire"), which provided that, upon the terms and subject to the conditions and limitations set forth therein, Aspire was committed to purchase up to an aggregate of $30,000 of shares of the Company's common stock at the Company's request from time to time during the 30-month term of the July 2020 Aspire CSPA. Upon execution of the July 2020 Aspire CSPA, the Company agreed to sell to Aspire 555,555 shares of its common stock at $9.00 per share for proceeds of $5,000. In consideration for entering into the July 2020 Aspire CSPA, upon satisfaction of certain conditions under the July 2020 Aspire CSPA, the Company issued to Aspire 100,000 shares of the Company's common stock (the "July 2020 Commitment Shares"). The July 2020 Commitment Shares, valued at approximately $847, were recorded in July 2020 as non-cash costs of equity financing and included within general and administrative expenses. The July 2020 Aspire CSPA replaced the June 2020 Aspire Common Stock Purchase Agreement, which was terminated under the terms of the July 2020 Aspire CSPA.

On March 9, 2022, the Company provided notice to Aspire electing to terminate the July 2020 CSPA effective as of March 10, 2022. By its terms, the July 2020 CSPA could be terminated by the Company at any time, at its discretion, without any penalty or additional cost to the Company.

During the year ended December 31, 2022, there were no sales of common stock under the July 2020 CSPA. During the year ended December 31, 2021, the Company sold 493,163 shares of its common stock at an average price of $1.28 for total proceeds of $6,334.

Common Stock

The Company's common stock has a par value of $0.0001 per share and consists of 200,000,000 authorized shares as of December 31, 2022 and December 31, 2021. There were 24,722,308 and 18,815,892 shares of common stock outstanding as of December 31, 2022 and December 31, 2021, respectively.

The Company had reserved shares of common stock for future issuance as follows:

	December 31,	
	2022	2021
Outstanding warrants to purchase common stock (Note 11)	5,535,637	1,274,176
Outstanding stock options (Note 16)	1,032,570	518,553
Nonvested restricted stock units (Note 16)	457,406	—
Outstanding stock appreciation rights (Note 16)	60,000	60,000
For possible future issuance under the 2016 Stock Plan (Note 16)	241,801	1,213,224
	7,327,414	3,065,953

Related Party Stock Repurchase

In April 2016, the Company repurchased 950 shares of its common stock for an aggregate price of $155 from an executive of the Company who was also a member of the Company's board of directors at that time. The repurchase of these shares is recorded as treasury stock on the accompanying consolidated balance sheets as of December 31, 2022 and December 31, 2021.

Preferred Stock

The Company's restated certificate of incorporation provides the Company's board of directors with the authority to issue $0.0001 par value preferred stock from time to time in one or more series by adopting a resolution and filing a certificate of designations. Voting powers, designations, preferences, dividend rights, conversion rights and liquidation preferences shall be stated and expressed in such resolutions. There were 10,000,000 shares designated as preferred stock and no shares outstanding as of December 31, 2022 and December 31, 2021.

Note 12: License and Collaboration Agreements

Wynzora Agreement

Effective as of January 1, 2022, EPI Health entered into an amended and restated promotion and collaboration agreement with MC2 Therapeutics Limited ("MC2"), relating to the commercialization of Wynzora for treatment of plaque psoriasis in adults in the United States (the "MC2 Agreement"). Pursuant to the MC2 Agreement, which sets forth the collaborative efforts between EPI Health and MC2 to commercialize and promote Wynzora with MC2 in the United States, MC2 granted EPI Health an exclusive right and license under MC2's intellectual property rights to sell, or detail (as defined in the MC2 Agreement), and engage in certain commercialization activities with respect to Wynzora in the United States.

In exchange for the provision of promotional and commercialization activities, under the terms of the MC2 Agreement, EPI Health is entitled to receive:

- Reimbursement for all incremental costs incurred by the Company for the promotion and commercialization of Wynzora, including the incremental portion of the Company's personnel and commercial operating costs. The supply price of Wynzora product inventory is also considered to be an incremental cost that is reimbursed by MC2.
- A commercialization fee equivalent to a percentage of net sales ranging from the mid-teens for net sales less than or equal to $65,000 to the upper single digits for annual net sales greater than $105,000. EPI Health collects this commercialization fee by retaining its portion of the Wynzora product net sales it collects from its customers, with the remainder of the net sales being remitted by EPI Health to MC2 periodically in the form of a royalty payment, pursuant to the MC2 Agreement.
- A contingent incentive fee equal to 5% of the first $30,000 in net sales of Wynzora sold in the United States by EPI Health in each of the 2022 and 2023 calendar years; provided that such incentive fee shall not exceed $1,500 each year and such incentive fee shall not be credited to EPI Health until the royalty payments paid to MC2 surpass the amount of certain commercialization payments made previously by MC2.

The term of the MC2 Agreement runs until the seventh anniversary of the first commercial sale of Wynzora (as defined in the MC2 Agreement) or June 30, 2028, whichever is earlier. Either party may terminate the MC2 Agreement for the other party's material uncured breach or the bankruptcy or insolvency of the other party. MC2 may terminate the MC2 Agreement under certain scenarios, including for convenience with twelve months' advance notice to EPI Health, provided that the termination is not effective unless MC2 pays any unpaid historical liabilities related to commercialization of Wynzora owed by MC2. In the case of such termination, MC2 is also required to make an additional sunset payment to EPI Health, paid in installments over the 24 month period following termination. EPI Health may terminate the MC2 Agreement for convenience with twelve months' advance notice to MC2 provided that the termination is not effective unless the Company provides MC2 with a guarantee of the payment of any outstanding royalty payments, to the extent such royalty payments owed by EPI Health exceed any unpaid historical liabilities related to commercialization of Wynzora owed by MC2.

Rhofade Agreements

In connection with the Rhofade Acquisition Agreement that is described in Note 9—"Commitments and Contingencies", EPI Health acquired rights to that certain Assignment and License Agreement, whereby EPI Health licenses certain intellectual property from Aspect Pharmaceuticals, LLC ("Aspect" and such agreement, the "Aspect Agreement"). Under the terms of the Aspect Agreement, EPI Health, as successor-in-interest, has exclusive rights to, and is required to use commercially reasonable efforts to, commercialize the Rhofade product. EPI Health also has a duty to certain other parties to use commercially reasonable efforts to commercialize the Rhofade product based on historical acquisition agreements for Rhofade that were assumed by EPI Health.

The Aspect Agreement expires upon the last-to-expire of patent claims made under the assigned and licensed patents under the Aspect Agreement. Aspect may terminate the agreement upon a material breach by EPI Health after providing an opportunity to cure. Upon such termination by Aspect, EPI Health will cease all development and commercialization of Rhofade and EPI Health will assign and convey to Aspect its entire right, title and interest in and to the assigned intellectual property transferred under the Aspect Agreement.

Additionally, under the Aspect Agreement, the Rhofade Acquisition Agreement and the other historical acquisitions related to Rhofade, EPI Health is also required to pay a combined royalty on net sales of Rhofade and related products initially in the low double digits, which rate may increase based on the thresholds of net sales achieved by EPI Health. EPI Health is also required to pay 25% of any upfront, license, milestone or other related payments received by EPI Health related to any sublicenses of Rhofade and related products.

In connection with two abbreviated new drug application ("ANDA") settlement agreements that EPI Health entered into in connection with Rhofade in 2021, EPI Health granted two ANDA filers a license to launch their own generic product for the treatment of erythema in rosacea. The actual timing of the launch of such generic products is uncertain because the launch dates of such products under the settlement agreements are subject to acceleration under certain circumstances. In the absence of any circumstances triggering acceleration, the earliest launch of such a generic product would be in the third quarter of 2026.

Minolira Agreements

In connection with the Minolira acquisition that is described in Note 9—"Commitments and Contingencies", EPI Health assumed the royalty obligation related to an ANDA settlement in connection with Minolira. Accordingly, EPI Health is required to pay a royalty to an ANDA filer in the low double digits of any generic form of Minolira that is the pharmaceutical equivalent of the 105 mg or 135 mg strength Minolira product.

Sitavig Agreements

On February 21, 2020, EPI Health entered into an agreement with Vectans Pharma ("Vectans") in which the parties terminated an existing license agreement dated March 17, 2014 which granted EPI Health the exclusive right to develop and commercialize a prescription Sitavig product in the United States and Canada, and instead provided that EPI Health would purchase outright certain intellectual property (and license other intellectual property) related to the prescription Sitavig Rx product in the United States and Canada (the "Vectans Agreement").

At the time it entered into the Vectans Agreement, EPI Health also entered into an OTC Switch License Agreement (the "OTC License Agreement") with Bayer Healthcare LLC ("Bayer"). Under the OTC License Agreement, EPI Health granted to Bayer an exclusive and sublicensable license to develop and commercialize an OTC product in the United States and Canada.

Under the OTC License Agreement, Bayer has agreed to pay EPI Health various regulatory milestone payments upon the achievement of such regulatory milestones equaling a maximum aggregate amount of $9,500, along with various commercial milestone payments upon the achievement of such commercial milestones equaling a maximum aggregate amount of $20,000. Under the Vectans Agreement, EPI Health is required to pay Vectans various milestone and royalty payments in amounts ranging from 32% - 50% of the amounts paid by Bayer to EPI Health pursuant to the OTC License Agreement, and the Company will also be required to pay a portion of such milestone payments to EPG under the EPI Health Purchase Agreement.

Bayer has also agreed to pay to EPI Health a tiered royalty ranging from a mid-single digit to a low-double digit percentage of net sales of licensed products in the licensed territory, subject to a reduction in the royalty payments in certain circumstances.

Bayer is responsible for funding the development and commercial costs for the OTC product in the United States and Canada. The Company is obligated to perform certain oversight, review and supporting activities for Bayer, including (i) maintaining existing EPI Health patents related to the Sitavig product, and (ii) participating in a joint committee that oversees, reviews and approves development and commercialization activities under the OTC License Agreement.

The OTC License Agreement expires on the tenth anniversary of the first commercial sale of an OTC product on a country-by-country basis. The OTC License Agreement may be terminated by (i) Bayer without cause upon nine months' advance written notice to EPI Health, (ii) either party in the event of the other party's uncured material breach upon 60 days' advance written notice, (iii) either party, upon three months' notice, in the event Bayer provides EPI Health with notice that Bayer has elected to permanently discontinue development of the OTC product in the United States and Canada, and (iv) either party in the event of the other party's dissolution, liquidation, bankruptcy or insolvency. On the tenth anniversary of the first commercial sale of the OTC product on a country-by-country basis, assuming Bayer is not in breach and the OTC License Agreement has not been terminated, Bayer will have an irrevocable, royalty-free license to commercialize the OTC product without any further obligations to EPI Health.

Nuvail Agreements

On November 7, 2021, a predecessor of EPI Health entered into an exclusive license agreement with Chesson Laboratory Associates, Inc. ("Chesson"), as subsequently amended, for the sale of Nuvail, and pursuant to such agreement, EPI Health serves as an exclusive distributor of this product in the United States. Pursuant to the Nuvail license agreement, EPI Health is required to pay a tiered royalty up to a low double digit percentage of net sales of Nuvail, subject to a minimum annual royalty payment. The initial term of the license agreement expired in 2021 and was automatically extended for an additional five year renewal period. The license agreement may be terminated by either party for material breach. Chesson may terminate the license agreement early for convenience upon 12 months' notice but is required to pay a termination fee based on a multiple of

trailing twelve months gross sales. EPI Health is not currently actively promoting this product as part of its commercial portfolio.

UNC Agreements

The Amended, Restated and Consolidated License Agreement dated June 27, 2012, as amended, with the University of North Carolina at Chapel Hill ("UNC," and such agreement, the "UNC License Agreement") provides the Company with an exclusive license to issued patents and pending applications directed to the Company's library of Nitricil compounds, including patents issued in the United States, Japan and Australia, with claims intended to cover NVN1000, the new chemical entity ("NCE") for the Company's current product candidates. The UNC License Agreement requires the Company to pay UNC up to $425 in regulatory and commercial milestones on a licensed product by licensed product basis and a running royalty percentage in the low single digits on net sales of licensed products. Licensed products include any products being developed by the Company or by its sublicensees.

Unless earlier terminated by the Company at its election, or if the Company materially breaches the agreement or becomes bankrupt, the UNC License Agreement remains in effect on a country by country and licensed product by licensed product basis until the expiration of the last to expire issued patent covering such licensed product in the applicable country. The projected date of expiration of the last to expire of the patents issued under the UNC License Agreement is 2036.

Other Research and Development Agreements

The Company has entered into various licensing agreements with universities and other research institutions under which the Company receives the rights, and in some cases substantially all of the rights, of the inventors, assignees or co-assignees to produce and market technology protected by certain patents and patent applications. In addition to the UNC License Agreement, which is the Company's primary license agreement, the counterparties to the Company's various other licensing agreements are the University of Akron Research Foundation, Hospital for Special Surgery, Strakan International S.a.r.l., which is a licensee of the University of Aberdeen, KIPAX AB and KNOW Bio.

The Company is required to make payments based upon achievement of certain milestones and will be required to make royalty payments based on a percentage of future sales of covered products or a percentage of sublicensing revenue. As future royalty payments are directly related to future revenues (either sales or sublicensing), future commitments cannot be determined. No accrual for future payments under these agreements has been recorded, as the Company cannot estimate if, when or in what amount payments may become due.

KNOW Bio Agreements

On December 30, 2015, the Company completed the distribution of 100% of the outstanding membership interests of KNOW Bio, LLC ("KNOW Bio"), a former wholly owned subsidiary of the Company, to Novan's stockholders (the "Distribution"), pursuant to which KNOW Bio became an independent privately held company. In connection with the Distribution, the Company entered into exclusive license agreements and sublicense agreements with KNOW Bio, as described below. The agreements will continue for so long as there is a valid patent claim under the respective agreement, unless earlier terminated, and upon expiration, will continue as perpetual non-exclusive licenses. KNOW Bio has the right to terminate each such agreement, for any reason upon 90 days advance written notice to the Company.

License of existing and potential future intellectual property to KNOW Bio. The Company and KNOW Bio entered into an exclusive license agreement dated December 29, 2015 (the "KNOW Bio License Agreement"). Pursuant to the terms of the KNOW Bio License Agreement, the Company granted to KNOW Bio exclusive licenses, with the right to sublicense, under certain United States and foreign patents and patent applications that were controlled by the Company as of December 29, 2015 or that became controlled by the Company between that date and December 29, 2018, directed towards nitric-oxide releasing compositions and methods of manufacturing thereof, including methods of manufacturing Nitricil compounds and other nitric oxide-based therapeutics.

Sublicense of UNC and other third party intellectual property to KNOW Bio. The Company and KNOW Bio also entered into sublicense agreements dated December 29, 2015 (the "KNOW Bio Sublicense Agreements" and together with the KNOW Bio License Agreement, the "Original KNOW Bio Agreements"). Pursuant to the terms of the KNOW Bio Sublicense Agreements, the Company granted to KNOW Bio exclusive sublicenses, with the ability to further sublicense, under certain of the United States and foreign patents and patent applications exclusively licensed to the Company from UNC under the UNC License Agreement, and another third party directed towards nitric oxide-releasing compositions, to develop and commercialize products utilizing the licensed technology. Under the exclusive sublicense to the UNC patents and applications (the "UNC Sublicense Agreement"), KNOW Bio is subject to the terms and conditions under the UNC License Agreement, including milestone and diligence payment obligations. However, pursuant to the terms of the UNC License Agreement, the Company is directly obligated to pay UNC any future milestones or royalties, including those resulting from actions conducted by the Company's sublicensees, including KNOW Bio. Therefore, in the event of KNOW Bio non-performance with respect to its obligations under the UNC Sublicense Agreement, the Company would be obligated to make such payments to UNC. KNOW

Bio would then become obligated to repay the Company pursuant to the UNC Sublicense Agreement, otherwise KNOW Bio would be in breach of its agreements with the Company and intellectual property rights would revert back to the Company. There were no milestone or royalty payments required during the years ended December 31, 2022 and December 31, 2021.

On October 13, 2017, the Company and KNOW Bio entered into certain amendments to the Original KNOW Bio Agreements (the "KNOW Bio Amendments"). Pursuant to the terms of the KNOW Bio Amendments, the Company re-acquired from KNOW Bio exclusive, worldwide rights under certain United States and foreign patents and patent applications controlled by the Company as of December 29, 2015, and that became controlled by the Company between December 29, 2015 and December 29, 2018, directed towards nitric oxide-releasing compositions and methods of manufacturing thereof, including methods of manufacturing Nitricil compounds, and other nitric oxide-based therapeutics, to develop and commercialize products for all diagnostic, therapeutic, prophylactic and palliative uses for any disease, condition or disorder caused by certain oncoviruses (the "Oncovirus Field").

KNOW Bio also granted to the Company an exclusive license, with the right to sublicense, under any patents and patent applications which became controlled by KNOW Bio during the three-year period between December 29, 2015 and December 29, 2018 and directed towards nitric oxide-releasing compositions and methods of manufacturing thereof, including methods of manufacturing Nitricil compounds, and other nitric oxide-based therapeutics, but not towards medical devices, to develop and commercialize products for use in the Oncovirus Field.

Upon execution of the KNOW Bio Amendments, in exchange for the Oncovirus Field rights, the Company paid KNOW Bio a non-refundable upfront payment of $250. Products the Company develops in the Oncovirus Field based on Nitricil will not be subject to any further milestones, royalties or sublicensing payment obligations to KNOW Bio under the KNOW Bio Amendments. However, if the Company develops products in the Oncovirus Field that incorporate a certain nitric oxide-releasing composition specified in the KNOW Bio Amendments and (i) are covered by KNOW Bio patents or (ii) materially use or incorporate know-how of KNOW Bio or the Company related to such composition that was created between December 29, 2015 and December 29, 2018, the Company would be obligated to make the certain contingent milestone and royalty payments to KNOW Bio under the KNOW Bio Amendments.

The rights granted to the Company in the Oncovirus Field in the KNOW Bio Amendments continue for so long as there is a valid patent claim under the Original KNOW Bio Agreements, and upon expiration continue on a perpetual non-exclusive basis, and are subject to the termination rights of KNOW Bio and the Company that are set forth in the Original KNOW Bio Agreements. In addition, under the KNOW Bio Amendments, KNOW Bio may terminate the rights granted to the Company in the Oncovirus Field without terminating the Original KNOW Bio Agreements.

The KNOW Bio Amendments also provide a mechanism whereby either party may cause a NCE covered by the Original KNOW Bio Agreements to become exclusive to such party by filing an investigational new drug application ("IND") on the NCE. An NCE that becomes exclusive to a party under this provision may not be commercialized by the other party until the later of expiration of patents covering the NCE or regulatory exclusivity covering the NCE. A party who obtains exclusivity for an NCE must advance development of the NCE pursuant to terms of the KNOW Bio Amendments in order to maintain such exclusivity; otherwise, such exclusivity will expire.

See Note 13—"Net Product Revenues" and Note 14—"License and Collaboration Revenues" for additional detail regarding revenue generating license and collaboration agreements, including related accounting treatments.

Note 13: Net Product Revenues

The Company has the following commercial products that generate net product revenues:

Rhofade (oxymetazoline hydrochloride cream, 1%), or Rhofade, is an alpha1A adrenoceptor agonist indicated for the topical treatment of persistent facial erythema associated with rosacea in adults.

Wynzora (calcipotriene and betamethasone dipropionate cream), or Wynzora, is a combination of calcipotriene, a vitamin D analog, and betamethasone dipropionate, a corticosteroid, indicated for the topical treatment of plaque psoriasis in patients 18 years of age or older.

Minolira (biphasic minocycline hydrochloride immediate release/extended release 105 mg and 135 mg tablets), or Minolira, is indicated to treat inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 12 years of age and older.

Cloderm (clocortoline pivalate cream 0.1%), or Cloderm, is indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.

The post-acquisition operating results of EPI Health are reflected within the Company's consolidated statement of operations and comprehensive loss for the year ended December 31, 2022, specifically from March 11, 2022 through December 31, 2022.

Net product revenues are summarized as follows:

	Year Ended December 31, 2022	
	Total Net Product Revenues	Percentage of Net Product Revenues
Rhofade	$ 11,488	72.7 %
Wynzora	1,640	10.4 %
Minolira	1,572	10.0 %
Cloderm	505	3.2 %
Other	591	3.7 %
Net product revenues	$ 15,796	100.0 %

For the period March 11, 2022 through December 31, 2022, the Company recorded adjustments for certain commercial products for accruals that were assumed as of the EPI Health Acquisition date within the Other category in the table above.

For the year ended December 31, 2022, one of the Company's wholesaler customers accounted for more than 10% of its total gross product revenues, at 12%.

For the year ended December 31, 2022, the Company recorded $3,995 of expense related to royalties on net sales for its commercial product portfolio, including Wynzora residual net sales royalty payments due to the collaboration partner.

MC2 Agreement

The Company assessed the MC2 Agreement and determined it is a collaboration arrangement within the scope of ASC 808. Per the MC2 agreement, the Company proposes a commercialization plan and incremental cost budget annually, which is developed in consultation with and subject to the approval of MC2. The Company is required to use commercially reasonable efforts to perform its commercialization activities in accordance with the commercialization plan.

The Company and MC2 work collaboratively in promoting and commercializing Wynzora by performing their respective promotional and commercialization responsibilities, as established within the MC2 Agreement. Pursuant to the MC2 Agreement, MC2 is responsible for leading the overall strategy of messaging for the promotional materials for Wynzora and the Company is responsible for generating such promotional materials and executing all field promotional and sales activities via the Company's existing commercial sales force. MC2 is responsible for the manufacturing of Wynzora via a third-party contract manufacturer, and subject to MC2's obligation to supply product under the supply terms, the Company purchases product inventory from MC2 (and its third-party contract manufacturer) by periodically placing firm purchase orders and then taking title, physical possession and control of the product inventory. The Company then fulfills orders and distributes Wynzora to the Company's wholesale, distributor and other pharmacy customers. The parties share regulatory responsibilities, and except for the regulatory responsibilities assigned to the Company under the terms of the MC2 Agreement, MC2 is responsible for maintaining the NDA for Wynzora and all remaining regulatory activities. The MC2 Agreement also establishes a joint steering committee, which monitors and oversees the development, promotion, commercialization, and manufacturing of Wynzora, coordinates the collaborative activities of the parties and resolves disputes.

MC2 pays advance payments to the Company on a quarterly basis, prior to the beginning of each calendar quarter, for incremental costs expected to be incurred by the Company during such calendar quarter for the promotion and commercialization of Wynzora, including (i) promotional campaigns and related services performed by third parties, (ii) a portion of the Company's personnel and commercial operating costs, and (iii) the supply price of Wynzora product inventory. The Company records an accrued deposit liability within accrued expenses on its balance sheets upon receipt of an advance payment for promotional and commercialization services not yet performed or incurred by the Company. As such services are performed and qualifying incremental expenses are incurred, the Company recognizes a contra-expense pursuant to the Company's accounting policy described in Note 1—"Organization and Significant Accounting Policies".

During the year ended December 31, 2022, the Company recognized contra-expenses of $8,284 under this agreement. The accrued deposit liability related to the receipt of advance payments from MC2 for future incremental costs was $1,149 as of December 31, 2022, which is presented within accrued expenses in the accompanying consolidated balance sheets.

The Company also identified the wholesalers, distributors and other pharmacies (collectively referred to as "End Customers") who purchase Wynzora from the Company to be customers pursuant to ASC 606. When more than one party is involved in providing goods or services to the End Customer, ASC 606 requires an entity to determine whether it is a principal or an agent in such transactions by evaluating the nature of its promise to the End Customer. Control of the specified good or service prior to transfer of control to the customer is the determining factor when assessing whether an entity is a principal or an agent. The Company determined it is a principal in this arrangement because it takes title and physical possession of the Wynzora product

inventory, at which point it can direct the inventory to any End Customer that submits an enforceable purchase order issued under an active, stand-alone agreement between the Company and the End Customer.

With respect to its performance obligations to the End Customers and associated revenue recognition, the Company recognizes all Wynzora revenues pursuant to its accounting policies for net product revenues as described further in Note 1 —"Organization and Significant Accounting Policies".

Note 14: License and Collaboration Revenues

The Company has license and collaboration revenues summarized as follows:

	Year Ended December 31, 2022	
	Total License and Collaboration Revenues	Percentage of License and Collaboration Revenues
Sato Agreement - SB206 and SB204	$ 2,586	33.1 %
Sato Rhofade Agreement	5,000	64.0 %
Prasco Agreement - Cloderm AG	227	2.9 %
License and collaboration revenues	$ 7,813	100.0 %

The post-acquisition operating results of EPI Health are reflected within the Company's consolidated statement of operations for the year ended December 31, 2022, specifically from March 11, 2022 through December 31, 2022. For the year ended December 31, 2021, all license and collaboration revenues related to the Sato Agreement (related to SB206 and SB204).

For the year ended December 31, 2022, the Company recorded $1,407 of expense related to milestones, including cumulative sales-based milestones and amounts related to the receipt of certain upfront payments.

Sato Agreement - SB206 and SB204

On January 12, 2017, the Company entered into a license agreement, and related first amendment, with Sato Pharmaceutical Co., Ltd. ("Sato"), relating to SB204, its drug candidate for the treatment of acne vulgaris in Japan (the "Sato Agreement"). Pursuant to the Sato Agreement, the Company granted to Sato an exclusive, royalty-bearing, non-transferable right and license under certain of the Company's intellectual property rights, with the right to sublicense with the Company's prior written consent, to develop, use and sell products in Japan that incorporate SB204 in certain topical dosage forms for the treatment of acne vulgaris, and to make the finished form of such products.

On October 5, 2018, the Company and Sato entered into the second amendment (the "Sato Amendment") to the Sato Agreement (collectively, the "Amended Sato Agreement"). The Sato Amendment expanded the Sato Agreement to include SB206, the Company's drug candidate for the treatment of viral skin infections. Pursuant to the Amended Sato Agreement, the Company granted to Sato an exclusive, royalty-bearing, non-transferable license under certain of its intellectual property rights, with the right to sublicense with the Company's prior written consent, to develop, use and sell products in Japan that incorporate SB204 or SB206 in certain topical dosage forms for the treatment of acne vulgaris or viral skin infections, respectively, and to make the finished form of such products. The Company or its designated contract manufacturer will supply finished product to Sato for use in the development of SB204 and SB206 in the licensed territory. The rights granted to Sato do not include the right to manufacture the API of SB204 or SB206; rather, the parties agreed to negotiate a commercial supply agreement pursuant to which the Company or its designated contract manufacturer would be the exclusive supplier to Sato of the API for the commercial manufacture of licensed products in the licensed territory. Under the terms of the Amended Sato Agreement, the Company also has exclusive rights to certain intellectual property that may be developed by Sato in the future, which the Company could choose to use for its own development and commercialization of SB204 or SB206 outside of Japan.

The term of the Amended Sato Agreement (and the period during which Sato must pay royalties under the amended license agreement) expires on the twentieth anniversary of the first commercial sale of a licensed product in the licensed field in the licensed territory (adjusted from the tenth anniversary of the first commercial sale in the Sato Agreement). The term of the Amended Sato Agreement may be renewed with respect to a licensed product by mutual written agreement of the parties for additional two-year periods following expiration of the initial term. All other material terms of the Sato Agreement remain unchanged by the Sato Amendment.

Sato is responsible for funding the development and commercial costs for the program that are specific to Japan. The Company is obligated to perform certain oversight, review and supporting activities for Sato, including: (i) using commercially reasonable efforts to obtain marketing approval of SB204 and SB206 in the United States; (ii) sharing all future scientific information the Company may obtain during the term of the Amended Sato Agreement pertaining to SB204 and SB206; (iii) performing certain additional preclinical studies if such studies are deemed necessary by the Japanese regulatory authority, up to and not to exceed a total cost of $1,000; and (iv) participating in a joint committee that oversees, reviews and approves Sato's development and commercialization activities under the Amended Sato Agreement. Additionally, the Company has granted Sato the option to use the Company's trademarks in connection with the commercialization of licensed products in the licensed territory for no additional consideration, subject to the Company's approval of such use.

The Amended Sato Agreement may be terminated by (i) Sato without cause upon 120 days' advance written notice to the Company; (ii) either party in the event of the other party's uncured material breach upon 60 days' advance written notice; (iii) force majeure; (iv) either party in the event of the other party's dissolution, liquidation, bankruptcy or insolvency; and (v) the Company immediately upon written notice if Sato challenges the validity, patentability, or enforceability of any of the Company's patents or patent applications licensed to Sato under the Amended Sato Agreement. In the event of a termination, no portion of the upfront fees received from Sato are refundable.

The Company assessed the Sato Agreement in accordance with ASC 606 and concluded that the contract counterparty, Sato, is a customer within the scope of ASC 606. The Company identified the following promises under the Sato Agreement (i) the grant of the intellectual property license to Sato, (ii) the obligation to participate in a joint committee that oversees, reviews, and approves Sato's research and development activities and provides advisory support during Sato's development process, (iii) the obligation to manufacture and supply Sato with all quantities of licensed product required for development activities in Japan, and (iv) the stand-ready obligation to perform any necessary repeat preclinical studies, up to $1,000 in cost. The Company determined that these promises were not individually distinct because Sato can only benefit from these licensed intellectual property rights and services when bundled together; they do not have individual benefit or utility to Sato. As a result, all promises have been combined into a single performance obligation.

The Sato Agreement also provides that the two parties agree to negotiate in good faith the terms of a commercial supply agreement pursuant to which the Company or a third-party manufacturer would be the exclusive supplier to Sato of the API for the commercial manufacture of licensed products in the licensed territory. The Company concluded this obligation to negotiate the terms of a commercial supply agreement does not create (i) a legally enforceable obligation under which the Company may have to perform and supply Sato with API for commercial manufacturing, or (ii) a material right because the incremental commercial supply fee consideration framework in the Sato Agreement is representative of a stand-alone selling price for the supply of API and does not represent a discount. Therefore, this contract provision is not considered to be a promise to deliver goods or services and is not a performance obligation or part of the combined single performance obligation described above.

Sato Amendment

On October 5, 2018, the Company and Sato entered into the second amendment to the Sato Agreement (the "Sato Amendment"). The Sato Amendment expanded the Sato Agreement to include SB206, the Company's drug candidate for the treatment of viral skin infections. The Company assessed the Sato Agreement in accordance with ASC 606 and concluded the contract modification should incorporate the additional goods and services provided for in the Sato Amendment into the existing, partially satisfied single bundled performance obligation that will continue to be delivered to Sato over the remaining development period. The Company determined that this contract modification accounting is appropriate as the additional goods and services conveyed under the Sato Amendment were determined to not be distinct from the single performance obligation, and the additional consideration provided did not reflect the standalone selling price of those additional goods and services. As such, the Company recorded a cumulative adjustment as of the amendment execution date to reflect revenue that would have been recognized cumulatively for the partially completed bundled performance obligation.

The Company concluded that the following consideration would be included in the transaction price as they were (i) received prior to December 31, 2022, or (ii) payable upon specified fixed dates in the future and not contingent upon clinical or regulatory success in Japan:

- The 1.25 billion JPY (approximately $10,813 USD) original upfront payment received on January 19, 2017 following the execution of the Sato Agreement on January 12, 2017.
- A milestone payment of 0.25 billion JPY (approximately $2,162 USD) received during the fourth quarter of 2018 following Sato's initiation of a Phase 1 trial in Japan.
- The Sato Amendment upfront payment of 1.25 billion JPY, payable in installments of 0.25 billion JPY, 0.5 billion JPY and 0.5 billion JPY on October 5, 2018, February 14, 2019 and September 13, 2019, respectively. On October 23, 2018, the Company received the first installment from the Amended Sato Agreement of 0.25 billion JPY (approximately $2,224 USD). On March 14, 2019, the Company received the second installment payment related to

the Amended Sato Agreement of 0.5 billion JPY (approximately $4,460 USD). On November 7, 2019, the Company received the third installment payment related to the Amended Sato Agreement of 0.5 billion JPY (approximately $4,554 USD).

- An aggregate of 1.0 billion JPY in non-contingent milestone payments that become payable upon the earlier occurrence of specified fixed dates in the future or the achievement of specified milestone events. On May 20, 2021, the Company received one such non-contingent milestone payment in the form of a payment of 0.5 billion JPY (approximately $4,572 USD) related to achievement of a time-based developmental milestone. On February 28, 2022, the Company received the remaining time-based milestone payment of 0.5 billion JPY (approximately $4,323 USD).

The Company concluded that the following elements of consideration would not be included in the transaction price as they are contingent upon clinical or regulatory success in Japan:

- Up to an aggregate of 0.5 billion JPY upon the achievement of various development and regulatory milestones.
- Up to an aggregate of 3.9 billion JPY upon the achievement of various commercial milestones.
- A tiered royalty ranging from a mid-single digit to a low-double digit percentage (adjusted from a mid-single digit percentage in the Sato Agreement) of net sales of licensed products in the licensed territory, subject to a reduction in the royalty payments in certain circumstances.

The payment terms contained within the Sato Agreement related to upfront, developmental milestone and sales milestone payments are of a short-term nature and, therefore, do not represent a financing component requiring additional consideration.

The following tables present the Company's contract assets, contract liabilities and deferred revenue balances for the dates indicated.

	Contract Asset	Contract Liability	Net Deferred Revenue
December 31, 2021	$ —	$ 13,251	$ 13,251
December 31, 2022	$ —	$ 10,665	$ 10,665

	Short-term Deferred Revenue	Long-term Deferred Revenue	Net Deferred Revenue
December 31, 2021	$ 2,586	$ 10,665	$ 13,251
December 31, 2022	$ 2,586	$ 8,079	$ 10,665

The Company has recorded the Sato Agreement (both the initial agreement and as amended by the Sato Amendment) transaction price, including the upfront payments received and the unconstrained variable consideration, as deferred revenue.

The change in the net deferred revenue balance during the year ended December 31, 2022 was associated with the recognition of license and collaboration revenue associated with the Company's performance during the period (continued amortization of deferred revenue).

During the year ended December 31, 2022 and December 31, 2021, the Company recognized $2,586 and $2,822, respectively, in license and collaboration revenue under the Sato Agreement. The Company has concluded that the above consideration is probable of not resulting in a significant revenue reversal and therefore included in the transaction price and is allocated to the single performance obligation. No other variable consideration under the Sato Agreement is probable of not resulting in a significant revenue reversal as of December 31, 2022 and therefore, is currently fully constrained and excluded from the transaction price.

The Company evaluated the timing of delivery for its performance obligation and concluded that a time-based input method is most appropriate because Sato is accessing and benefiting from the intellectual property and technology (the predominant items of the combined performance obligation) ratably over the duration of Sato's estimated development period in Japan. Although the Company concluded that the intellectual property is functional rather than symbolic, the services provided under the performance obligation are provided over time. Therefore, the allocated transaction price will be recognized using a time-based input method that results in straight-line recognition over the Company's performance period.

The Company monitors and reassesses the estimated performance period for purposes of revenue recognition during each reporting period. In late July 2021, Sato communicated an updated plan regarding its amended design for its additional Japanese Phase 1 study for SB206. The amended study design included evaluation of potential lower dose strengths, including potential

further refinement in a subsequent dose tolerability study. As part of the communication regarding these Phase 1 studies, Sato also communicated an updated comprehensive timeline for the Japanese SB206 program.

The Company currently estimates a 10-year performance period, completing in the first quarter of 2027, based upon a Sato-prepared SB206 Japanese development program timeline. The SB204 Japanese development plan and program timeline has not been presented by Sato and remains under evaluation by the Company and Sato. Currently, the Company understands that the progression of the Japanese SB204 program could follow the same timeline as the Japanese SB206 program, subject to the nature of the results of Sato's comprehensive asset developmental program, including SB206.

The estimated timeline remains subject to prospective reassessment and adjustment based upon Sato's interaction with the Japanese regulatory authorities and other developmental and timing considerations. The combined SB204 and SB206 development program timeline in Japan is continuously reevaluated by Sato and the Company, and may potentially be further affected by various factors, including (i) the analyses, assessments and decisions made by the joint development committee and the applicable regulatory authorities, which will influence and establish the combined SB204 and SB206 Japan development program plan, (ii) the remaining timeline and progression of the SB206 NDA approval process in the United States, (iii) the API and drug product supply chain progression, including the Company's in-house drug manufacturing capabilities, (iv) the Company's manufacturing technology transfer projects with third-party CMOs, and (v) a drug delivery device technology enhancement project with a technology manufacturing vendor.

If the duration of the combined SB204 and SB206 development program timeline is further affected by the establishment of or subsequent adjustments to, as applicable, the mutually agreed upon SB204 and SB206 development plan in the Japan territory, the Company will adjust its estimated performance period for revenue recognition purposes accordingly, as needed.

In future periods, the Company would lift the variable consideration constraint from each contingent payment if there were no longer a probable likelihood of significant revenue reversal. When the constraint is lifted from a milestone payment, the Company will recognize the incremental transaction price using the same time-based input method that is being used to recognize the revenue, which results in straight-line recognition over the performance period. If the Company's performance is not yet completed at the time that the constraint is lifted, a cumulative catch-up adjustment will be recognized in the period. If no other performance is required by the Company at the time the constraint is lifted, the Company expects to recognize all revenue associated with such milestone payments at the time that the constraint is lifted.

Performance Obligations under the Amended Sato Agreement

The net amount of existing performance obligations under long-term contracts unsatisfied as of December 31, 2022 was $10,665. The Company expects to recognize approximately 24% of the remaining performance obligations as revenue over the next 12 months, and the balance thereafter. The Company applied the practical expedient and does not disclose information about variable consideration related to sales-based or usage-based royalties promised in exchange for a license of intellectual property. This expedient specifically applied to the sales-based milestone payments that are present in the Amended Sato Agreement (3.9 billion JPY), as well as percentage-based royalty payments in the Amended Sato Agreement that are contingent upon future sales.

Sato Rhofade Agreement

In December 2022, the Company entered into a license agreement with Sato in which they were granted an exclusive, royalty-bearing, non-transferable right and license under certain of EPI Health's intellectual property rights to develop, manufacture and market Rhofade (oxymetazoline hydrochloride cream, 1%) for the treatment of rosacea in Japan (the "Sato Rhofade Agreement"). In addition, per the Sato Rhofade Agreement, during a specified time period, Sato has an exclusive option to negotiate the terms under which its license would be expanded to include certain other countries in the Asia-Pacific region.

The Company assessed the Sato Rhofade Agreement in accordance with ASC 606 and concluded that the contract counterparty, Sato, is a customer within the scope of ASC 606. The Company also identified one performance obligation within the Sato Rhofade Agreement, comprised of the delivery of a functional intellectual property license including scientific information, or know-how. The Company assessed certain options provided to Sato within the agreement, including the option to enter into additional licenses for other geographies, but concluded these rights were not material in regards to the determination of the performance obligation that was fixed and determinable as they would involve separate negotiations. Therefore, the contract provisions to provide certain options to Sato is not considered to be a material right and is not a performance obligation or part of the performance obligation described above.

In exchange for the license granted to Sato, Sato agreed to pay the Company the following: (i) an upfront payment of $5,000; and (ii) a milestone payment of $2,500 upon receipt of marketing approval of Rhofade for rosacea in the Japan territory. Sato also agreed to pay tiered royalty payments on net sales of the licensed product ranging over time from a percentage of net sales in the mid-teens to a percentage of net sales in the low single digits. Therefore, the Company concluded that the transaction price was comprised of both fixed and variable consideration. The Company's assessment of variable consideration related to the milestone payment and potential future royalty payments were completely constrained at contract inception.

The Company concluded that the performance obligation related to the recognition of the upfront payment was satisfied at a point in time, in which the license and related know-how were transferred. Therefore, the upfront payment was recognized on the Sato Rhofade Agreement effective date. The milestone will be recognized when marketing approval in Japan is probable. The Company applied the practical expedient related to sales-based or usage-based royalties promised in exchange for a license of intellectual property and will record any royalties as the future sales occur.

In addition, the Company is required to pay 25% of the upfront and milestone payment amounts to a third party under existing contractual obligations related to Rhofade and will also be required to pay a portion of the royalty amounts received under the Sato Rhofade Agreement to third parties, after which the Company will retain net royalties in the low single digits. See Note 9 —"Commitments and Contingencies" for additional detail regarding this obligation.

The initial term of the Sato Rhofade Agreement expires on the fifteenth anniversary of the first marketing approval of the licensed product for rosacea in the Japan territory. The term of the Sato Rhofade Agreement automatically extends for a further period of two years, unless either party gives one year's notice before the end of the initial term.

The Sato Rhofade Agreement may be terminated, among other reasons, (i) by Sato without cause upon 120 days' advance written notice to the Company; (ii) by either party in the event of the other party's uncured material breach upon 60 days' advance written notice; and (iii) by the Company if Sato challenges the validity, patentability or enforceability of any of the Company's patents licensed to Sato under the Sato Rhofade Agreement.

Prasco Agreement - Cloderm AG

In connection with the Cloderm acquisition that is described in Note 9—"Commitments and Contingencies", on September 28, 2018, EPI Health entered into a distribution and supply agreement with Prasco, LLC ("Prasco"), whereby EPI Health has agreed to supply and Prasco has the right to purchase, distribute and sell an authorized generic ("AG") version of the Cloderm product in the United States. Prasco is required to pay EPI Health the supply price for the products, along with an amount equal to net sales of the product, minus an amount for certain fees and expenses of Prasco initially equal to the low double digits of net sales of such product, which is retained by Prasco. The agreement will continue, on a product-by-product basis, for an initial five-year term from the first commercial sale of such product, which will automatically renew for an additional one-year term unless either party elects not to renew. The agreement may be terminated for convenience by EPI Health upon nine months' written notice. Prasco may terminate with respect to a specific product based, among other factors, on a failure by EPI Health to deliver launch quantities. Either party may terminate immediately upon the occurrence of certain regulatory matters or based on a force majeure event.

Note 15: Research and Development Agreements

Royalty and Milestone Payments Purchase Agreement with Reedy Creek Investments LLC

On April 29, 2019, the Company entered into a royalty and milestone payments purchase agreement (the "Reedy Creek Purchase Agreement") with Reedy Creek Investments LLC ("Reedy Creek"), pursuant to which Reedy Creek provided funding to the Company in an amount of $25,000 for the Company to use primarily to pursue the development, regulatory approval and commercialization activities (including through out-license agreements and other third-party arrangements) for SB206, a topical gel with anti-viral properties being developed as a treatment for molluscum, and advancing programmatically such activities with respect to SB204, a once-daily, topical monotherapy being developed for the treatment of acne vulgaris, and SB414, a topical cream-based product candidate being developed for the treatment of atopic dermatitis. If the Company successfully commercializes any such product, following regulatory approval, the Company will be obligated to pay Reedy Creek a low single digit royalty on net sales of such products in the United States, Mexico or Canada.

The Company determined that the Reedy Creek Purchase Agreement is within the scope of ASC 730-20, *Research and Development Arrangements* ("ASC 730-20"), and that there has not been a substantive and genuine transfer of risk related to the Reedy Creek Purchase Agreement. As such, the Company determined that the appropriate accounting treatment under ASC 730-20 was to record the proceeds of $25,000 as cash and cash equivalents, as the Company had the ability to direct the usage of funds, and a long-term liability within its classified balance sheet.

Development Funding and Royalties Agreement with Ligand Pharmaceuticals Incorporated

On May 4, 2019, the Company entered into a development funding and royalties agreement (the "Ligand Funding Agreement") with Ligand Pharmaceuticals Incorporated ("Ligand"), pursuant to which Ligand provided funding to the Company of $12,000, for the Company to use to pursue the development and regulatory approval of SB206, a topical gel with anti-viral properties being developed as a treatment for molluscum.

Pursuant to the Ligand Funding Agreement, the Company will pay Ligand up to $20,000 in milestone payments upon the achievement by the Company of certain regulatory and commercial milestones associated with SB206 or any product that incorporates or uses NVN1000, the API for the Company's clinical stage product candidates, as a treatment for molluscum. In addition to the milestone payments, the Company will pay Ligand tiered royalties ranging from 7% to 10% based on annual aggregate net sales of such products in the United States, Mexico or Canada.

The Company determined that the Ligand transaction is within the scope of ASC 730-20 as it represents an obligation to perform contractual services for the development of SB206 using commercially reasonable efforts. As such, the Company concluded that the appropriate accounting treatment under ASC 730-20 was to record the proceeds of $12,000 as a liability and amortize the liability ratably during each reporting period, based on the Ligand funding as a percentage of the total direct costs incurred by the Company during the reporting period related to the estimated total cost to progress the SB206 program to a regulatory approval in the United States. The ratable Ligand funding is presented within the accompanying consolidated statements of operations and comprehensive loss within research and development expenses associated with the SB206 program.

For the years ended December 31, 2022 and December 31, 2021, the Company recorded $968 and $88, respectively, of contra-research and development expense related to the SB206 developmental program, funded by Ligand. During the year ended December 31, 2021, after the announcement of the B-SIMPLE4 positive top-line results on June 11, 2021, the Company reassessed and identified additional estimated costs necessary to progress the SB206 program to a potential United States regulatory approval. As such, the estimated regulatory costs subject to the Ligand funding increased from prior periods. The Company will continue to monitor and adjust its estimated regulatory costs, through approval, as needed.

Note 16: Stock Based Compensation

2016 Incentive Award Plan

For the years ended December 31, 2022 and December 31, 2021, the Company continued to administer and grant awards under the 2016 Incentive Award Plan, as amended (the "2016 Plan"), the Company's only active equity incentive plan. Certain of the Company's stock options granted under the Company's 2008 Stock Plan (the "2008 Plan"), which was the predecessor to the 2016 Plan and became inactive upon adoption of the 2016 Plan effective September 20, 2016, remain outstanding and exercisable. The 2016 Plan provides for the grant of the following awards: (i) incentive stock options, (ii) nonstatutory stock options, (iii) SARs, (iv) restricted stock awards, (v) restricted stock unit awards and (vi) other stock awards. Eligible plan participants include employees, directors, and consultants.

At the Company's Annual Meeting of Stockholders held on May 4, 2021, the Company's stockholders approved an amendment to the 2016 Plan (the "2016 Plan Amendment"), to increase the aggregate number of shares of the Company's common stock authorized for issuance thereunder by 1,500,000 shares. This amendment was approved by the Company's board of directors on March 10, 2021. The approval by the Company's stockholders of the 2016 Plan Amendment was contingent upon the occurrence of certain other events, including that the 2016 Plan Amendment would become effective at the effective time of a certificate of amendment to the Company's certificate of incorporation filed with the Secretary of State of the State of Delaware in relation to a potential reverse stock split pursuant to the authority previously granted to the Company's board of directors by the Company's stockholders at the 2020 Annual Meeting. The Certificate of Amendment filed in connection with the Reverse Stock Split became effective at 5:00pm on May 25, 2021, and thus, the 2016 Plan Amendment became effective on May 25, 2021. As of December 31, 2022, there were 241,801 shares available for future issuance under the 2016 Plan.

Under both the 2008 Plan and the 2016 Plan, options to purchase the Company's common stock may be granted at a price no less than the fair value of a common stock share on the date of grant. The Black-Scholes option-pricing model uses the common stock fair value based on the closing sales price for a share as quoted on any established securities exchange for such grant date or the last preceding date for which such quotation exists. Vesting terms of options issued are determined by the board of directors or compensation committee of the board. The Company's stock options vest based on terms in the stock option agreements and have a maximum term of ten years.

Restricted Stock Units

The Company accounts for restricted stock units ("RSUs") based on their estimated fair values on the date of grant. The fair value of RSUs is estimated based on the closing price of the underlying common stock on the date of grant. Stock-based compensation expense related to the RSUs is recognized on a straight-line basis over the requisite service period, net of estimated forfeitures.

The terms of the RSUs, including the vesting provisions, are determined by the board of directors. Each RSU represents the contingent right to receive one share of common stock of the Company. The RSUs granted typically cliff vest after a one-year period for grants to directors and a two-year period for grants to employees, provided that the grantee remains a director, employee or consultant of the Company as of such vesting date.

For the year ended December 31, 2022, 263,000 and 216,606 RSUs were granted to employees and directors, respectively. There were no RSU grants for the year ended December 31, 2021.

Stock Appreciation Rights

The Company has occasionally used stock appreciation rights ("SARs") as a component of executive compensation. As of December 17, 2019, the Company entered into an amended and restated employment agreement with Paula Brown Stafford which provided for a grant of 60,000 SARs with an exercise price of $8.20 per share (the fair market value of the Company's common stock on the grant date) and with a ten-year term. These SAR awards were vested in full as of December 31, 2021. As of December 31, 2022, there were a total of 60,000 SARs outstanding, which were fully exercisable.

Tangible Stockholder Return Plan

On August 2, 2018, the Company's board of directors approved and established the Tangible Stockholder Return Plan, which was a performance-based long-term incentive plan (the "Performance Plan"). The Performance Plan was effective immediately upon approval and expired on March 1, 2022. The Performance Plan covered all employees, including the Company's executive officers, consultants and other persons deemed eligible by the Company's compensation committee. The core underlying metric of the Performance Plan was the potential achievement of two share price goals for the Company's common stock, which, if achieved, could have represented measurable increases in stockholder value.

The Performance Plan expired on March 1, 2022. As the Company's stock price did not reach the minimum share price targets necessary to trigger a payment, no payments were made under the Performance Plan to any participants during the period the Performance Plan was effective.

Inducement Grants

In prior years, the Company awarded nonstatutory stock options to purchase shares of common stock to newly-hired employees as inducements material to the individuals' entering into employment with the Company within the meaning of Nasdaq Listing Rule 5635(c)(4) (the "Inducement Grants"). The Inducement Grants were awarded outside of the Company's 2016 Plan, pursuant to Nasdaq Listing Rule 5635(c)(4), but have terms and conditions generally consistent with the Company's 2016 Plan and vest over three years, subject to the employee's continued service as an employee or consultant through the vesting period. As of December 31, 2022, there were a total of 1,250 Inducement Grants outstanding.

Stock Compensation Expense

During the years ended December 31, 2022 and December 31, 2021, the Company recorded employee stock-based compensation expense, including fair value adjustments of the Tangible Stockholder Return Plan, as follows:

	Year Ended December 31,	
	2022	2021
Stock options	$ 1,333	$ 826
Restricted stock units	547	—
Stock appreciation rights	—	115
Tangible Stockholder Return Plan	—	(666)
Total	$ 1,880	$ 275

Total stock-based compensation expense for the years ended December 31, 2022 and December 31, 2021 included in the accompanying consolidated statements of operations and comprehensive loss is as follows:

	Year Ended December 31,	
	2022	2021
Research and development	$ 449	$ (250)
General and administrative	1,431	525
Total	$ 1,880	$ 275

The fair value of each option grant is estimated on the grant date using the Black-Scholes option-pricing model, and the following weighted average assumptions:

	Year Ended December 31,	
	2022	2021
Estimated dividend yield	— %	— %
Expected volatility	110.97 %	107.54 %
Risk-free interest rate	2.59 %	1.02 %
Expected life of options (in years)	5.95	5.79
Weighted-average fair value per share	$ 2.72	$ 7.13

The Company estimates forfeitures based on various classes of option grantees and the rates used ranged from 12.2% to 11.9% during the years ended December 31, 2022 and December 31, 2021, respectively.

Stock compensation activity for the periods indicated is as follows:

	Shares Available for Grant	Shares Subject to Outstanding Options	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Options outstanding as of December 31, 2020	52,378	199,199	$ 30.71		
Additional shares reserved under plan	1,500,000	—			
SARs forfeited	1,000	—			
Options granted	(385,885)	385,885	8.82		
Options forfeited	45,731	(53,689)	26.72		
Options exercised	—	(12,842)	4.74		
Options outstanding as of December 31, 2021	1,213,224	518,553	$ 15.48		
RSUs granted	(479,606)	—			
RSUs forfeited	22,200	—			
Options granted	(543,300)	543,300	3.25		
Options forfeited	29,283	(29,283)	4.92		
Options outstanding as of December 31, 2022	241,801	1,032,570	$ 9.34	8.47	$ —
Vested and expected to vest as of December 31, 2021		470,773	$ 16.24	8.67	$ 2
Exercisable as of December 31, 2021		200,638	$ 26.59	7.46	$ 2
Vested and expected to vest as of December 31, 2022		943,355	$ 9.82	8.42	$ —
Exercisable as of December 31, 2022		352,915	$ 18.70	7.38	$ —

The total intrinsic value of options exercised during the years ended December 31, 2022 and December 31, 2021 was zero and $3, respectively. As of December 31, 2022 and December 31, 2021, total unrecognized compensation expense related to non-vested stock options was $1,912 and $1,852, respectively, which is expected to be recognized over a weighted average period of 1.91 and 2.26 years, respectively.

RSU activity for the year ended December 31, 2022 is as follows:

	Shares Subject to Outstanding RSUs	Weighted-Average Grant Date Fair Value
Nonvested RSUs outstanding as of December 31, 2021	—	$ —
RSUs granted	479,606	2.87
RSUs forfeited	(22,200)	2.98
RSUs vested	—	—
Nonvested RSUs outstanding as of December 31, 2022	457,406	$ 2.86

As of December 31, 2022, total unrecognized compensation expense related to non-vested RSUs was $762, which is expected to be recognized over a weighted average period of 0.96 years.

As of December 31, 2022, there were a total of 1,032,570 stock options, 457,406 RSUs and 60,000 SARs outstanding; and there were 241,801 shares available for future issuance under the 2016 Plan.

Note 17: Income Taxes

There was no income tax benefit recognized for the years ended December 31, 2022 and December 31, 2021 due to the Company's history of net losses combined with an inability to confirm recovery of the tax benefits from the Company's losses and other net deferred tax assets. The Company has established a valuation allowance against its deferred tax assets due to the uncertainty surrounding the realization of such assets.

Net operating loss ("NOL") and tax credit carryforwards are subject to review and possible adjustment by the Internal Revenue Service and state tax authorities. NOL and tax credit carry forwards may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant stockholders over a three-year period in excess of 50%, as defined under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or "the Code," as well as similar state tax provisions. The amount of the annual limitation, if any, will be determined based on the value of the company immediately prior to an ownership change. Subsequent ownership changes may further affect the utilization in future years. Additionally, U.S. tax laws limit the time during which certain of these carry forwards may be applied against future taxable income (in the case of NOL carryforwards) and tax liabilities (in the case of tax credits). Therefore, the Company may not be able to take full advantage of these carry forwards for federal or state income tax purposes.

During the course of preparing the Company's consolidated financial statements as of and for the year ended December 31, 2021, the Company completed an assessment of the available NOL and tax credit carryforwards under Sections 382 and 383, respectively, of the Code. The Company determined that it underwent multiple ownership changes throughout its history as defined under Section 382, including most recently in 2015 and 2020. As a result of the identified ownership changes, the portion of NOL and tax credit carryforwards attributable to the pre-ownership change periods are subject to a substantial annual limitation under Sections 382 and 383 of the Code. The Company adjusted its NOL and tax credit carryforwards to address the impact of the Section 382 ownership changes, resulting in a reduction of available federal and state NOLs of $113.8 million and $149.4 million, respectively. The Company has not experienced another cumulative ownership change since 2020.

The reasons for the difference between actual income tax benefit for the years ended December 31, 2022 and December 31, 2021, and the amount computed by applying the statutory federal income tax rate to losses before income tax benefit are as follows:

	Year Ended December 31,	
	2022	2021
Income tax benefit at federal statutory rate	$ (6,569)	$ (6,235)
State income taxes, net of federal benefit	(389)	—
Non-deductible expenses	98	63
Research and development tax credits	(775)	(768)
Change in State Tax Rate	(545)	1,532
Other	163	(96)
Change in valuation allowance	8,017	5,504
Total income tax provision	$ —	$ —

In 2021, following the enactment of North Carolina's 2021 Appropriations Act, which included a gradual corporate income tax rate decrease to 0% by 2030, the Company reduced all of its North Carolina deferred tax assets, including the NOLs, to zero, as no benefit is expected to be realized from these deferred tax assets prior to 2030 when there would be no income tax in North Carolina. With the acquisition of EPI Health, the Company now has nexus in states other than North Carolina, and has revalued its deferred tax assets and the corresponding valuation allowance accordingly.

Deferred income taxes reflect the net tax effects of 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 deferred tax assets and deferred tax liabilities are as follows:

	As of December 31,	
	2022	2021
Deferred tax assets:		
Accrued compensation	$ 28	$ 247
Accrued liabilities	2,332	117
Tax loss carryforwards	22,041	21,008
Intangible assets	7	213
Stock-based compensation	778	499
Tax credits	2,427	1,653
Research and development service obligation	5,701	5,575
Right-of-use lease liabilities	867	736
Deferred revenue	2,377	1,849
Capitalized research expenses	3,454	—
Fixed assets	—	305
Other	280	50
Total deferred tax assets	40,292	32,252
Less valuation allowance	(39,823)	(31,808)
Net deferred tax asset	469	444
Deferred tax liabilities:		
Fixed assets	(18)	—
Right-of-use lease assets	(389)	(356)
Other	(62)	(88)
Net noncurrent deferred tax asset (liability)	$ —	$ —

As of December 31, 2022, the Company had federal and state NOL carryforwards of $104,745 and $65,061, respectively. The NOLs begin to expire in 2029 and 2024 for federal and state tax purposes, respectively. As of December 31, 2022, the Company had government research and development tax credits of approximately $2,427 to offset future federal taxes which begin to expire in 2041.

The Company had no unrecognized tax benefits as of December 31, 2022 and December 31, 2021. The Company does not anticipate a significant change in total unrecognized tax benefits within the next 12 months. Tax years 2019-2021 remain open to examination by the major taxing jurisdictions to which the Company is subject. Additionally, years prior to 2019 are also open to examination to the extent of loss and credit carryforwards from those years.

Note 18: Retirement Plan

The Company maintains a defined contribution savings plan under Section 401(k) of the Internal Revenue Code. This plan covers all employees who meet minimum age requirements and allows participants to defer a portion of their annual compensation on a pre-tax basis. The Company has made discretionary matching contributions up to 5% of gross wages during 2022 and 2021. The Company contributed $524 and $258 for the years ended December 31, 2022 and December 31, 2021, respectively.

Note 19: Fair Value

The Company has contingent consideration associated with the EPI Health Acquisition that is required to be measured at fair value on a recurring basis, presented within the consolidated balance sheets as both current and long-term liabilities, beginning as of March 11, 2022.

For assets and liabilities recorded at fair value, it is the Company's policy to maximize the use of observable inputs and minimize the use of unobservable inputs when developing fair value measurements, in accordance with the fair value hierarchy. Fair value measurements for assets and liabilities where there exists limited or no observable market data and therefore, are based primarily upon estimates, are often calculated based on the economic and competitive environment, the characteristics of the asset or liability and other factors. Therefore, the results cannot be determined with precision and may not be realized in an actual sale or immediate settlement of the asset or liability. Additionally, there may be inherent uncertainties in any calculation technique, and changes in the underlying assumptions used, including discount rates and estimates of future cash flows, could significantly affect the results of current or future values. The Company utilizes fair value measurements to record fair value adjustments to certain assets and liabilities and to determine fair value disclosures.

The Company's contingent consideration liability is measured on a recurring basis using level 3 inputs.

The following table summarizes the change in fair value, as determined by Level 3 inputs for the contingent consideration liabilities for the year ended December 31, 2022:

Balance at March 31, 2022	$	3,773
Change in fair value		(454)
Balance at June 30, 2022	$	3,319
Change in fair value		186
Measurement period adjustment (see Note 2)		(125)
Balance at September 30, 2022	$	3,380
Change in fair value		(892)
Balance at December 31, 2022	$	2,488
Contingent consideration liability, current portion	$	451
Contingent consideration liability, net of current portion		2,037
Balance at December 31, 2022	$	2,488

The following tables present the significant inputs and valuation methodologies used for the Company's fair value of the contingent consideration liabilities as of March 11, 2022, in addition to EPI Health's forecasted net sales from the EPI Health legacy products:

	Transition Services Agreement	Sitavig Milestone (Regulatory)
Valuation methodology	Probability-Weighted	Probability-Weighted
Term	0.81	1.89
Payment term	1.05	2.14
Adjusted discount rate	12.11 %	13.15 %

	First Sales Based Legacy Milestone	Wynzora Milestone	Second Sales Based Legacy Milestone	Sitavig Milestone (Commercial)
Valuation methodology	Monte Carlo	Monte Carlo	Monte Carlo	Monte Carlo
Risk-adjusted discount rates (minimum)	5.39%	5.39%	5.39%	6.89%
Risk-adjusted discount rates (maximum)	6.99%	6.23%	6.99%	7.15%
Net sales volatility (per annum)	13.0%	12.0%	13.0%	13.0%
Credit spread (continuous)	10.42%	10.55%	10.42%	11.13%

The following tables present the significant inputs and valuation methodologies used for the Company's fair value of the contingent consideration liabilities as of December 31, 2022, in addition to EPI Health's forecasted net sales from the EPI Health legacy products:

	Transition Services Agreement	Sitavig Milestone (Regulatory)
Valuation methodology	Probability-Weighted	Probability-Weighted
Term	0.2	3.25
Payment term	0.44	3.5
Adjusted discount rate	19.17 %	19.50 %

	First Sales Based Legacy Milestone	Wynzora Milestone	Second Sales Based Legacy Milestone	Sitavig Milestone (Commercial)
Valuation methodology	Monte Carlo	Monte Carlo	Monte Carlo	Monte Carlo
Risk-adjusted discount rates (minimum)	8.90%	8.90%	8.90%	8.70%
Risk-adjusted discount rates (maximum)	9.53%	8.97%	9.53%	8.90%
Net sales volatility (per annum)	13.0%	12.0%	13.0%	13.0%
Credit spread (continuous)	14.82%	14.01%	14.82%	15.57%

For the year ended December 31, 2022, there was a $1,160 change in fair value related to contingent consideration related to the EPI Health Acquisition recorded in the accompanying consolidated statements of operations and comprehensive loss related primarily to changes in market assumptions, management forecasts and discount rates since the transaction date.

Significant increases or decreases in any of the probabilities of success or changes in expected achievement of any of the milestones underlying the contingent consideration would result in a significantly higher or lower fair value of the contingent consideration liability. The contingent consideration is revalued at each reporting period and changes in fair value are recognized in the consolidated statements of operations and comprehensive loss until settlement.

The following table presents information about the classification and potential earnout periods for the Company's contingent consideration liabilities as of December 31, 2022:

	Fair Value	Classification	Earnout Period
Transition Services Agreement	$ 451	Current portion	11-Mar-2022 to 11-Mar-2023
First Sales Based Legacy Milestone	—	Current portion	1-Apr-2022 to 31-Mar-2023
Wynzora Milestone	—	Current portion	1-Apr-2022 to 31-Mar-2023
Second Sales Based Legacy Milestone	620	Non-current portion	1-Apr-2023 to 31-Mar-2026
Sitavig Milestones	1,417	Non-current portion	1-Apr-2026 to 1-Oct-2036
	$ 2,488		

See Note 2—"Acquisition of EPI Health" for additional detail regarding contingent consideration related to the transaction.

Note 20: Segment Information

The Company has determined that it operates in two segments, which represent (i) the promotion of commercial products for the treatment of medical dermatological conditions (the "Commercial Operations" segment), and (ii) research and development activities related to the Company's nitric oxide-based technology to develop product candidates (the "Research and Development Operations" segment).

- The Commercial Operations segment consists of the Company's portfolio of commercial products.
- The Research and Development Operations segment consists of multiple drug product candidates under clinical development.

Costs associated with the development of SB206 are currently included in the Research and Development Operations segment. There are no significant inter-segment sales. The Company evaluates the financial performance of each segment based on operating profit or loss. There is no inter-segment allocation of non-operating expenses and income taxes. The Company's chief operating decision-maker ("CODM") is the Company's Chairman, President and Chief Executive Officer.

Segment revenue, net and comprehensive loss and total assets were as follows:

	Twelve Months Ended December 31, 2022	Twelve Months Ended December 31, 2021
Revenue		
Commercial operations	$ 21,023	$ —
Research and Development operations	2,659	2,958
Total revenue	$ 23,682	$ 2,958
Net loss		
Commercial operations	$ (1,776)	$ —
Research and Development operations	(29,535)	(29,692)
Net loss and comprehensive loss	$ (31,311)	$ (29,692)

	As of December 31, 2022
Assets	
Commercial operations	$ 63,564
Research and Development operations	26,766
Total assets	$ 90,330

The net revenues attributed to the Commercial Operations segment are primarily derived from the sale of the Company's commercial products and licensing agreements of those commercial products, such as the Sato Rhofade Agreement, and the net revenues attributed to the Research and Development Operations segment are primarily derived from the arrangement with the Company's licensing partner in Japan for SB206 and SB204. Drug development and potential commercialization costs are included in the Research and Development Operations segment. Total assets by reporting segment are not reviewed by the CODM when evaluating the reporting segments' performance, however, the Commercial Operations segment includes the acquired assets associated with the EPI Health Acquisition and changes in such assets, while the Research and Development Operations segment is comprised of the assets associated with the historical business of the Company related to the Company's product candidates that are in development.

Substantially all revenue was derived from product sales or from licensing agreements originating in the United States. All of the Company's long-lived assets are maintained in the United States.

Although all of the Company's operations are based in, and all net product revenue is generated from, sales in the United States, the revenue generated from its licensing partner in Japan was $7,586, or 32% of total revenue, during the year ended December 31, 2022, of which $5,000 was attributed to the Commercial Operations segment and $2,586 was attributed to the Research and Development Operations segment. During the year ended December 31, 2021, the Company generated revenue from its licensing partner in Japan of $2,822, or 95% of total revenue. Prior to the quarter ended March 31, 2022, the Company operated in only one segment, which was the Research and Development Operations segment.

Note 21: Subsequent Events

March 2023 Registered Direct Offering

On March 13, 2023, the Company entered into a securities purchase agreement with an institutional investor pursuant to which the Company agreed to issue and sell to the purchaser, in a registered direct offering, an aggregate of (i) 5,042,017 shares of its common stock (or pre-funded warrants to purchase common stock in lieu thereof) and (ii) warrants to purchase up to 5,042,017 shares of common stock, at an effective combined purchase price of $1.19 per share (or pre-funded warrant) and associated common warrant. The offering closed on March 16, 2023.

The gross proceeds to the Company from the offering were approximately $6,000, before deducting placement agent fees and offering expenses, and excluding the exercise of any warrants. The Company estimates that its net proceeds from its issuance and sale of shares, pre-funded warrants and common warrants will be approximately $5,400.

In connection with the offering, the Company and the purchaser agreed to amend the June 2022 Common Warrants to reduce the exercise price thereof from $2.851 to $1.20 per share of common stock, to delay the exercisability of the June 2022 Common Warrant until six months after the closing of the March 2023 Registered Direct Offering, and to extend the exercise period of the June 2022 Common Warrant until December 13, 2027. No other changes to the June 2022 Common Warrants

were made. Outstanding common stock warrants, including pre-funded warrants, totaled 12,869,671 after the March 2023 Registered Direct Offering with a weighted-average exercise price of $1.03.

March 2022 Equity Distribution Agreement – At-the-Market Facility

Subsequent to December 31, 2022, the Company sold 543,063 shares of its common stock at an average price of approximately $1.64 per share for total net proceeds of $865 under the Equity Distribution Agreement.

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

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, refers to controls and procedures that are designed to ensure that 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. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that such information is accumulated and communicated to a company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure.

In designing and evaluating our disclosure controls and procedures, management recognizes that disclosure controls and procedures, no matter how well conceived and operated, cannot provide absolute assurance that the objectives of the disclosure controls and procedures are met. Additionally, in designing disclosure controls and procedures, our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures. Our disclosure controls and procedures are designed to provide reasonable assurance of achieving their objectives. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a control system, misstatements due to error or fraud may occur and not be detected.

We closed the EPI Health Acquisition on March 11, 2022, and EPI Health's total assets and revenues constituted 70.4% and 88.8%, respectively, of our consolidated total assets (including intangible assets, net) and revenues as shown on our consolidated financial statements as of and for the year ended December 31, 2022. As the EPI Health Acquisition occurred in the first quarter of fiscal 2022, we excluded the internal control over financial reporting of EPI Health from the scope of our assessment of the effectiveness of our disclosure controls and procedures as of December 31, 2022. This exclusion is in accordance with the general guidance issued by the Staff of the Securities and Exchange Commission that an assessment of a recently-acquired business may be omitted from our scope in the year of acquisition, if specified conditions are satisfied.

As of December 31, 2022, our management, with the participation of our principal executive and financial officers, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based upon such evaluation, our principal executive and financial officers have concluded that, as of December 31, 2022, our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in the Exchange Act Rule 13a-15(f). Our internal control over financial reporting is designed to provide reasonable assurance to our management and board of directors regarding the preparation and fair presentation of published financial statements. A control system, no matter how well designed and operated, can only provide reasonable, not absolute, assurance that the objectives of the control system are met. Because of these inherent limitations, management does not expect that our internal controls over financial reporting will prevent all error and all fraud. Management conducted an evaluation of our internal control over financial reporting based on the framework in Internal Control—Integrated Framework issued in 2013 by the Committee of Sponsoring Organizations of the Treadway Commission (the "2013 Framework"). Based on our evaluation under the 2013 Framework, management concluded that our internal control over financial reporting was effective as of December 31, 2022.

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

Changes in Internal Control over Financial Reporting

As noted above, on March 11, 2022, we completed the EPI Health Acquisition. We are in the process of integrating the operations of EPI Health into our overall internal control over financial reporting process.

We have devoted, and plan to continue to devote, significant efforts and resources to our internal control over financial reporting with respect to the complex accounting matters associated with a commercial pharmaceutical business. During the quarter ended December 31, 2022, we have hired additional personnel with technical expertise to assist in accounting for our Commercial Operations segment, in addition to engaging additional external resources to assist the Company.

There have been no other changes in the Company's internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) during the last quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

On March 29, 2023, our board of directors approved an amendment to the Novan, Inc. 2016 Incentive Award Plan, as amended ("2016 Plan"), to increase the number of shares reserved for future issuance under the 2016 Plan and also make changes to withhold payment of dividends and dividend equivalents to those that receive grants under the 2016 Plan until such awards vest in full. Such approval is contingent on stockholder approval of the amendment, which we will seek at our upcoming annual meeting.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Directors

Our board of directors consists of six directors and is divided into three classes with staggered, three-year terms. The terms of office of directors in Class I will expire at our annual meeting of stockholders to be held in 2023, or the 2023 Annual Meeting, and when such director's successor is elected and qualified, or upon such director's death, resignation or removal, and our Class I directors are expected to stand for re-election at the 2023 Annual Meeting. The terms of office of directors in Class II and Class III do not expire until our annual meetings of stockholders to be held in 2024 and 2025, respectively, and until his or her successor is elected and qualified, or until his or her death, resignation or removal.

Information about our directors, their ages as of February 4, 2023, occupations and length of board service are provided in the table below. Additional biographical descriptions are set forth in the text below the tables and include the primary individual experience, qualifications, qualities and skills of each director that led to the conclusion that such director should serve as a member of our board of directors at this time.

Name of Director	Age	Principal Occupation	Director Since
Class I Directors:			
Steven D. Skolsky (1)(3)	66	Principal, Expis Partners	2021
Paula Brown Stafford	58	President and Chief Executive Officer, Novan, Inc.	2017
Class II Directors:			
James L. Bierman (2)(3)	70	Retired President and Chief Executive Officer, Owens & Minor, Inc.	2020
Machelle Sanders (2)(3)	59	Secretary of the N.C. Department of Commerce	2017
Class III Directors:			
W. Kent Geer (1)	68	Managing Director—Finance and Investor Relations, Med1 Ventures, LLC	2015
Robert J. Keegan (1)(2)	75	Retired Chief Executive Officer, Goodyear Tire and Rubber Co.	2016

(1) Member of our audit committee

(2) Member of our compensation committee

(3) Member of our nominating and corporate governance committee

Steven D. Skolsky has served as a member of our board of directors since 2021. Since January 2010, Mr. Skolsky has served as the founding principal of Expis Partners, a strategic consulting firm to the biotech, pharmaceutical, life science and clinical services community, with a focused expertise in commercialization, marketing strategy, drug development, operations, strategic planning and corporate and business development. From September 2011 to December 2016, Mr. Skolsky held senior executive roles at Quintiles Transnational Holdings Inc. (now IQVIA Holdings Inc.), a leading multinational provider of biopharmaceutical development services and commercial outsourcing service, most recently as senior vice president & managing director and previously, senior vice president and head of global clinical operations. Prior to joining Quintiles, from August 2007 to December 2009, he served as the president and chief executive officer of Sequoia Pharmaceuticals, Inc., and from June 2004 to December 2006, he served as the chief executive officer of Trimeris, Inc. Prior to that, Mr. Skolsky served for more than 20 years at GlaxoSmithKline plc where he held a number of positions including senior leadership roles as managing director of GlaxoSmithKline's operations in Australia and New Zealand and senior vice president, global product strategy and clinical development. We believe that Mr. Skolsky's significant experience and leadership in the biotechnology and pharmaceutical industries with a focus on drug development, commercialization and operations qualifies him to serve on our board of directors.

Paula Brown Stafford is our President and Chief Executive Officer and was appointed as Chairman of our board of directors effective July 28, 2020. Mrs. Stafford has served as our President since January 2019. Prior to her appointment as our Chief Executive Officer effective February 2, 2020, Mrs. Stafford served as our Chief Operating Officer from January 2019 to February 2020 after serving as our Chief Development Officer from March 2017 to January 2019. Mrs. Stafford has served as a member of our board of directors since August 2017. Prior to joining Novan, Mrs. Stafford held various roles of increasing importance at Quintiles Transnational Holdings Inc. (now IQVIA Holdings Inc.), a leading multinational provider of biopharmaceutical development services and commercial outsourcing services, since 1985, including serving as president of clinical development from 2010 to 2015, where she was responsible for all Phase I-IV clinical development operations globally

and served on the Quintiles Executive Committee. Mrs. Stafford has served as an adjunct professor in Public Health Leadership at the Gillings School of Global Public Health at the University of North Carolina, Chapel Hill, and operates her own third-party consulting business. In early 2022, Mrs. Stafford joined the board of the Alliance For Multispecialty Research, LLC, a private clinical research company comprised of more than 20 experienced clinical research centers in the U.S. We believe that Mrs. Stafford's extensive experience and leadership in clinical research and pharmaceutical product development, along with her extensive executive experience and her service as our Chief Executive Officer, qualifies her to serve as Chairman of our board of directors.

James L Bierman was appointed to our board of directors in September 2020. Mr. Bierman served as president and chief executive officer and as a member of the board of directors of Owens & Minor, Inc., a Fortune 500 company and a leading distributor of medical and surgical supplies, from September 2014 to June 2015. Previously, he served in various other senior roles at Owens & Minor, including president and chief operating officer from August 2013 to September 2014, executive vice president and chief operating officer from March 2012 to August 2013, executive vice president and chief financial officer from April 2011 to March 2012 and senior vice president and chief financial officer from June 2007 to April 2011. Earlier in his career, Mr. Bierman served as executive vice president and chief financial officer at Quintiles Transnational Corp. (now IQVIA Holdings Inc.). Before joining Quintiles, Mr. Bierman was a partner with Arthur Andersen LLP from 1988 to 1998. Mr. Bierman currently serves on the board of directors of Tenet Healthcare Corporation, a public healthcare services companies listed on the New York Stock Exchange, and MiMedX Group, Inc., a public biomedical company listed on the Nasdaq stock exchange. Mr. Bierman earned his B.A. from Dickinson College and his M.B.A. at Cornell University's Johnson Graduate School of Management. We believe that Mr. Bierman's extensive board and executive experience, particularly in the healthcare and pharmaceutical services industries, as well as his substantial public accounting experience, qualifies him to serve on our board of directors.

Machelle Sanders joined our board of directors in September 2017 and is a seasoned executive with over 30 years of progressive pharmaceutical and biotechnology experience. Ms. Sanders is Secretary of the N.C. Department of Commerce, appointed by Governor Roy Cooper. Prior to her appointment as the Secretary of the N.C. Department of Commerce, Ms. Sanders served as Secretary of the N.C. Department of Administration after being appointed by Governor Cooper in January 2017. In the private sector, Ms. Sanders was most recently responsible for the pharmaceutical operations and technology operational strategy for Biogen's multiple sclerosis franchise (i.e. AVONEXTM, PLEGRIDYTM, TECFIDERATM, and TYSABRITM). She held the title of vice president of manufacturing and general manager of the company's largest and most advanced manufacturing facility in Research Triangle Park, North Carolina. Ms. Sanders has also held leadership positions in manufacturing, global quality assurance and quality control at Biogen, Purdue Pharmaceuticals, a pharmaceutical company, and Diosynth-Akzu Nobel, a company that develops and offers manufacturing processes for active ingredients for pharmaceutical companies. Ms. Sanders currently serves on the board of directors of BioCryst Pharmaceuticals, Inc., a public biopharmaceutical company listed on Nasdaq. She previously served on the Board of Radius Health, Inc. She holds a Bachelor of Science degree in Biochemistry from North Carolina State University and a Master of Health Administration from Pfeiffer University. We believe that Ms. Sanders' broad and extensive knowledge of pharmaceutical manufacturing and quality systems and leadership experience, particularly among early and developing stage companies, qualifies her to serve on our board of directors.

W. Kent Geer has served as a member of our board of directors since 2015 and as our Lead Independent Director since June 2017. Mr. Geer is a retired audit partner with Ernst & Young, LLP. His 37-year career working with public and private companies includes an extensive track record in a variety of industries including biotechnology, pharmaceuticals, and other technology companies. During his tenure, Mr. Geer was the audit practice leader for the Ernst & Young Entrepreneurial Services Group in Raleigh, North Carolina and was the market team leader for the technology industry practice of the Carolinas. Beginning in 2012, Mr. Geer served as the chairman of the board of directors of PowerSecure International, Inc., a NYSE registered company, until the successful sale of the company in May 2016. Mr. Geer is a partner in Med1 Ventures LLC, a medical device incubator and service provider that provides general management, engineering and financial management services to investee companies. During 2022, Mr. Geer became chairman of the board of Utility Innovations Holdings, a privately held company in the utility services industry. We believe that Mr. Geer's significant experience and leadership in public accounting and the biotechnology, pharmaceutical and technology industries qualifies him to serve on our board of directors.

Robert J. Keegan has served as a member of our board of directors since 2016. Mr. Keegan held the roles of chief executive officer and chairman of the board of directors of Goodyear Tire and Rubber Co. from 2003 to 2010. Most recently, he served as the non-executive chairman of the board of directors of Xerox Corporation and was an operating partner of the San Francisco-based private equity firm Friedman, Fleischer & Lowe. From 1972 to 2000, Mr. Keegan held various marketing, financial and managerial posts at Eastman Kodak, except for a two-year period from 1995 to 1997 when he worked as an executive vice president of the Avery Dennison Corporation. Mr. Keegan serves on the board of directors of the Heart Center of Duke University and the Duke Health Board of Visitors. Mr. Keegan is a trustee of the University of Rochester and a partner of L&K

Properties of North Carolina, LLC. We believe that Mr. Keegan's broad business experience, executive leadership expertise and extensive knowledge of financial and operational matters qualifies him to serve on our board of directors.

Executive Officers

Certain information regarding our executive officers is set forth below as of February 4, 2023. Executive officers are appointed by our board of directors to hold office until their successors are duly appointed and qualified, or until their resignation or removal.

Name	Age	Position(s)
Paula Brown Stafford	58	President, Chief Executive Officer and Chairman of the Board of Directors
John M. Gay	46	Chief Financial Officer
John A. Donofrio	55	Chief Operating Officer
Brian M. Johnson	56	Chief Commercial Officer

For information regarding Mrs. Stafford, please refer to "Directors," above.

John M. Gay was appointed as our Chief Financial Officer in September 2020, and also serves as our principal financial officer and Corporate Secretary. He joined Novan in May of 2018 and previously held the position of Senior Director of Finance and Corporate Controller through January 2019, and Vice President, Finance and Corporate Controller from January 2019 until September 2020. Prior to Novan, Mr. Gay held previous director positions, including director of SEC reporting, with Valassis Digital Corp. and MaxPoint Inc., from May 2014 to April 2018. Mr. Gay also served as corporate controller of Furiex Pharmaceuticals, Inc. from June 2010 to May 2014, including from its initial listing on the Nasdaq stock exchange through the execution of an agreement providing for the acquisition of the company by Forest Laboratories, Inc., a subsidiary of Actavis plc, in an all-cash transaction valued at approximately $1.1 billion. Prior to joining Furiex Pharmaceuticals, Inc., Mr. Gay served as audit senior manager and in other roles of increasing responsibilities at Deloitte and Arthur Andersen from September 2000 to May 2010. Mr. Gay is a certified public accountant and holds Bachelor's degrees in Economics and History, and a Master of Accounting degree from the University of North Carolina at Chapel Hill.

John A. Donofrio was appointed as our Executive Vice President and Chief Operating Officer on March 11, 2022, following the EPI Health Acquisition, and Mr. Donofrio also serves as President of EPI Health. Mr. Donofrio served as President and Chief Executive Officer of EPI Health, LLC from March 2019 through the closing date of the EPI Health Acquisition. From March 2018 through March 2019, Mr. Donofrio served as chief financial officer at TrialCard Incorporated, and from August 2013 through March 2018, Mr. Donofrio served as chief financial officer and head of North America business development for Merz North America, Inc. In addition to his executive positions, Mr. Donofrio spent over 20 years with GlaxoSmithKline in various US and international roles of increasing responsibility, including global vice president of finance for the global dermatology business unit, Stiefel, a GSK company. Mr. Donofrio is also a board member, the independent lead director and audit chair for Aytu Bioscience and serves on the board of directors of the Children's Skin Disease Foundation and Alliance Medical Ministries, He holds a Bachelor's degree in Accounting from North Carolina State University.

Brian M. Johnson was appointed as our Chief Commercial Officer effective November 1, 2021. In addition to previously serving as the Chief Commercial Officer at Novan from 2015 to 2018, Mr. Johnson most recently served as a principal at Two Hearts Group, a pharmaceutical and life science consulting firm where he acted as UCB's head, digital marketing, psoriasis in the global mission for bimekizumab. Additionally, Mr. Johnson served as the vice president of prescription marketing and chief digital officer at Galderma, Mr. Johnson has also served as president at Revian, Inc, director, peer to peer marketing at Novartis and positions of increasing seniority at Ortho Pharmaceutical Corporation and Medicis. Mr. Johnson holds an MBA from Southern Methodist University and a BS in Business Administration from the University of Kansas. He is a member of the American Acne and Rosacea Society, Masters of Dermatologic Society, Women's Dermatology Society and the American Academy of Dermatology.

Audit Committee and Audit Committee Financial Experts

Our board of directors has a standing audit committee, which consists of W. Kent Geer, Robert J. Keegan, and Steven D. Skolsky, and included John Palmour prior to his death in November 2022. The chair of our audit committee is W. Kent Geer, who our board of directors has determined is an "audit committee financial expert," as that term is defined by the rules of the SEC implementing Section 407 of the Sarbanes-Oxley Act, and possesses financial sophistication, as defined under the listing standards of the Nasdaq Capital Market. Our board of directors has also determined that each member of our audit committee can read and understand fundamental financial statements in accordance with applicable SEC and Nasdaq requirements. To arrive at these determinations, our board of directors has examined each audit committee member's scope of experience and the nature of his experience in the corporate finance sector.

Code of Business Conduct and Ethics

We have adopted a Code of Business Conduct and Ethics that applies to our directors, officers (including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions) and other employees. Our Code of Business Conduct and Ethics is available on the "Corporate Governance" page of the "Investor Relations" section of our website, which may be accessed by navigating to http://novan.com/investors/, by clicking the link under "Corporate Governance" and then by clicking on "Code of Business Conduct and Ethics" under "Governance Documents." We intend to post on our website and (if required) file on Form 8-K all disclosures that are required by applicable law, the rules of the SEC or the Nasdaq listing standards, concerning any amendment to, or waiver from, our Code of Business Conduct and Ethics. However, the reference to our website does not constitute incorporation by reference of the information contained on or available through our website, and you should not consider it to be a part of this Annual Report.

Delinquent Section 16(a) Reports

Section 16(a) of the Exchange Act requires our executive officers, directors and persons who beneficially own more than 10% of our common stock to file initial reports of ownership and reports of changes in ownership with the SEC. To our knowledge, based solely on a review of the copies of such reports filed electronically on the SEC's website and written representations that no other reports were required during the fiscal year ended December 31, 2022, we believe that all Section 16(a) filing requirements applicable to the executive officers, directors and persons who beneficially own more than 10% of our common stock were complied with in 2022, except for a Form 4 filed late on January 25, 2022 for Mrs. Stafford, to report an option award that became effective on January 3, 2022, a Form 4 filed late on March 18, 2022 for Mr. Donofrio, to report an option award granted on March 11, 2022, and a Form 4 filed late on June 9, 2022 for Mr. Novak, to report a restricted stock unit and option award granted on April 21, 2022.

Item 11. Executive Compensation.

This section discusses the material components of the executive compensation program with respect to the 2022 fiscal year for the individuals who served as our principal executive officer during the year and our other most highly compensated executive officers who were serving as an executive officer as of December 31, 2022. We refer to these persons as our "named executive officers" elsewhere in this Annual Report.

Our named executive officers for the 2022 fiscal year were:

- Paula Brown Stafford, *Chairman, President and Chief Executive Officer*;
- John M. Gay, *Chief Financial Officer and Corporate Secretary*; and
- John A. Donofrio, *Executive Vice President and Chief Operating Officer*

Summary Compensation Table

The following table sets forth information concerning the compensation of our named executive officers for the years ended December 31, 2022 and December 31, 2021.

Name and Principal Position	Fiscal Year	Salary ($)	Bonus ($)	Option Awards ($)(1)	Stock Awards ($)(2)	All Other Compensation ($)(3)	Total ($)
Paula Brown Stafford (4)	2022	$ 604,608	$ —	$ 269,954	$ —	$ 18,617	$ 893,179
President and Chief Executive Officer	2021	598,850	389,253	432,150	—	18,780	1,439,033
John M. Gay (5)	2022	340,913	35,000	101,055	80,282	10,982	568,232
Chief Financial Officer and Corporate Secretary	2021	318,544	146,421	308,049	—	17,300	790,314
John A. Donofrio (6)	2022	317,366	200,000	223,584	—	8,979	749,929
Executive Vice President and Chief Operating Officer	2021	—	—	—	—	—	—

1. Amounts reflect the grant-date fair value of equity-based awards granted to our named executive officers, as applicable, including stock options in 2022 and 2021. Stock option fair values are estimated using the Black Scholes Option Pricing Model in accordance with ASC Topic 718, rather than the amounts paid to or realized by the named individual. For a discussion of the assumptions used to estimate the value of the options made to our named executive officers, see the section entitled "Management's Discussion and Analysis of Financial Condition and Results of

Operations—Critical Accounting Policies and Use of Estimates—Stock-Based Compensation" in this Annual Report, "Note 1—"Organization and Significant Accounting Policies"" and "Note 11—Stock-Based Compensation" to the accompanying consolidated financial statements included in this Annual Report.

2. Amounts reflect the grant-date fair value of equity-based awards granted to our named executive officers, as applicable, including restricted stock units in 2022. Restricted stock unit fair values are based on their estimated fair values on the date of grant based on the closing price of the underlying common stock in accordance with ASC Topic 718. For a discussion of the assumptions used to estimate the value of the restricted stock units made to our named executive officers, see the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Policies and Use of Estimates—Stock-Based Compensation" in this Annual Report, "Note 1—"Organization and Significant Accounting Policies" and "Note 11—Stock-Based Compensation" to the accompanying consolidated financial statements included in this Annual Report.
3. All other compensation includes matching contributions made under our 401(k) plan for 2022 and 2021 and Health Savings Account contributions for 2022 and 2021 for Mrs. Stafford and Mr. Gay, and premiums for executive life insurance for the benefit of Mrs. Stafford in 2022 and 2021.Life insurance premiums payment made for the benefit of Mrs. Stafford were $1,480 in 2022 and 2021.
4. Mrs. Stafford became our Chief Executive Officer effective February 2, 2020, and in connection therewith, Mrs. Stafford entered into an amended and restated employment agreement, as further amended by that first amended dated as of November 9, 2021, or the Stafford Employment Agreement, as described in further detail within the section entitled "Executive Compensation—Arrangements with our Named Executive Officers—Arrangements with Paula Brown Stafford."
5. Mr. Gay was appointed as our Chief Financial Officer effective September 23, 2020, and we entered into a new employment agreement with Mr. Gay, as amended August 11, 2021, or the Gay Employment Agreement, as described in further detail within the section entitled "Executive Compensation—Arrangements with our Named Executive Officers—Arrangements with John M. Gay."
6. Mr. Donofrio was appointed as our Executive Vice President and Chief Operating Officer effective March 11, 2022, and we entered into an employment agreement with Mr. Donofrio, or the Donofrio Employment Agreement, as described in further detail within the section entitled "Executive Compensation—Arrangements with our Named Executive Officers—Arrangements with John A. Donofrio."

Narrative to Summary Compensation Table

Elements of Compensation

During 2022, we compensated our named executive officers through a combination of base salary, cash bonuses, long-term performance-based awards under the Performance Plan and 2016 Incentive Award Plan, or the 2016 Plan, and other perquisites and benefits as described below.

Please see the section entitled "Executive Compensation—Arrangements with our Named Executive Officers" in this Annual Report for further description of each named executive officer's employment agreement.

Annual Base Salaries

The named executive officers receive a base salary to compensate them for services rendered to us. The base salary payable to each named executive officer is intended to provide a fixed component of compensation reflecting the executive's skill set, experience, role(s) and responsibilities. In 2022, our named executive officers were entitled to the following total base salaries:

- Mrs. Stafford was entitled to $604,608 pursuant to the Stafford Employment Agreement;
- Mr. Gay was entitled to $340,913 pursuant to the Gay Employment Agreement; and
- Mr. Donofrio was entitled to $317,366, which reflects the prorated amount of Mr. Donofrio's $400,000 annual base salary for services rendered from March 11, 2022, through December 31, 2022, pursuant to the Donofrio Employment Agreement.

Bonuses

Each named executive officer's employment agreement provided for certain cash bonuses for the year ended December 31, 2022, as described below:

- In 2022, the Stafford Employment Agreement provided Mrs. Stafford with an annual target cash bonus opportunity equal to not less than 55% and up to a maximum of 75% of her base salary, payable based on performance criteria.

Our compensation committee has determined that Mrs. Stafford will not receive a bonus for the year ended December 31, 2022.

- In 2022, the Gay Employment Agreement provided Mr. Gay with an annual target cash bonus opportunity equal to 35% of his base salary, payable based on performance criteria. Our compensation committee has determined that Mr. Gay will not receive a bonus for the year ended December 31, 2022. On March 17, 2022, a $35,000 one-time payment was approved for Mr. Gay in connection with success bonuses paid to employees following the EPI Health Acquisition.
- In 2022, the Donofrio Employment Agreement provided Mr. Donofrio with an annual target cash bonus opportunity equal to not less than 50% and up to a maximum of 75% of his base salary, payable based on performance criteria. In the first year, following the completion of the EPI Health Acquisition, the Donofrio Employment Agreement provides that the bonus will be guaranteed at the target level, and thus will be paid out at $200,000 for the year ended December 31, 2022.

Long-term Performance-based Compensation—2016 Incentive Award Plan

We currently sponsor the 2016 Plan, for purposes of granting stock options, SARs, RSUs and other equity-based instruments to our executive officers, directors and employees.

Initial and promotion option grants to our executive officers are generally set forth in their employment agreements. These initial and promotion grants are the product of negotiation with the executive officer, but we generally seek to establish equity ownership levels that we believe are commensurate with the equity positions held by executive officers serving in similar roles at comparable biopharmaceutical companies. Stock option grants made to our executive officers include (i) time-based vesting awards with vesting provisions ranging from six months to three years and (ii) awards that have also included performance-based vesting conditions.

In 2022, Ms. Stafford received an option to purchase 75,000 shares of common stock, granted in the first quarter of 2022, granted in accordance with the terms of the Stafford Employment Agreement.

In 2022, Mr. Gay received an option to purchase 41,100 shares of common stock and an RSU covering 27,400 shares of common stock, both granted in the third quarter of 2022.

In 2022, Mr. Donofrio received an option to purchase 75,000 shares of common stock, which was granted in the first quarter of 2022 in connection with completion of the EPI Health Acquisition and Mr. Donofrio entering into the Donofrio Employment Agreement.

Long-term Performance-based Compensation—Performance Plan

In August 2018, our board of directors approved and established the Performance Plan, which is a performance-based long-term incentive plan. The Performance Plan was intended to tie long-term employee incentive compensation to specific, significant increases in our underlying common stock price and thus directly align employee and stockholder objectives. The Performance Plan provided for employees to receive long-term incentive compensation payments only if the established stock price targets ($111.70 per share and $254.50 per share, subject to adjustment) were achieved. The Performance Plan provided for the bonus pool to generally be paid in the form of cash.

The Performance Plan was effective immediately upon approval and expired on March 1, 2022. As our stock price did not reach the minimum share price targets necessary to trigger a payment, no payments were made under the Performance Plan to any participants during the period the Performance Plan was effective.

Other Elements of Compensation

Retirement Plans

We currently maintain the Novan, Inc. 401(k) Plan, a defined contribution retirement savings plan, or the 401(k) Plan, for the benefit of our employees, including our named executive officers, who satisfy certain eligibility requirements. Our named executive officers were eligible to participate in the 401(k) Plan on the same terms as our other full-time employees. The Internal Revenue Code allows eligible employees to defer a portion of their compensation, within prescribed limits, on a pre-tax basis through contributions to the 401(k) Plan. Each participant in the 401(k) Plan was eligible to receive matching contributions of up to 5% in 2022, of such participant’s gross wages. These matching contributions are fully vested after one full year of employment. We believe that providing a vehicle for retirement savings though our 401(k) Plan and making matching contributions adds to the overall desirability of our executive compensation package and further incentivizes our employees, including our named executive officers.

Employee Benefits and Perquisites

All of our full-time employees, including our named executive officers, are eligible to participate in our health and welfare plans, including:

- medical, dental and vision benefits;
- medical and dependent care flexible spending accounts;
- short-term and long-term disability insurance; and
- life insurance.

In addition to the health and welfare benefits described above, certain named executive officers may participate in a company-paid executive life insurance plan. In 2022, we also paid certain executive life insurance premiums for the benefit of Mrs. Stafford. We generally do not provide any other perquisites to our named executive officers.

We believe the benefits and perquisites described above are necessary and appropriate to provide a competitive compensation package to our named executive officers.

No Tax Gross-Ups

We do not make gross-up payments to cover our named executive officers' personal income taxes that may pertain to any of the compensation or perquisites paid or provided by us.

Outstanding Equity Awards at Fiscal Year End

The following table provides information regarding outstanding equity awards held by our named executive officers as of December 31, 2022.

		Option Awards				Stock Awards	
Name	Grant Date	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($/Share)	Option Expiration Date	Equity Incentive Plan Awards: Number of unearned shares, units or other right that have not vested (#)	Equity Incentive Plan Awards: Payout value of unearned shares, units or other right that have not vested ($)
Paula Brown Stafford	03/20/17 (1)	5,400	—	$ 65.30	03/20/27		
Chairman, President and	08/25/17 (2)	3,050	—	42.70	08/14/27		
Chief Executive Officer	10/12/17 (3)	6,840	—	50.30	09/14/27		
	02/12/18 (4)	1,215	—	30.30	02/11/28		
	01/28/19 (5)	5,500	—	13.50	01/01/29		
	09/06/19 (6)	13,000	—	26.80	09/05/29		
	02/01/20 (7)	60,000	—	8.20	01/05/30		
	11/09/21 (15)	37,500	37,500	7.09	11/08/31		
	01/03/22 (8)	—	75,000	4.41	01/02/32		
John M. Gay	05/31/18 (10)	1,250	—	31.50	05/20/28		
Chief Financial Officer	11/16/18 (11)	250	—	24.30	11/12/28		
and Corporate Secretary	01/28/19 (12)	3,500	—	13.50	01/27/29		
	09/06/19 (6)	500	—	26.80	09/05/29		
	04/06/20 (13)	3,400	—	3.69	04/06/30		
	05/17/21 (16)	2,500	—	11.80	05/16/31		
	05/26/21 (17)	12,586	25,164	9.19	05/25/31		
	8/8/2022 (9)	—	41,100	2.93	3/14/2032		
	8/8/2022 (14)					27,400	$ 80,282
John A. Donofrio	03/11/22 (18)	—	75,000	3.56	03/10/32		
Executive Vice President							
and Chief Operating Officer							

(1) The option was granted under the 2016 Plan and vested six months from March 20, 2017.

(2) The option was granted under the 2016 Plan and vested in four equal quarterly installments, with the first installment vesting on September 5, 2017.

(3) The option was granted under the 2016 Plan and vested six months from vesting commencement date of September 15, 2017.

(4) The option was granted under the 2016 Plan and vested in thirty-six equal monthly installments on the first day of each month following February 12, 2018.

(5) This option was granted under the 2016 Plan, one-half vested six months from the January 2, 2019 vesting commencement date, and subsequent to the six-month anniversary of the vesting commencement date, one-twelfth vested each successive monthly anniversary following July 2, 2019.

(6) The option was granted under the 2016 Plan and vested in its entirety on June 25, 2020.

(7) The SARs were granted in connection with entering into the Stafford Employment Agreement and vested in equal quarterly installments over the initial term of the agreement, such that the SARs were fully vested on December 31, 2021.

(8) The option was granted under the 2016 Plan and vests in three installments, with one-half vesting upon the first anniversary of the grant date and one-half of the remaining options vesting on each of the next two anniversaries of the grant date.

(9) The option was granted under the 2016 Plan and vests in three equal annual installments, with the first installment vesting on March 15, 2023.

(10) The option was granted as an inducement grant in accordance with Nasdaq Listing Rule 5635(c)(4), and vested in three equal annual installments with the first installment vesting on May 21, 2019.

(11) The option was granted under the 2016 Plan and vested in three equal annual installments with the first installment vesting on November 13, 2019.

(12) The option was granted under the 2016 Plan and vests in three equal annual installments with the first installment vesting on January 28, 2020.

(13) The option was granted under the 2016 Plan, and one half vested on June 30, 2020, one quarter vested on September 30, 2020, and the remaining one quarter vested on December 31, 2020.

(14) The restricted stock unit was granted under the 2016 Plan and shall be fully vested on March 15, 2024, which is the second anniversary of the vesting commencement date.

(15) The option was granted under the 2016 Plan and vests in three installments with one-half vesting upon the first anniversary of the grant date and one-half of the remaining options vesting on each of the next two anniversaries of the grant date.

(16) The option was granted under the 2016 Plan and vests in four equal quarterly installments with the first installment vesting on June 30, 2021.

(17) The option was granted under the 2016 Plan and vests in three equal annual installments with the first installment vesting on May 26, 2022.

(18) The option was granted under the 2016 Plan and vests in three equal annual installments with the first installment vesting on March 11, 2023.

Arrangements with our Named Executive Officers

We have entered into employment arrangements with our named executive officers that set forth certain terms and conditions of their employment, including base salary and employee benefits.

Arrangements with Paula Brown Stafford

Mrs. Stafford serves as our President and Chief Executive Officer and is compensated pursuant to the Stafford Employment Agreement. Pursuant to the Stafford Employment Agreement, Mrs. Stafford receives an annual base salary of $598,850 and is eligible to receive an annual performance-based bonus with a target bonus of 55% to 75% of her base salary. Mrs. Stafford is also eligible to participate in our incentive award plans. Mrs. Stafford continues to be eligible to participate in standard benefit plans as well as an executive life insurance plan, as well as for reimbursement of reasonable business expenses. In addition, our board of directors approved a stock appreciation right, or the Stafford SAR Award, for Mrs. Stafford under the 2016 Plan covering 60,000 shares of our common stock. The Stafford SAR Award was granted on a contingent basis and would have been considered irrevocably forfeited and voided in full if sufficient shares of our common stock were not available under the 2016 Plan or if we failed to obtain stockholder approval for amendments to the 2016 Plan at the next annual stockholders' meeting to provide sufficient shares for the Stafford SAR Award. In such event, we would have been required to pay Mrs. Stafford the cash-equivalent value of the amount that would have been due and payable per the Stafford SAR Award upon any properly noticed exercise of any vested portion of the Stafford SAR Award. Such condition was satisfied, and the SARs were no longer considered to be granted on a contingent basis, as of February 1, 2020. In connection with the amendment of the Stafford Employment Agreement in November 2021, Mrs. Stafford was awarded 75,000 nonqualified stock options to purchase shares of the Company's common stock in November 2021 and January 2022.

In the event of Mrs. Stafford's termination of employment either upon nonrenewal by the Company of the term of the Stafford Employment Agreement, by the Company without "cause" or by Mrs. Stafford for "good reason" (except as set forth below), then in addition to any accrued amounts and subject to Mrs. Stafford timely delivering an effective release of claims in the Company's favor and her continued compliance with the previously signed Restrictive Covenants Agreement between the Company and Mrs. Stafford, Mrs. Stafford will be entitled to receive payment of her then-current base salary, plus a prorated annual bonus calculated at the minimum target level of the calendar year in which the "separation date," as defined in the Stafford Employment Agreement, occurs based on the percentage of the calendar year actually worked by Mrs. Stafford as of the separation date, each multiplied by 1.5, plus the amount of any unpaid Annual Bonus for the prior calendar year. Such amounts will be paid in equal monthly installments over 12 months in accordance with standard payroll practices and provided, that to the extent that any such cash award constitutes nonqualified deferred compensation under Section 409A, the cash payment will be paid subject to any delay required by Section 409A. Mrs. Stafford will also be entitled to vesting of any then unvested portion of the Stafford SAR Award or any then unvested portion of any other equity award from the Company to give credit for the pro-rated portion of such equity awards for which Mrs. Stafford would have qualified based on service through the twelve-month period following the separation date, upon Mrs. Stafford's termination without "cause" or for "good reason" not due to a "change in control" (each as defined in the Stafford Employment Agreement) . Upon termination of employment by Mrs. Stafford other than for good reason or due to her death or disability, or by the Company for cause, Mrs. Stafford will not be entitled to any additional compensation beyond any accrued amounts.

Notwithstanding the foregoing, the Stafford Employment Agreement further provides that, in the event of a "double trigger" event, Mrs. Stafford will be entitled to receive payment of her then-current base salary, plus a prorated annual bonus calculated at the minimum target level of the calendar year in which the separation date occurs based on the percentage of the calendar year actually worked by Mrs. Stafford as of the separation date, each multiplied by 2.5, plus the amount of any unpaid Annual Bonus for the prior calendar year. Such amounts will be paid in equal monthly installments over 24 months in accordance with standard payroll practices and provided, that to the extent that any such cash award constitutes nonqualified deferred compensation under Section 409A, the cash payment will be paid subject to any delay required by Section 409A. Mrs. Stafford will also be entitled to vesting of any then unvested portion of the Stafford SAR Award and any other equity grant as of the separation date.

The following circumstances are considered a "double trigger" event:

(i) a "change in control," as defined in the Stafford Employment Agreement (which incorporates the definition from the 2016 Plan), and

(ii) Mrs. Stafford is terminated from employment by the Company without cause or upon the nonrenewal by the Company of the term of the Stafford Employment Agreement or by Mrs. Stafford for good reason (other than due to certain changes on the Company's board of directors) within 12 months after a change in control, subject to Mrs. Stafford timely delivering an effective release of claims in the Company's favor and her continued compliance with the Restrictive Covenants Agreement between the Company and Mrs. Stafford.

Arrangements with John M. Gay

Mr. Gay serves as our Chief Financial Officer and Corporate Secretary and is compensated pursuant to the Gay Employment Agreement. The Gay Employment Agreement may be terminated at-will by the Company or Mr. Gay at any time, for any or no cause or reason, and with or without prior notice. Pursuant to the Gay Employment Agreement, Mr. Gay receives an annual base salary of $319,725, is eligible to receive an annual performance-based bonus with a target bonus equal to 35% of his base

salary, is eligible to participate in the Company's incentive award plans and is entitled to the maximum amount of paid time-off allowed under the Company's policies. The Gay Employment Agreement also provides Mr. Gay with eligibility to participate in the Company's employee benefit plans, programs and arrangements as are provided generally from time to time to all other similarly situated employees of the Company, as well as for reimbursement of reasonable business expenses.

In the event of termination of Mr. Gay's employment by the Company without "cause" or by Mr. Gay for "good reason," in each case not in connection with a "change in control," with such terms as defined in the Gay Employment Agreement, then in addition to any accrued amounts and subject to Mr. Gay timely delivering an effective release of claims in the Company's favor and continued compliance with the existing Restrictive Covenants Agreements, as defined in the Gay Employment Agreement, Mr. Gay will be entitled to receive (i) payment of an amount equal to twelve months of his base salary, plus a prorated annual bonus, calculated at the target bonus level for the calendar year in which the separation date occurs based on the percentage of the calendar year actually worked by Mr. Gay as of the separation date, with such amount generally to be paid in equal installments over twelve months in accordance with the Company's standard payroll practices, (ii) vesting of any of Mr. Gay's then-unvested equity awards that would have otherwise vested through the end of the calendar year in which the separation date occurs, and (iii) reimbursement of a portion of Mr. Gay's applicable Consolidated Omnibus Budget Reconciliation Act of 1985, as amended, or COBRA, premiums for up to six months after such separation date. In the event of termination of Mr. Gay's employment by the Company without "cause" or by Mr. Gay for "good reason," at the time of or within twelve months after a "change in control," then in addition to any accrued amounts and subject to Mr. Gay timely delivering an effective release of claims in the Company's favor and continued compliance with the existing Restrictive Covenants Agreements, Mr. Gay will be entitled to receive (i) payment of an amount equal to twelve months of his base salary, plus an amount equal to an annual bonus calculated at the target bonus level for the calendar year in which the separation date occurs, with such amount generally to be paid in equal installments over twelve months in accordance with the Company's standard payroll practices, (ii) accelerated vesting of the remaining unvested portion of any and all equity awards issued to Mr. Gay as of the separation date and (iii) reimbursement of a portion of Mr. Gay's applicable COBRA premiums for up to twelve months after such separation date. In the event of termination of Mr. Gay's employment by the Company for "cause," by Mr. Gay other than for "good reason," or due to Mr. Gay's death or "disability," as defined in the Gay Employment Agreement, Mr. Gay will not be entitled to any additional compensation under the Gay Employment Agreement beyond any accrued amounts.

Arrangements with John A. Donofrio

As of March 11, 2022, Mr. Donofrio serves as our Chief Operating Officer and is compensated pursuant to the Donofrio Employment Agreement. The Donofrio Employment Agreement may be terminated at-will by the Company or Mr. Donofrio at any time, for any or no cause or reason, and with or without prior notice. Pursuant to the Donofrio Employment Agreement, Mr. Donofrio receives an annual base salary of $400,000, is eligible to receive an annual performance-based bonus with a target bonus equal to not less than 50% and up to a maximum of 75% of his base salary, payable based on performance criteria. The Donofrio Employment Agreement provided that Mr. Donofrio's annual bonus for fiscal 2022 was guaranteed to equal at least the target level. Mr. Donofrio is eligible to participate in the Company's incentive award plans and is entitled to the maximum amount of paid time-off allowed under the Company's policies. The Donofrio Employment Agreement also provides Mr. Donofrio with eligibility to participate in the Company's employee benefit plans, programs and arrangements as are provided generally from time to time to all other similarly situated employees of the Company, as well as for reimbursement of reasonable business expenses.

In the event of Mr. Donofrio's termination of employment by the Company without "cause" or by Mr. Donofrio for "good reason," not due to a "change in control," each as defined in the Employment Agreement, then in addition to any accrued amounts and subject to Mr. Donofrio timely delivering an effective release of claims in the Company's favor and substantial and material compliance with existing confidentiality and noncompetition agreements, Mr. Donofrio will be entitled to receive (i) payment of an amount equal to 12 months of his base salary, plus an amount equal to an annual bonus calculated at the target bonus level for the calendar year in which the separation date occurs but prorated based on the percentage of the calendar year actually worked by Mr. Donofrio as of the separation date, paid in installments over 12 months in accordance with standard payroll practices, (ii) vesting of any of Mr. Donofrio's time-based options that would have vested through the end of the calendar year in which the separation occurred and (iii) reimbursement of Mr. Donofrio's applicable COBRA premiums for up to 12 months after such separation. In the event of Mr. Donofrio's termination of employment by the Company without "cause" or by Mr. Donofrio for "good reason," within 12 months of a "change in control," each as defined in the Employment Agreement, then in addition to any accrued amounts and subject to Mr. Donofrio timely delivering an effective release of claims in the Company's favor and substantial and material compliance with existing confidentiality and noncompetition agreements, Mr. Donofrio will be entitled to receive (i) payment of an amount equal to 12 months of his base salary, plus an amount equal to an annual bonus calculated at the target bonus level for the calendar year in which the separation date occurs, paid in installments over 12 months in accordance with standard payroll practices, (ii) vesting of all of Mr. Donofrio's outstanding unvested options and (iii) reimbursement of Mr. Donofrio's applicable COBRA premiums for up to 12 months after such separation.

Director Compensation

The following table sets forth information concerning the compensation of our directors, other than Mrs. Stafford, for the year ended December 31, 2022.

Name	Fees Earned or Paid in Cash (1)	Option Awards (2)	Total
James L. Bierman	$ 62,750	$ 100,000	$ 162,750
W. Kent Geer	102,896	100,000	202,896
Robert J. Keegan	82,813	100,000	182,813
Machelle Sanders	63,125	100,000	163,125
Steven D. Skolsky	62,188	100,000	162,188
John Palmour (3)	73,438	100,000	173,438

(1) Amounts reflected in this column include the fees earned during the fourth quarter ended December 31, 2021, but paid in cash to the applicable director during the year ended December 31, 2022, and fees earned during the fourth quarter ended December 31, 2022, but paid in cash to the applicable director during the year ended December 31, 2023. In this column we are required to report all fees either earned or paid to directors during 2022. As a result, fees earned in 2021 for fourth quarter service in 2021 but paid in 2022 are also included; thus the dollar amount represents fees paid for five (not four) successive quarters. Fees earned in 2021 but paid in 2022 were as follows: Mr. Bierman, $11,250; Mr. Geer, $21,875; Mr. Keegan, $16,563; Dr. Palmour, $13,438; and Ms. Sanders, $11,875.

(2) Amounts reflect the grant-date Black-Scholes value of stock awards and stock options granted during 2022, computed in accordance with ASC Topic 718, rather than the amounts paid to or realized by the named individual. For a discussion of the assumptions used to calculate the value of all stock awards and option awards made to our directors, see the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Policies and Use of Estimates—Stock-Based Compensation" in this Annual Report, "Note 1—"Organization and Significant Accounting Policies"" and "Note 11—Stock-Based Compensation" to the accompanying consolidated financial statements included in this Annual Report. These amounts do not necessarily correspond to the actual value that may be recognized from the option awards by the applicable directors.

(3) Dr. Palmour served on the board of directors until his death in November 2022.

The table below shows the aggregate numbers of option awards and restricted stock unit awards (exercisable and unexercisable) held as of December 31, 2022, by each director who served as a member of our board of directors during the year ended December 31, 2022, other than Mrs. Stafford. No such director held any other equity awards.

Name	Options Outstanding at Fiscal Year End December 31, 2022	RSUs Outstanding at Fiscal Year End December 31, 2022
James L. Bierman	14,423	36,101
W. Kent Geer	24,797	36,101
Robert J. Keegan	23,272	36,101
Machelle Sanders	20,347	36,101
Steven D. Skolsky	15,620	36,101
John Palmour	—	—

Non-Employee Director Compensation Policy

Effective March 29, 2023, we amended the Novan, Inc. Non-Employee Director Compensation Policy, or the Director Compensation Policy, for our non-employee directors that consists of annual retainer fees and equity awards that will be paid or made automatically and without further action by our board of directors. Pursuant to the Director Compensation Policy, subject to continued service on our board, (i) each non-employee director receives an annual cash retainer of $40,000; (ii) each non-employee director serving as a committee chair receives an additional annual retainer between $10,000 and $20,000; (iii) each non-employee director serving as a committee member (unless also serving as the committee chair) receives an additional annual retainer between $5,000 and $8,750, or in the event our board of directors creates a special committee, such additional cash compensation in the form of a retainer or a per meeting fee paid at the rate established by our board of directors at the time our board of directors establishes such committee; (iv) the non-employee chairman of our board of directors receives an additional annual retainer of $32,500; and (v) the lead independent director receives an additional annual retainer of $22,500. The Director Compensation Policy also provides each non-employee director with an annual equity award, contingent upon

service on our board of directors as of the date of any annual meeting of our stockholders and continued service on our board of directors immediately following such annual meeting and automatically granted on the date of such annual meeting, of an option to purchase the number of shares of our common stock (at a per-share exercise price equal to the closing price per share of our common stock on the date of such annual meeting, or on the last preceding trading day if the annual meeting is not a trading day) equal to the number of shares that have an aggregate grant-date fair value of $100,000 (as determined in accordance with ASC Topic 718, with the number of shares of our common stock underlying each such award subject to adjustment as provided in the 2016 Plan); provided that at the discretion of the Compensation Committee and pursuant to the exercise of its business judgment, taking into account such factors, circumstances and considerations as it shall deem relevant from time to time, the Compensation Committee can impose a cap on the number of shares subject to such annual equity award. The equity awards described in the Director Compensation Policy are granted under and subject to the terms and provisions of the 2016 Plan or any other applicable Company equity incentive plan then-maintained by the Company. Each non-employee director who is initially elected or appointed on any date other than the date of an annual meeting of stockholders will receive a prorated portion of such annual equity award for the year of such election or appointment. Notwithstanding the foregoing, our board of directors in its sole discretion may determine that the annual equity award for any year or the prorated portion of any such annual equity award, as applicable, be granted in the form of restricted stock units with equivalent value on the date of grant. Each director option award will vest and become exercisable in four equal quarterly installments, and each RSU award will vest on the first anniversary, such that each such award shall be fully vested and exercisable on the first anniversary of the date of grant, subject to the director's continued service on our board of directors through each applicable vesting date. The equity awards will accelerate and vest in full upon the death or disability of any director.

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.

EQUITY COMPENSATION PLAN INFORMATION

The following table presents information as of December 31, 2022, with respect to compensation plans under which shares of our common stock may be issued. The category "Equity Compensation Plans approved by security holders" in the table below consists of the 2016 Plan and the Company's 2008 Stock Plan, or the 2008 Plan.

Plan Category	Number of Securities to be Issued upon Exercise of Outstanding Options, RSUs and SARs (a)	Weighted Average Exercise Price of Outstanding Options, RSUs and SARs ($)(b)	Number of Securities Remaining Available for Future Issuances under Equity Compensation Plans (excluding securities reflected in column (a)) (c)
Equity Compensation Plans approved by security holders	1,548,726 (1)	$ 7.36 (2)	241,801 (3)
Equity Compensation Plans not approved by security holders (4)	1,250	31.50	-
Total	1,549,976	7.38	241,801

(1) Includes shares of common stock issuable upon exercise of outstanding options under the 2008 Plan – 3,633 shares; outstanding options and SARs under the 2016 Plan – 1,087,687 shares; and outstanding RSUs under the 2016 Plan – 457,406.

(2) The weighted-average remaining contractual term (in years) was 6.20.

(3) Includes shares remaining for future issuance under the 2016 Plan.

(4) In May 2018, we awarded nonstatutory stock options to purchase an aggregate of 10,050 shares of common stock to newly-hired employees, not previously employees or directors of the Company, as inducements material to the individuals' entering into employment with us within the meaning of Nasdaq Listing Rule 5635(c)(4), or the Inducement Grants. The Inducement Grants had a grant date of May 31, 2018 and an exercise price of $31.50 per share. The Inducement Grants were awarded outside of the 2016 Plan, pursuant to Nasdaq Listing Rule 5635(c)(4), but had terms and conditions generally consistent with our 2016 Plan and vested over three years, subject to the employee's continued service as an employee or consultant through the vesting period. As of December 31, 2021, there were a total of 1,250 Inducement Grants outstanding.

SECURITY OWNERSHIP OF MANAGEMENT AND CERTAIN BENEFICIAL OWNERS

The following table sets forth information regarding the beneficial ownership of our common stock as of March 16, 2023, by the following:

- each stockholder known by us to be the beneficial owner of more than 5% of our common stock;
- each of our directors;
- each of our named executive officers; and
- all of our directors and executive officers as a group.

Applicable percentages are based on 28,015,371 shares outstanding on March 16, 2023, adjusted as required by rules promulgated by the SEC.

The number of shares beneficially owned by each stockholder is determined under rules issued by the SEC. Under these rules, beneficial ownership includes any shares as to which the individual or entity has sole or shared voting power or investment power. The following table is based upon information supplied by officers, directors and principal stockholders and Schedules 13D and 13G filed with the SEC. In computing the number of shares beneficially owned by an individual or entity and the percentage ownership of that person, shares of common stock issuable upon the exercise of stock options, SARs or warrants exercisable or RSUs that will vest within 60 days of March 16, 2023, are considered outstanding, although these shares are not considered outstanding for purposes of computing the percentage ownership of any other person. Unless otherwise indicated, the address of each of the individuals and entities named below is c/o Novan, Inc., 4020 Stirrup Creek Drive, Suite 110, Durham, NC 27703. Each of the stockholders listed has sole voting and investment power with respect to the shares beneficially owned by the stockholder unless noted otherwise, subject to community property laws where applicable.

Name of Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Outstanding Shares
5% Stockholders:		
None	—	—
Directors and Named Executive Officers:		
Paula Brown Stafford (1)	185,074	*
John M. Gay (2)	40,189	*
John A. Donofrio (3)	25,000	*
James L. Bierman (4)	18,423	*
W. Kent Geer (5)	26,379	*
Robert J. Keegan (6)	29,575	*
Machelle Sanders (7)	21,747	*
Steven D. Skolsky (8)	15,620	*
All current directors and executive officers, as a group (9 persons) (9)	378,677	1.3%

* Represents beneficial ownership of less than one percent.

(1) Consists of (i) 15,069 shares of common stock held by Mrs. Stafford (ii) options to purchase 110,005 shares of common stock that are exercisable within 60 days of March 16, 2023, 2023 and (iii) 60,000 SARs exercisable within 60 days of March 16, 2023.

(2) Consists of (i) 2,500 shares of common stock held by Mr. Gay and (ii) options to purchase 37,689 shares of common stock that are exercisable within 60 days of March 16, 2023.

(3) Consists of options to purchase 25,000 shares of common stock that are exercisable within 60 days of March 16, 2023.

(4) Consists of (i) 4,000 shares of common stock held by Mr. Bierman and (ii) options to purchase 14,423 shares of common stock that are exercisable within 60 days of March 16, 2023.

(5) Consists of (i) 1,582 shares of common stock held by Mr. Geer and (ii) options to purchase 24,797 shares of common stock that are exercisable within 60 days of March 16, 2023.

(6) Consists of (i) 6,303 shares of common stock held by the Robert J. Keegan Trust, with Mr. Keegan as trustee and (ii) options to purchase 23,272 shares of common stock that are exercisable within 60 days of March 16, 2023.

(7) Consists of (i) 700 shares of common stock held by Ms. Sanders, (ii) warrants to purchase 700 shares of common stock that are exercisable within 60 days of March 16, 2023 and (iii) options to purchase 20,347 shares of common stock that are exercisable within 60 days of March 16, 2023.

(8) Consists of options to purchase 15,620 shares of common stock that are exercisable within 60 days of March 16, 2023.

(9) Consists of (i) 30,154 common shares held by our current executive officers and current directors, (ii) warrants to purchase 700 shares of common stock that are exercisable within 60 days of March 16, 2023 and (iii) options and SARs to purchase 347,823 shares of common stock exercisable within 60 days of March 16, 2023.

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

Policies and Procedures for Related Party Transactions

Our board of directors has adopted a written related person transaction policy setting forth the policies and procedures for the review and approval or ratification of related person transactions. This policy covers, with certain exceptions set forth in Item 404 of Regulation S-K under the Securities Act, any transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships, in which we were or are to be a participant, the amount involved exceeds the lesser of (i) $120,000 or (ii) one percent of the average of our total assets at year-end for the last two completed fiscal years, and in which a related person had, has or will have a direct or indirect material interest, including without limitation, purchases of goods or services by or from the related person or entities in which the related person has a material interest, indebtedness, guarantees of indebtedness and employment by us of a related person. In reviewing and approving any such transactions, our audit committee is tasked to consider all relevant facts and circumstances, including, but not limited to, whether the transaction is on terms comparable to those that could be obtained in an arm's length transaction and the extent of the related person's interest in the transaction. All of the transactions described in this section either were approved or ratified pursuant to this policy or occurred prior to the adoption of this policy.

Certain Relationships and Related Transactions

The following includes a summary of transactions since January 1, 2020, to which we were or are to be a participant, in which the amount involved exceeded or will exceed the lesser of (i) $120,000 or (ii) one percent of the average of our total assets at year-end for the last two completed fiscal years, and in which any of our directors, executive officers or, to our knowledge, beneficial owners of more than 5% of our common stock or any member of the immediate family of any of the foregoing persons had or will have a direct or indirect material interest, other than equity and other compensation, termination, change in control and other arrangements, which are described in "Executive Compensation." We also describe below certain other transactions with our directors, executive officers and stockholders.

2020 Registered Direct Offering

On March 24, 2020, we entered into a securities purchase agreement with certain institutional investors, pursuant to which we agreed to sell and issue, in a registered direct offering priced at the market, an aggregate of 1,860,465 shares of our common stock (or pre-funded warrants to purchase shares of common stock in lieu thereof). The purchase price for each share of common stock was $4.30, and the price for each pre-funded warrant was $4.299. Each pre-funded warrant had an exercise price of $0.001 per share. The pre-funded warrants were exercisable immediately upon issuance until all of the pre-funded warrants were exercised in full.

In the offering, Sabby Volatility Warrant Master Fund, Ltd., a greater than 5% stockholder at the time of the offering, purchased 620,000 shares of common stock and pre-funded warrants to purchase up to 260,233 shares of common stock for approximately $3.8 million. Based solely on information reported in a Schedule 13G/A filed with the SEC on January 5, 2021, Sabby no longer held any of our common stock or pre-funded warrants to purchase shares of our common stock as of that date.

Joseph Moglia, a greater than 5% stockholder at the time of the offering, purchased 100,000 shares of common stock for $430,000. Based solely on information reported in a Schedule 13D/A filed with the SEC on January 27, 2021, Mr. Moglia was no longer a greater than 5% stockholder as of that date.

Arrangements with Executive Officers and Directors

We have entered into employment arrangements with our named executive officers. For more information regarding our arrangements with our named executive officers, see the section entitled "Executive Compensation—Arrangements with our Named Executive Officers."

We have entered, or will enter, into an indemnification agreement with each of our directors and executive officers. The indemnification agreements and our bylaws require us to indemnify our directors and officers to the fullest extent permitted by Delaware law.

Independence of Directors

Our common stock is listed on the Nasdaq Capital Market. Under the listing requirements and rules of the Nasdaq Capital Market, independent directors must comprise a majority of our board of directors, and each member of our audit committee, compensation committee and nominating and governance committee must be independent. Under the rules of the Nasdaq Capital Market, 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.

Audit committee members must also satisfy independence criteria set forth in Rule 10A-3 under the Exchange Act. To be considered independent for purposes of Rule 10A-3, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of a company's audit committee, the company's 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.

Our board of directors has undertaken a review of its composition, the composition of its committees and the independence of each director. Based upon information requested from and provided by each director concerning his or her background, employment and affiliations, including family relationships, our board of directors has determined that James L. Bierman, W. Kent Geer, Robert J. Keegan, Machelle Sanders and Steven D. Skolsky, and John Palmour, during his service on the board until his death in November 2022, do not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each of these directors is "independent" as that term is defined under the applicable rules and regulations of the listing requirements and rules of the Nasdaq Capital Market. In making these determinations, our board of directors considered the current and prior relationships that each non-employee director has with us and all other facts and circumstances our board of directors deemed relevant in determining their independence, including the beneficial ownership of our capital stock by each non-employee director.

Our board of directors determined that W. Kent Geer, Robert J. Keegan, and Steven D. Skolsky, each of the three members of our audit committee, and John Palmour, until his death in November 2022, satisfy the independence standards for our audit committee established by applicable SEC rules and the listing standards of the Nasdaq Capital Market and Rule 10A-3.

Our board of directors has determined that Robert J. Keegan, James L. Bierman and Machelle Sanders, each of the three current members of our compensation committee, satisfy the independence standards for our compensation committee established by applicable SEC Rules and the listing standards of the Nasdaq Capital Market, taking into consideration all factors specified in the applicable standards.

Our board of directors has determined that James L. Bierman, Machelle Sanders and Steven D. Skolsky, each of the three members of our nominating and corporate governance committee, and John Palmour, during his service on the committee until his death in November 2022, are independent within the meaning of the applicable listing standards of the Nasdaq Capital Market.

Item 14. Principal Accountant Fees and Services.

Principal Accountant Fees and Services

The following table represents the aggregate fees and expenses for services provided by BDO USA, LLP, or BDO, our independent registered public accounting firm for the fiscal years ended December 31, 2022 and 2021.

	Fiscal Year Ended	
	2022	2021
	(in thousands)	
Audit Fees (1)	$ 756	$ 329
Audit-Related Fees	—	—
Tax Fees	—	—
All Other Fees	—	—
Total Fees	$ 756	$ 329

1. Audit fees consist of fees billed, or expected to be 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.

All fees described above were approved by our audit committee.

Pre-Approval Policies and Procedures

Our 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 our 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 our audit committee's members, but the decision must be reported to the full audit committee at its next scheduled meeting.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

(a) The following financial statements are included in this Annual Report:

(1) List of Financial Statements:

The financial statements required by this item are listed in Item 8, "Financial Statements and Supplementary Data" herein.

(2) List of Financial Statement Schedules:

All financial statement schedules have been omitted because they are not applicable, not required or the information required is shown in the financial statements or notes thereto.

(3) List of Exhibits.

				INCORPORATED BY REFERENCE			
EXHIBIT NO.		DESCRIPTION	Filed Herewith	FORM	File No.	Exhibit	Filing Date
2.1	††	Unit Purchase Agreement, dated as of March 11, 2022, by and among Novan, Inc., Evening Post Group, LLC and EPI Health, LLC.		8-K	001-37880	2.1	March 11, 2022
3.1		Restated Certificate of Incorporation of Novan, Inc., effective September 26, 2016.		8-K	001-37880	3.1	September 27, 2016
3.2		Certificate of Amendment to the Restated Certificate of Incorporation of Novan, Inc., effective May 25, 2021.		8-K	001-37880	3.1	May 25, 2021
3.3		Amended and Restated Bylaws of Novan, Inc., effective September 26, 2016.		8-K	001-37880	3.2	September 27, 2016
4.1		Form of Common Stock Certificate.		S-1/A	333-213276	4.1	September 8, 2016
4.2		Description of Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934.	X				
4.3		Registration Rights Agreement, dated August 30, 2019, by and between Novan, Inc. and Aspire Capital Fund, LLC.		8-K	001-37880	4.1	September 5, 2019
4.4		Registration Rights Agreement, dated July 21, 2020, by and between Novan, Inc. and Aspire Capital Fund, LLC.		8-K	001-37880	4.1	July 22, 2020
4.5		Form of March 2020 Public Offering Common Warrant.		8-K	001-37880	4.1	March 3, 2020
4.6		Form of March 2020 Public Offering Underwriter Warrant.		8-K	001-37880	4.3	March 3, 2020
4.7		Form of March 2020 Registered Direct Offering Placement Agent Warrant.		8-K	001-37880	4.2	March 26, 2020
4.8		Form of June 2022 Registered Direct Offering Common Warrant, as amended.		8-K	001-37880	4.3	March 16, 2023
4.9		Form of June 2022 Registered Direct Offering Pre-Funded Warrant.		8-K	001-37880	4.2	June 10, 2022

EXHIBIT NO.		DESCRIPTION	Filed Herewith	INCORPORATED BY REFERENCE			
				FORM	File No.	Exhibit	Filing Date
10.1	#	Form of Director and Executive Officer Indemnification Agreement.		10-Q	001-37880	10.6	October 30, 2020
10.2	#	2008 Stock Plan, as amended, and form of option agreements thereunder.		S-1	333-213276	10.2	August 24, 2016
10.3	#	2016 Incentive Award Plan, as amended and restated.		8-K	001-37880	10.1	May 25, 2021
10.4	#	Form of Award Agreement Awarding Non-Qualified Stock Options to Employees under the Novan, Inc. 2016 Incentive Award Plan.		10-Q	001-37880	10.1	November 14, 2016
10.5	#	Form of Award Agreement Awarding Incentive Stock Options to Employees under the Novan, Inc. 2016 Incentive Award Plan.		10-Q	001-37880	10.2	November 14, 2016
10.6	#	Form of Award Agreement Awarding Non-Qualified Stock Options to Non-Employee Directors under the Novan, Inc. 2016 Incentive Award Plan.		10-Q	001-37880	10.3	November 14, 2016
10.7	#	Form of Award Agreement Awarding Restricted Stock Units under the Novan, Inc. 2016 Incentive Award Plan.		10-Q	001-37880	10.1	May 16, 2022
10.8	#	Form of Employment Inducement Stock Option Agreement.		10-Q	001-37880	10.3	August 8, 2018
10.9	#	Amended and Restated Employment Agreement dated December 17, 2019, by and between Novan, Inc. and Paula Brown Stafford.		10-K	001-37880	10.12	February 24, 2020
10.10	#	First Amendment, dated November 9, 2021, to Amended and Restated Employment Agreement dated December 17, 2019, by and between Novan, Inc. and Paula Brown Stafford.		10-Q	001-37880	10.1	November 10, 2021
10.11	#	Stock Appreciation Right Grant Notice and Agreement between Novan, Inc. and Paula Brown Stafford.		10-K	001-37880	10.13	February 24, 2020
10.12	#	Employment Agreement, dated September 23, 2020, by and between Novan, Inc. and John M. Gay.		8-K	001-37880	10.2	September 24, 2020
10.13	#	First Amendment, dated August 11, 2021, to Employment Agreement, dated September 23, 2020, by and between Novan, Inc. and John M. Gay.		10-Q	001-37880	10.3	August 12, 2021
10.14	#	Employment Agreement, dated March 11, 2022, by and between Novan, Inc. and John Donofrio.		10-Q	001-37880	10.2	May 16, 2022
10.15	#	Non-Employee Director Compensation Policy.	X				

EXHIBIT NO.		DESCRIPTION	Filed Herewith	INCORPORATED BY REFERENCE			
				FORM	File No.	Exhibit	Filing Date
10.16	††	Amended, Restated and Consolidated License Agreement between The University of North Carolina and Novan, Inc., dated as of June 27, 2012, and as amended on November 30, 2012.		10-Q	001-37880	10.8	May 16, 2022
10.17	††	Second Amendment, dated April 12, 2016, to the Amended, Restated and Consolidated License Agreement between The University of North Carolina and Novan, Inc., dated as of June 27, 2012.		10-Q	001-37880	10.9	May 16, 2022
10.18	†	Third Amendment, dated November 1, 2018, to the Amended, Restated and Consolidated License Agreement between The University of North Carolina and Novan, Inc., dated as of June 27, 2012.		10-K	001-37880	10.23	March 27, 2019
10.19	††	Fourth Amendment, dated November 26, 2018, to the Amended, Restated and Consolidated License Agreement between the University of North Carolina and Novan, Inc., dated as of June 27, 2012.		10-K	001-37880	10.19	February 18, 2022
10.20	††	Fifth Amendment, dated October 27, 2021, to the Amended, Restated and Consolidated License Agreement between the University of North Carolina and Novan, Inc., dated as of June 27, 2012.		10-K	001-37880	10.20	February 18, 2022
10.21	††	UNC Sublicense Agreement, dated December 29, 2015, by and between Novan, Inc. and KNOW Bio, LLC.		10-Q	001-37880	10.10	May 16, 2022
10.22	†	First Amendment, dated October 13, 2017, to the UNC Sublicense Agreement, dated December 29, 2015, by and between Novan, Inc. and KNOW Bio, LLC.		10-K	001-37880	10.21	March 27, 2018
10.23	†	Second Amendment, dated November 2, 2018, to the UNC Sublicense Agreement, dated December 29, 2015, by and between Novan, Inc. and KNOW Bio, LLC.		10-K	001-37880	10.26	March 27, 2019
10.24	††	Novan Patent and Know-How License Agreement, dated December 29, 2015, by and between Novan, Inc. and KNOW Bio, LLC.		10-Q	001-37880	10.11	May 16, 2022
10.25	†	First Amendment, dated October 13, 2017, to the Novan Patent and Know-How License Agreement, dated December 29, 2015, by and between Novan, Inc. and KNOW Bio, LLC.		10-K	001-37880	10.23	March 27, 2018

EXHIBIT NO.		DESCRIPTION	Filed Herewith	INCORPORATED BY REFERENCE			
				FORM	File No.	Exhibit	Filing Date
10.26	†	Second Amendment, dated November 2, 2018 to the Novan Patent and Know-How License Agreement, dated December 29, 2015, by and between Novan, Inc. and KNOW Bio, LLC.		10-K	001-37880	10.29	March 27, 2019
10.27	††	License Agreement, dated January 12, 2017, by and between Novan, Inc. and Sato Pharmaceutical Co. Ltd.	X				
10.28	††	First Amendment, dated January 12, 2017 to the License Agreement, dated January 12, 2017, by and between Novan, Inc. and Sato Pharmaceutical Co. Ltd.	X				
10.29	†	Second Amendment, dated October 5, 2018 to the License Agreement, dated January 12, 2017, by and between Novan, Inc. and Sato Pharmaceutical Co. Ltd.		10-Q	001-37880	10.1	November 5, 2018
10.30	††	License Agreement, effective December 21, 2022, by and between Sato Pharmaceutical Co., Ltd., and EPI Health, LLC.		8-K	001-37880	10.1	December 21, 2022
10.31	††	Amended and Restated Promotion and Collaboration Agreement, effective as of January 1, 2022, by and between MC2 Therapeutics Limited and EPI Health, LLC.		10-Q	001-37880	10.6	May 16, 2022
10.32	††	Assignment and License Agreement, effective as of August 3, 2009, by and between Aspect Pharmaceuticals, LLC and EPI Health, LLC (as successor-in-interest to Vicept Therapeutics, Inc.).		10-Q	001-37880	10.7	May 16, 2022
10.33	††	Master Manufacturing and Supply Agreement, dated August 16, 2018, by and between DPT Laboratories, Ltd. and EPI Health, LLC (as successor-in-interest to Allergan Sales, LLC).		10-Q	001-37880	10.12	May 16, 2022
10.34	††	Royalty and Milestone Payments Purchase Agreement, dated April 29, 2019, by and between Novan, Inc. and Reedy Creek Investments LLC.		10-K	001-37880	10.30	February 18, 2022
10.35	††	Development Funding and Royalties Agreement, dated May 4, 2019, by and between Novan, Inc. and Ligand Pharmaceuticals Incorporated.		10-K	001-37880	10.31	February 18, 2022
10.36		Lease, dated January 18, 2021, by and between Novan, Inc. and Copper II 2020, LLC, and as amended by the First Amendment to Lease as of March 18, 2021.		10-Q	001-37880	10.1	May 11, 2021

EXHIBIT NO.	DESCRIPTION	Filed Herewith	INCORPORATED BY REFERENCE			
			FORM	File No.	Exhibit	Filing Date
10.37	Equity Distribution Agreement, dated March 11, 2022, by and between the Company and Oppenheimer & Co. Inc.		8-K	001-37880	10.1	March 11, 2022
10.38	Factoring Agreement, effective December 1, 2022, by and among CSNK Working Capital Finance Corp. d/b/a Bay View Funding, and EPI Health, LLC.		8-K	001-37880	10.1	December 6, 2022
10.39	Continuing Guaranty Agreement, effective December 1, 2022, by and among CSNK Working Capital Finance Corp. d/b/a Bay View Funding, and Novan, Inc.		8-K	001-37880	10.2	December 6, 2022
21.1	Subsidiaries of the Registrant.	X				
23.1	Consent of BDO USA, LLP.	X				
23.2	Consent of Elliott Davis, LLC.	X				
31.1	Certification of Chief Executive Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	X				
31.2	Certification of Chief Financial Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	X				
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	X				
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	X				
99.1	Audited financial statements of EPI Health, LLC as of and for the fiscal years ended September 30, 2021 and 2020.		8-K	001-37880	99.1	March 11, 2002
99.2	Unaudited financial statements of EPI Health, LLC as of and for the three months ended December 31, 2021 and 2020.		8-K	001-37880	99.2	March 11, 2002
99.3	Unaudited pro forma condensed combined financial information of Novan, Inc. as of and for the year ended December 31, 2021.		8-K	001-37880	99.3	March 11, 2002
101.INS	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.	X				
101.SCH	Inline XBRL Taxonomy Extension Schema Document.	X				

EXHIBIT NO.	DESCRIPTION	Filed Herewith	INCORPORATED BY REFERENCE			
			FORM	File No.	Exhibit	Filing Date
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.	X				
101.DEF	Inline XBRL Taxonomy Extension Definition Document.	X				
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.	X				
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.	X				
104	Cover Page Interactive Data File - the cover page XBRL tags are embedded within the Inline XBRL Instance document included in Exhibit 101.	X				

† Confidential treatment has been granted with respect to certain portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.

†† Certain confidential information contained in these exhibits were omitted by means of redacting a portion of the text and replacing it with [***], pursuant to Regulation S-K Item 601(b) of the Securities Act of 1933, as amended. Certain

# Indicates management contract or compensatory plan.

Item 16. Form 10-K Summary.

None.

SIGNATURES

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

Novan, Inc.

Date: March 30, 2023

By: /s/ Paula Brown Stafford
Paula Brown Stafford
Chairman, President and Chief Executive Officer
(Principal Executive Officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Annual Report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Name	Title	Date
/s/ Paula Brown Stafford **Paula Brown Stafford**	Chairman, President, Chief Executive Officer (Principal Executive Officer)	March 30, 2023
/s/ John M. Gay **John M. Gay**	Chief Financial Officer (Principal Financial Officer)	March 30, 2023
/s/ Andrew J. Novak **Andrew J. Novak**	Vice President, Accounting and Business Operations (Principal Accounting Officer)	March 30, 2023
/s/ James L. Bierman **James L. Bierman**	Director	March 30, 2023
/s/ W. Kent Geer **W. Kent Geer**	Director	March 30, 2023
/s/ Robert J. Keegan **Robert J. Keegan**	Director	March 30, 2023
/s/ Machelle Sanders **Machelle Sanders**	Director	March 30, 2023
/s/ Steven D. Skolsky **Steven D. Skolsky**	Director	March 30, 2023

Board of Directors

Paula Brown Stafford – *Chairman*
W. Kent Geer – *Lead Independent Director*
James L. Bierman
Robert J. Keegan
Machelle Sanders
Steven D. Skolsky

Management Team

Paula Brown Stafford – *President*, *Chief Executive Officer*
John A. Donofrio – *Executive Vice President, Chief Operating Officer*
John M. Gay – *Chief Financial Officer, Corporate Secretary*
Brian M. Johnson – *Chief Commercial Officer*
Carri Geer – *Senior Vice President*, *Chief Technology Officer*
Tomoko Maeda-Chubachi – *Chief Medical Officer*

Corporate Information

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Suite 110
Durham, North Carolina 27703
T: (919) 485-8080
F: (919) 237-9212
www.novan.com

Stock Exchange:
Nasdaq
NOVN ticker symbol

Transfer Agent:
American Stock Transfer & Trust Company, LLC
www.amstock.com

Independent Registered Public Accounting Firm:
BDO USA, LLP
421 Fayetteville Street
Suite 300
Raleigh, North Carolina 27601

Investor Relations & Media:
Jenene Thomas
JTC Team, LLC
833-475-8247
NOVN@jtcir.com

Information Request:

Copies of the Company's Annual Report on Form 10-K and other investor information are available without charge to stockholders upon written request to:

Novan, Inc., Attention: Investor Relations, 4020 Stirrup Creek Drive, Suite 110, Durham, North Carolina 27703