Table of Contents

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, 2023
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 001-36193

Trevena, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**26-1469215**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
955 Chesterbrook Blvd., Suite 110, Chesterbrook, PA	**19087**
(Address of Principal Executive Offices)	(Zip Code)

Registrant's telephone number, including area code: **(610) 354-8840**

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	TRVN	The Nasdaq Stock Market LLC

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

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

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting 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 ☒

The aggregate market value of the voting stock held by non-affiliates of the registrant, as of June 30, 2023, the last business day of the registrant's most recently completed second fiscal quarter, was approximately $12.0 million. Such aggregate market value was computed by reference to the closing price of the Common Stock as reported on the Nasdaq Stock Market LLC on June 30, 2023. For purposes of making this calculation only, the registrant has defined affiliates as including only directors and executive officers and stockholders holding greater than 10% of the voting stock of the registrant as of June 30, 2023.

The number of shares of the registrant's Common Stock outstanding as of March 28, 2024 was 18,321,010.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for its 2024 annual meeting of stockholders to be filed pursuant to Regulation 14A with the Securities and Exchange Commission not later than 120 days after the registrant's fiscal year ended December 31, 2023 are incorporated by reference into Part III of this Form 10-K.

TABLE OF CONTENTS

		Page
Cautionary Note Regarding Forward-Looking Statements		
	PART I	
Item 1.	Business	4
Item 1A.	Risk Factors	28
Item 1B.	Unresolved Staff Comments	71
Item 1C.	CyberSecurity	71
Item 2.	Properties	72
Item 3.	Legal Proceedings	72
Item 4.	Mine Safety Disclosures	72
	PART II	
Item 5.	Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	73
Item 6.	Selected Financial Data	73
Item 7.	Management's Discussion and Analysis of Financial Condition and Results of Operations	73
Item 7A.	Quantitative and Qualitative Disclosures About Market Risk	86
Item 8.	Financial Statements and Supplementary Data	87
Item 9.	Changes in and Disagreements With Accountants on Accounting and Financial Disclosure	119
Item 9A.	Controls and Procedures	119
Item 9B.	Other Information	120
Item 9C.	Disclosure Regarding Foreign Jurisdictoins That Prevent Inspections	120
	PART III	
Item 10.	Directors, Executive Officers and Corporate Governance	121
Item 11.	Executive Compensation	121
Item 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	121
Item 13.	Certain Relationships and Related Transactions, and Director Independence	122
Item 14.	Principal Accountant Fees and Services	122
	PART IV	
Item 15.	Exhibits and Financial Statement Schedules	123
SIGNATURES		128

Cautionary Note Regarding Forward-Looking Statements

This Annual Report on Form 10-K (this "Annual Report") contains forward-looking statements that involve substantial risks and uncertainties. The forward-looking statements are contained principally in the sections entitled "Business," "Risk Factors," and "Management's Discussion and Analysis of Financial Condition and Results of Operations," but also are contained elsewhere in this Annual Report. In some cases, you can identify forward-looking statements by the words "may," "might," "will," "could," "would," "should," "expect," "intend," "plan," "objective," "anticipate," "believe," "estimate," "predict," "project," "potential," "continue," and "ongoing," or the negative of these terms, or other comparable terminology intended to identify statements about the future. These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. Although we believe that we have a reasonable basis for each forward-looking statement contained in this Annual Report, we caution you that these statements are based on a combination of facts and factors currently known by us and our expectations of the future, about which we cannot be certain. Forward-looking statements include, among other things, statements about:

- our plans and expectations regarding our strategic alternative review process and the timing and success of such process regarding a potential transaction;
- success in retaining, or changes required in, our officers, key employees or directors;
- our sales of OLINVYK and our ability to successfully commercialize other product candidates for which we may obtain regulatory approval;
- our sales, marketing and manufacturing capabilities and strategies;
- any ongoing or planned clinical trials and nonclinical studies for our product candidates;
- the extent of future clinical trials potentially required by the U.S. Food and Drug Administration for our product candidates;
- our ability to fund future operating expenses and capital expenditures with our current cash resources or to secure additional funding in the future;
- the timing and likelihood of obtaining and maintaining regulatory approvals for our product candidates;
- our plan to develop and potentially commercialize our product candidates, if approved;
- the clinical utility and potential market acceptance of our product candidates, particularly in light of existing and future competition;
- the size of the markets for our product candidates;
- the performance of third-parties upon which we depend, including contract manufacturing organizations, suppliers, contract research organizations, distributors and logistics providers;
- our ability to identify or acquire additional product candidates with significant commercial potential that are consistent with our commercial objectives;
- the extent to which health epidemics and other outbreaks of communicable diseases could disrupt our operations and/or materially and adversely affect our business and financial conditions;
- our intellectual property position and our ability to obtain and maintain patent protection and defend our intellectual property rights against third parties; and
- our ability to satisfy all applicable Nasdaq continued listing requirements.

You should refer to the "Risk Factors" section of this Annual Report for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this Annual Report will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. We undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

PART I

ITEM 1. BUSINESS

Overview

We are a biopharmaceutical company focused on developing and commercializing novel medicines for patients affected by central nervous system, or CNS, disorders.

Our product, OLINVYK® (oliceridine) injection, or OLINVYK, was approved by the United States Food and Drug Administration, or FDA, in August 2020. We initiated commercial launch of OLINVYK in the first quarter of 2021. OLINVYK is an opioid agonist for use in adults for the management of acute pain severe enough to require an intravenous opioid analgesic and for whom alternative treatments are inadequate. OLINVYK is the first new chemical entity, or NCE, in this intravenous, or IV, drug class in decades and it offers a differentiated profile that addresses significant unmet needs in the acute pain management landscape. OLINVYK delivers IV opioid efficacy with a rapid 1-3 minute median onset of action. In addition, OLINVYK requires no dosage adjustments in patients with renal impairment, a large patient population with significant medical complications. The U.S. Drug Enforcement Administration, or DEA, has classified oliceridine as a Schedule II controlled substance.

In April 2024, we announced that OLINVYK remains available for purchase by customers, but that we are reducing commercial support for the product to preserve capital as we conduct a process to explore a range of strategic alternatives for OLINVYK. Potential alternatives that may be explored or evaluated include, but are not limited to, a sale, license, or divestiture of OLINVYK. There can be no assurance regarding the schedule for completion of the strategic review process, that this strategic review process will result in the Company pursuing any transaction or that any transaction, if pursued, will be completed.

Using our proprietary product platform, we also have identified and are developing the following product candidates:

- **TRV045:** TRV045 is our novel sphingosine-1-phosphate, or S1P, receptor modulator that may offer a new, non-opioid approach to managing chronic pain, as well as for treating epilepsy and seizure disorders. TRV045 has also demonstrated an anti-inflammatory effect in nonclinical studies that may have broad potential application in CNS disorders, autoimmune disease and inflammatory disease. TRV045 targets the S1P subtype 1 receptor and data suggests that TRV045 may effectively reverse neuropathic pain and reduce seizure risk without the immune-suppressing activity, or lymphopenia, observed with currently approved therapeutics targeting S1P receptors.

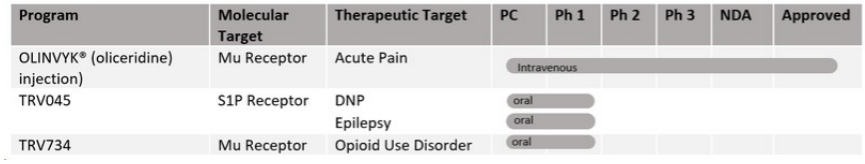
  In September 2023 we announced positive data from two clinical proof-of-concept studies. TRV045 demonstrated statistically significant analgesic effect in a capsaicin-induced model of neuropathic pain. TRV045 also demonstrated a statistically significant evidence of CNS activity as measured by resting state EEG power spectral analysis in a transcranial magnetic stimulation, or TMS, study. Subjects in both studies were enrolled outside of the United States, and the studies were not conducted under the Investigational New Drug Application for TRV045.

  TRV045 was well tolerated in these proof-of-concept studies, with no drug-related adverse events and no serious adverse events reported. In addition, no drug-related lymphopenia, bradycardia, or change in blood pressure, adverse events generally observed with currently approved therapeutics targeting S1P receptors, were reported.

- **TRV734:** We also have identified and have completed the initial Phase 1 studies for TRV734, an NCE targeting the same novel mechanism of action at the mu opioid receptor, or MOR, as OLINVYK. TRV734 was designed to be orally available, and its mechanism of action suggests it may offer valuable benefits for two distinct areas of important unmet medical need: acute and chronic pain, and maintenance-assisted therapy for patients with opioid use disorder, or OUD. We are collaborating with the National Institute on

Drug Abuse, or NIDA, to further evaluate TRV734 for the management of OUD, and NIDA initiated a proof-of-concept study for this indication in December 2019. In June 2021, we announced that the study, which had been paused due to the global COVID-19 pandemic, had resumed recruiting patients. We intend to continue to focus our efforts for TRV734 on securing a development and commercialization partner for this asset.

Our Product and Pipeline



OLINVYK ® (oliceridine) injection

OLINVYK is a G-protein biased MOR ligand approved for acute pain in adults that is severe enough to require an intravenous opioid analgesic and for whom alternative treatments are inadequate. It is an NCE with a novel mechanism of action.

Pain treatment options

Approximately 165 million units of IV opioids were used on average over the last three years, according to 2021 IQVIA data. Conventional IV opioid analgesics, such as morphine, fentanyl, and hydromorphone, have been core components of pain management protocols in the immediate postoperative period. The effectiveness of conventional opioids agonists is limited by severe dose dependent side effects such as respiratory depression, nausea, vomiting, constipation, and sedation which can be exacerbated by accumulation of active metabolites and by reduced renal clearance in patients with impaired kidney function. These shortcomings of conventional IV opioids create substantial challenges for healthcare providers in certain clinical practice situations.

Injectable non-opioid analgesics are often used together with IV opioids in multimodal protocols for post-surgical pain management. However, these drugs, such as IV non-steroidal anti-inflammatory drugs, or NSAIDs, IV acetaminophen, or local anesthetics such as bupivacaine, have their own potential for cardiovascular, hepatic and gastrointestinal side effects. In addition, none of these non-opioid analgesics offers sufficient efficacy to manage severe acute pain as a monotherapy in many patients.

We believe that OLINVYK addresses a significant unmet need for a highly effective IV opioid analgesic agent with a differentiated safety, tolerability, and PK/PD profile. OLINVYK delivers IV opioid efficacy with a rapid 1-3 minute median onset of action and requires no dosage adjustments in patients with renal impairment, a large patient population with significant medical complications.

OLINVYK was approved by the FDA in August 2020 for both bolus and patient-controlled analgesia, or PCA, delivery and we initiated commercial launch of OLINVYK in the first quarter of 2021. The DEA has classified oliceridine as a Schedule II controlled substance. Like other opioids, the label for OLINVYK contains a “boxed” warning and important safety information. Please consult www.olinvyk.com to view the prescribing information together with important safety information and boxed warning.

OLINVYK VOLITION Post-Approval Study

In 2023, we announced OLINVYK data from the VOLITION study, a 203-patient, real world, open-label, multi-site study led by clinical outcomes research experts from Cleveland Clinic and Wake Forest Baptist Health Medical Center. OLINVYK was dosed as the first-line analgesic during post-operative care, with a 1.5mg loading dose

of OLINVYK at surgical closure, and 0.35mg to 0.5mg of OLINVYK, as needed, administered with a PCA device, with a 6-minute lockout period. Additional boluses (≤1 mg) of OLINVYK were available if needed as soon as 15 minutes after the initial 1.5 mg loading dose.

OLINVYK demonstrated a 22.8% respiratory compromise, defined as any one of five pre-specified respiratory events over 48 hours of continuous monitoring. As with all opioids, serious, life-threatening, or fatal respiratory depression may occur in patients treated with OLINVYK, as indicated in the boxed warning. OLINVYK also demonstrated a 52.2% GI complete response rate, defined as no vomiting and no antiemetic use throughout the post-operative period. Over 90% of OLINVYK-treated patients reported feeling "alert and calm" from the morning of the first post-operative day and at every observation point thereafter, based on the Richmond Agitation-Sedation Scale, and 3.9% of OLINVYK-treated patients exhibited symptoms suggesting delirium at any point in the 48-hour post-operative period, based on the validated 3D-CAM screening tool. Sedation is an established risk of opioids including OLINVYK.

OLINVYK ARTEMIS Post-Approval Electronic Medical Records Study

In 2023, we also announced OLINVYK data from the ARTEMIS electronic medical records, or EMR, analysis that compared the health outcomes of VOLITION study patients with a matched population of patients, who underwent similar surgical procedures but were treated with other IV opioids, at the same institutions and during the same general time period as VOLITION. Matching was conducted with a greedy matching algorithm, using a propensity scoring method with eight different demographic and clinical characteristics including age, sex, type and duration of surgery, measures of overall surgical and medical morbidity, and type of hospital insurance.

OLINVYK-treated patients (n=201) had a $8,756 (19%) reduction in average cost per admission ($p<0.0001$) and 1.4-day (20%) reduction in average overall hospital length of stay ($p<0.0001$) compared to matched patients (n=982) treated with other IV opioids. Based on the data we have to date, there was not a statistically significant difference in the average duration of time in the post-anesthesia care unit (PACU) between OLINVYK-treated and matched patients.

Manufacturing

We have completed process development of the active pharmaceutical ingredient, or API, in OLINVYK and have manufactured multiple commercial-scale batches under current good manufacturing practices, or cGMP. We also have completed drug product process development and have manufactured multiple commercial-scale batches of drug product under cGMP conditions.

For OLINVYK, we have established commercial supply agreements for the manufacture of the API and finished (compounded, filled and packaged) drug product. Sterling Pharma Solutions (formerly Alcami Corporation), or Sterling, is contracted to supply all of our commercial API from its Germantown, WI manufacturing facility. We have existing commercial supply agreements with two separate companies for the supply of drug product. Alcami Corporation, or Alcami, is contracted to supply commercial drug product from its facilities in Charleston, SC and Wilmington, NC and was included as part of our approved new drug application, or NDA, submission. Pfizer CentreOne (formerly Hospira) is also contracted to supply commercial drug product in the future, but was not included in our NDA submission.

In October 2020, we announced that the DEA has classified OLINVYK as a Schedule II controlled substance. All third-party facilities throughout the supply chain have the appropriate licenses from the DEA for handling Schedule II controlled substances according to each of their respective contractual roles (manufacturing, testing, distribution, etc.).

Competition

OLINVYK is approved for use in adults for the management of acute pain severe enough to require an intravenous opioid analgesic and for whom alternative treatments are not adequate. OLINVYK competes with generic IV opioid analgesics, such as morphine, hydromorphone and fentanyl. IV opioid analgesics are limited by well-known adverse side effects, such as respiratory depression, nausea, vomiting, constipation, and post-operative ileus, which can be exacerbated by the way these molecules are metabolized or cleared. OLINVYK competes against, or is used in

combination with, IV acetaminophen; EXPAREL® (liposomal bupivacaine), marketed by Pacira Pharmaceuticals, Inc.; ZYNRELEF® (bupivacaine and meloxicam) marketed by Heron Therapeutics, Inc; CALDOLOR® (IV ibuprofen), marketed by Cumberland Pharmaceuticals; DSUVIA™ (sublingual sufentanil) marketed by Alora Pharmaceuticals, Inc.; XARACOLL™ (bupivacaine HCL) implant, marketed by Innocoll Holdings plc; and POSIMIR® (bupivacaine solution) marketed by INNOCOLL Biotherapeutic. Together with generic versions of IV NSAIDs such as ketorolac and acetaminophen, and generic versions of local anesthetics such as bupivacaine, these non-opioid analgesics are currently used in combination with opioids in the multimodal management of moderate-to-severe acute pain.

We also are aware of a number of products in mid- and late-stage clinical development that are aimed at improving the treatment of moderate-to-severe acute pain and may compete with OLINVYK. Avenue Therapeutics, Inc. is developing an IV version of generic opioid tramadol for moderate-to-severe acute pain.

Intellectual property

We wholly own the OLINVYK patent portfolio, including six issued U.S. patents (U.S. Patent Nos. 8,835,488; 9,309,234; 9,642,842; 9,849,119;11,077,098; and 11,931,350), which claim, among other things, OLINVYK, compositions comprising OLINVYK, and methods of using OLINVYK. The issued patents are expected to expire no earlier than 2032, subject to any disclaimers or extensions, and any U.S. patent to issue in the future is also expected to expire no earlier than 2032, subject to any disclaimers or extensions. We also have issued patents in Australia, Brazil, Canada, China, Eurasia, Europe, Hong Kong, Macau, Israel, Japan, India, South Korea, and New Zealand, which claim, among other things, OLINVYK, compositions comprising OLINVYK and methods of making or using OLINVYK. We have patent applications pending in the United States, Europe and Japan. The issued patents and patents that could issue in the future from these allowed or pending applications outside the United States are expected to expire no earlier than 2032, subject to any disclaimers or extensions. Following the FDA approval of OLINVYK, the FDA has added four issued U.S. patents to the Orange Book of Approved Drug Products with Therapeutic Equivalence Evaluations (U.S. Patent Nos. 8,835,488, 9,309,234, 9,642,842, and 11,077,098) and we expect the FDA to add a fifth patent (U.S. Patent No. 11,931,350) in the coming months. In addition, the Company has filed Patent Term Extension applications with the United States Patent and Trademark Office that could extend the life of one of the patents until 2034. Finally, the FDA has designated OLINVYK as an NCE in the Orange Book and it will therefore receive the exclusivity and protections afforded to NCE's.

TRV045 (S1P Modulators)

TRV045 is our novel sphingosine-1-phosphate, or S1P, receptor modulator that may offer a new, non-opioid approach to managing chronic pain, as well as for treating epilepsy and seizure disorders. TRV045 has also demonstrated an anti-inflammatory effect in nonclinical studies that may have broad potential application in CNS disorders, autoimmune disease and inflammatory disease. TRV045 targets the S1P subtype 1 receptor and nonclinical data suggests that TRV045 effectively reverses neuropathic pain and reduces seizure risk without the immune-suppressing activity, or lymphopenia, observed with currently approved therapeutics targeting S1P receptors.

Target Engagement, Neuropathic Pain Proof-of-Concept Study

In September 2023, we announced data from our Target Engagement proof-of-concept study in a validated model of neuropathic pain. The study was a randomized, double-blind, placebo-controlled, single dose four-way cross-over study (n=25 subjects) designed to evaluate evidence of target engagement for TRV045, using a select battery of pharmacodynamic outcomes. The study used the validated PainCart® set of analgesic tests to evaluate potential central and peripheral nervous system effects and to provide insight into the potential anti-inflammatory actions of TRV045. Each subject received three different single doses of TRV045 (50mg, 150mg and 300mg) and placebo on four separate visits across the study duration. Plasma exposures of TRV045 in this study were comparable to levels seen in the previously reported Phase 1, FIH study and reached the anticipated targeted active dose range.

TRV045 demonstrated a statistically significant, dose-dependent reduction in mechanical allodynia following topical capsaicin application at 150mg and 300mg v. placebo. Allodynia was assessed by cutaneous pain sensation upon mechanical stimulation with Von Frey hair filaments, a validated model of neuropathic pain. The difference was

measured for each dose of TRV045 compared to placebo as the change from baseline in both the secondary area of allodynic sensation and the total area of allodynia across 10 hours following the dose of study medication. The change from baseline in painful surface area at the final 10 hour timepoint is shown below, along with the associated P-values for each treatment difference across the entire 10 hour period of observation. Differences were evident for both the 150mg and 300mg doses beginning at hour 2 and continuing through the entire period of study observation at hour 10.

Outcome	Treatment	Change from Baseline in Painful Surface Area at Final 10 Hour Timepoint (mm2)*	P-Value for Overall Treatment Difference v Placebo
Total Allodynic Area (mm2)	Placebo	-67.19	—
	TRV045 50mg	-211.61	0.1844
	TRV045 150mg	-389.45	0.0002
	TRV045 300mg	-731.78	0.0001
Secondary Allodynic Area (mm2)	Placebo	-15.79	—
	TRV045 50mg	-54.98	0.5313
	TRV045 150mg	-186.14	0.0022
	TRV045 300mg	-393.05	0.0023

* Least squares (LS) mean change from baseline

TRV045 further demonstrated a dose-dependent trend in change from baseline in the cold pressor test, and also demonstrated trends in reduction to heat pain detection threshold on both unexposed and capsaicin-treated forearm skin, on heat pain detection threshold on unexposed skin on the upper back, and pain tolerance in the electrical burst stimulation test, though these endpoints did not achieve statistical significance. TRV045 did not show a statistically significant difference or trend compared to placebo in other pain modalities.

Diabetic neuropathy is a common complication of both type 1 and type 2 diabetes, with pain in the extremities being one of the main symptoms. Other symptoms may include numbness, tingling, allodynia and hyperalgesia. Diabetic neuropathic pain, or DNP, is usually characterized as moderate to severe in nature and can substantially affect patients' quality of life as well as their social and psychological well-being. Approximately one quarter of people with diabetes are affected by DNP, totaling over 5 million people in the United States. During their lifetime, approximately 50% to 70% of diabetic patients may experience symptoms of DNP.

TMS Proof-of-Concept Study.

In September 2023, we also announced data from our transcranial magnetic stimulation, or TMS, proof-of-concept study for epilepsy. The TMS study was a randomized, double-blind, placebo-controlled, multiple dose, two-way cross-over study (n=25 subjects) designed to evaluate the pharmacodynamic effects of TRV045 (250mg) on cortical excitability in healthy male adults, using both EEG and EMG to measure the impact of TRV045 on the electrical excitation of the brain. The goal of the study was to provide further insight into TRV045 CNS target engagement and mechanism of action for the potential treatment of epilepsy and other CNS disorders. Each subject received one of two treatment sequences in random order: TRV045 at a dose of 250mg, followed by placebo; or placebo followed by 250mg of TRV045, each treatment sequence given once daily for four consecutive days. Plasma exposures of TRV045 in this study were comparable to levels seen in the previously reported Phase 1, FIH study and reached the anticipated targeted active dose range.

Among the EEG-related endpoints measured in the study, resting state EEG obtained before and after administration of TRV045, demonstrated statistically significant increases in the power spectral density on Day 4 in several of the middle to higher frequency bands including alpha, beta and gamma waves. The changes in alpha waves are

generally considered to be associated with conscious arousal and alertness, while beta waves are thought to be associated with GABA-mediated inhibitory cortical neurotransmission, and gamma waves are generally associated with cognitive processing, learning and memory. Alpha waves demonstrated this statistically significant increase in power in the frontal region (P=0.0164), as well as both left parietal (P=0.0047), and right parietal (P=0.0418) regions. This statistically significant increase in power was observed in the frontal region for beta waves (P=0.0235) and gamma waves (P=0.0343).

With respect to slow brain waves, which are generally associated with sedation or sleep, TRV045 showed a statistically significant decrease in the delta brain waves on Day 4 in the right parietal region (P=0.0432), and no significant difference in theta brain waves at any of the three observed regions.

Among the EMG-related endpoints measured in the study, TRV045 demonstrated evidence of reduction in cortical excitability, as measured by change in peak motor-evoked potential (MEP) amplitude, on Day 1 comparable in magnitude to the reduction in cortical excitability reported in similar test conditions in the same laboratory for approved anti-epileptic drugs, though this result did not achieve statistical significance. There was no difference in mean peak MEP amplitude on Day 4, and no difference in resting motor threshold (RMT) on Day 1 or Day 4 or other EMG-related endpoints.

Epilepsy, one of the most common neurological diseases in the world, is a chronic disorder characterized by recurrent seizures. Nearly 50 million people suffer from epilepsy worldwide, including 3 million adults and 470,000 children in the United States. 150,000 new cases of epilepsy are reported in the United States each year. According to the CDC, 56% of adults living with diagnosed epilepsy continue to have seizures.

Subjects in both studies were enrolled outside of the United States, and the studies were not conducted under the Investigational New Drug Application for TRV045.

TMS Proof-of-Concept Studies – Safety and Tolerability

There were no drug-related adverse events and no serious adverse events were reported in either proof-of-cponcept study. Of the adverse events, 98% (102 of 104) were reported as mild in the Target Engagement study, and 99% (79 of 80) were reported as mild in the TMS study. The most common adverse events reported were headaches, somnolence, dizziness and fatigue.

In screening and follow-up physical exams, including ophthalmologic exams, there were no clinically significant observations. Laboratory results also showed no clinically significant reduction in total lymphocyte count, no clinically significant changes in heart rate or blood pressure, and no clinically significant changes in ECG interval measures (including no prolongation of PR or QTcF intervals).

This safety and tolerability data in 50 subjects is generally consistent with, and further builds upon, the 89-subject data from the first-in-human study of TRV045 reported in November 2022. The data supports the Company's belief that TRV045 has the potential to effectively target indications, such as neuropathic pain and epilepsy, without adverse events such as lymphopenia, bradycardia, pulmonary adverse events and ophthalmologic adverse events, which have been reported with other S1P receptor modulators.

Intellectual Property

We wholly own the S1P patent portfolio, including one pending provisional application, two issued U.S. patents (U.S. Patent Nos. 11,912,693 and 11,884,655) claiming S1P receptor modulators and/or methods of making or using the same. We also have issued patents in Japan, India, Israel, and South Africa, and pending applications in the United States, Australia, Brazil, Canada, China, Europe, Israel, India, Japan, South Korea, Hong Kong, Russia, United Arab Emirates, Mexico, and New Zealand. The applications are directed to, amongst other things, compounds that modulate the S1P receptor and methods of making or using these compounds, including methods of treating pain, epilepsy, mood disorders, anxiety disorders, and trauma-and stressor-related disorders. Patents that could issue in the future from the national phase applications would be expected to expire no earlier than 2038 subject to any disclaimers or extensions.

We are aware of a certain U.S. patent owned by a third party with claims that are broadly directed to a method of treating chemotherapy induced neuropathic pain with an S1P receptor agonist or an S1P receptor antagonist. Although we do not believe that this is a valid patent, this patent could be construed to cover our S1P compounds.

TRV734

TRV734 is a small molecule G-protein biased ligand of the MOR that we discovered and have developed through Phase 1 as a first-line, orally administered compound for the treatment of moderate-to-severe acute and chronic pain. Like OLINVYK, TRV734 utilizes a well-established mechanism of pain relief by targeting the MOR. Also like OLINVYK, it does so with enhanced selectivity for the G-protein signaling pathway, which in nonclinical studies was linked to analgesia, as opposed to the beta-arrestin signaling pathway, which in nonclinical studies was associated with the development of side effects. Subject to successful nonclinical and clinical development and regulatory approval, we believe TRV734 may have an improved efficacy and side effect profile as compared to current commonly prescribed oral analgesics, such as oxycodone. In addition, TRV734's mechanism of action suggests it may offer valuable benefits for another unmet medical need: the management of opioid dependence associated with OUD. We intend to continue to focus our efforts for TRV734 on securing a development and commercialization partner for this asset.

Clinical development

We have completed three Phase 1 trials of TRV734 in healthy volunteers, including a single ascending dose study, a multiple ascending dose study, and a pharmacokinetic study. In these studies, a total of 127 healthy volunteers were exposed to TRV734 at doses between 2 mg and 250 mg. We incorporated measures to assess the potential for analgesic efficacy and tolerability advantages in these studies. Based on these data and data for OLINVYK, we believe that TRV734 may offer an improved efficacy profile as compared to current opioid therapies or equivalent efficacy with an improved gastrointestinal tolerability and respiratory safety profile.

In collaboration with NIDA, we intend to pursue a clinical study to determine whether TRV734 decreases symptoms of opioid withdrawal in patients with OUD. We expect to initiate a randomized, double-blind, four-period, placebo- and positive-controlled study that will enroll approximately 50 opioid-dependent patients undergoing stable methadone maintenance therapy. The primary objective of the study is to assess the ability of TRV734 to reduce acute opioid craving symptoms, as measured by the Subjective Opioid Withdrawal Scale. The study will also evaluate whether TRV734 suppresses withdrawal signs using the Clinical Opioid Withdrawal Scale. Secondary outcomes will include assessments of safety and measures of neurocognitive changes. In June 2021, we announced that the study, which had been paused since March 2020 due to the global COVID-19 pandemic, had resumed recruiting patients.

NIDA has previously generated nonclinical data in a rodent model of maintenance treatment showing that chronic administration of TRV734 reduced oxycodone-seeking in rats. TRV734 may provide an alternative to existing therapies such as methadone and buprenorphine. Successful therapy with methadone is limited by side effects that include sedation and constipation, while use of buprenorphine is limited by lower maximal efficacy and challenges with initial induction of therapy. It is hypothesized that a MOR-biased agonist may provide high efficacy for preventing symptoms of opioid withdrawal while offering a more benign side-effect profile.

Intellectual property

We wholly own the TRV734 patent portfolio, including two issued U.S. patents (U.S. Patent Nos. 9,044,469 and 10,588,898) claiming TRV734, other compounds and/or methods of making or using the same. These patents are expected to expire no earlier than 2032, subject to any disclaimers or extensions. We also have issued patents in Australia, Brazil, Canada, China, Europe, Eurasia, Hong Kong, Macau, Israel, Japan, India, South Korea, and New Zealand claiming TRV734, other compounds and/or methods of making or using the same. We also have patent applications pending in the United States, Europe, and Japan. The issued patents and patents that could issue in the future from these allowed or pending applications outside the United States are expected to expire no earlier than 2032, subject to any disclaimers or extensions.

One of the two issued U.S. patents (U.S. Patent No. 10,588,898) also claims, among other things, methods of using TRV734 or compositions comprising TRV734 for treating drug abuse. We also have issued patents in Brazil, Canada, Israel, Japan, and South Korea, which claim, among other things, methods of using TRV734 or compositions comprising TRV734 for treating drug abuse. The issued patent (U.S. Patent No. 10,588,898) is expected to expire no earlier than 2032. The issued patents outside the United States are expected to expire no earlier than 2032, subject to any disclaimers or extensions.

Intellectual Property

We strive to protect the proprietary technologies that we believe are important to our business, including seeking and maintaining patent protection intended to cover the composition of matter of our product candidates, their methods of use, related technology and other inventions that are important to our business. We also rely on trade secrets and careful monitoring of our proprietary information to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection.

Our success will depend significantly on our ability to obtain and maintain patent and other proprietary protection for commercially important technology, inventions and know-how related to our business, defend and enforce our patents, maintain our licenses to use intellectual property owned by third parties, preserve the confidentiality of our trade secrets and operate without infringing valid and enforceable patents and other proprietary rights of third parties. We also rely on know-how, and continuing technological innovation to develop, strengthen and maintain our proprietary position in the field of modulating G-protein coupled receptors with biased ligands.

One or more third parties may hold intellectual property, including patent rights, that is important or necessary to the development of our products. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our products, in which case we would be required to obtain a license from these third parties on commercially reasonable terms, or our business could be harmed, possibly materially. If we were not able to obtain a license or were not able to obtain a license on commercially reasonable terms, our business could be harmed, possibly materially.

We plan to continue to expand our intellectual property estate by filing patent applications directed to dosage forms and methods of treatment for our product candidates. We anticipate seeking patent protection in the United States and internationally for compositions of matter covering the compounds, the chemistries and processes for manufacturing these compounds and the use of these compounds in a variety of therapies.

The patent positions of biopharmaceutical companies like us are generally uncertain and involve complex legal, scientific and factual questions. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and the patent's scope can be modified after issuance. Consequently, we do not know whether any of our product candidates will be protectable or remain protected by enforceable patents. We cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient proprietary protection from competitors. Any patents that we hold may be challenged, circumvented or invalidated by third parties.

Because many patent applications in the United States and certain other jurisdictions are maintained in secrecy for 18 months, and since publication of discoveries in the scientific or patent literature often lags behind actual discoveries, we cannot be certain that we will be able to obtain patent protection for the inventions disclosed and/or claimed in our pending patent applications. Moreover, we may have to participate in interference proceedings declared by the United States Patent and Trademark Office or a foreign patent office to determine priority of invention or in post grant challenge proceedings, such as oppositions, *inter partes* review, post grant review or a derivation proceeding, that challenge our entitlement to an invention or the patentability of one or more claims in our patent applications or issued patents. Such proceedings could result in substantial cost, even if the eventual outcome is favorable to us.

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the earliest date of filing a PCT application or a non-provisional patent application, subject to any disclaimers or extensions. The term of a patent in the United

States can be adjusted and extended due to the failure of the United States Patent and Trademark Office following certain statutory and regulation deadlines for issuing a patent.

In the United States, the patent term of a patent that covers an FDA approved drug also may be eligible for patent term extension, which permits patent term restoration as compensation for a portion of the patent term lost during clinical development and the FDA regulatory review process. The Hatch Waxman Act permits a patent term extension of up to five years beyond the expiration of the patent. The length of the patent term extension is related to the length of time the drug is under clinical development and regulatory review. Patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only one patent applicable to an approved drug may be extended. Similar provisions are available in Europe and other non-United States jurisdictions to extend the term of a patent that covers an approved drug. In the future, if and when our additional pharmaceutical products receive FDA approval, we expect to apply for patent term extensions on patents covering those products much in the same manner as we did for OLINVYK. Although, we intend to seek patent term extensions to any of our issued patents in any jurisdiction where these are available there is no guarantee that the applicable authorities, including the United States Patent and Trademark Office, will agree with our assessment of whether such extensions should be granted, and even if granted, the length of such extensions.

We also rely on trade secret protection for our confidential and proprietary information. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology. Thus, we may not be able to meaningfully protect our trade secrets. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual during the course of the individual's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. In the case of employees, the agreements provide that all inventions conceived by the individual, and which are related to our current or planned business or research and development or made during normal working hours, on our premises or using our equipment or proprietary information, are our exclusive property.

Manufacturing

We do not own or operate any manufacturing facilities. We currently rely, and expect to continue to rely, on third parties for the manufacture of our product candidates for nonclinical and clinical testing, as well as for commercial manufacture. See "—OLINVYK (oliceridine) injection—Manufacturing."

The use of contract development and manufacturing organizations, or CDMOs, and reliance on collaboration partners is cost-efficient and has eliminated the need for our direct investment in manufacturing facilities and additional staff early in development. We believe available CDMOs are capable of providing sufficient quantities of our commercial product and product candidates to meet anticipated full-scale commercial demands.

Commercialization

We launched the customer-facing elements of our commercial team in the first quarter of 2021 with Syneos Health, a contract sales organization, to assist in the sourcing, training and deployment of a range of customer-facing roles. In 2022, we transitioned to an in-house U.S. commercial team. In April 2024, we announced that OLINVYK remains available for purchase by customers, but that we are reducing commercial support for the product to preserve capital as we conduct a process to explore a range of strategic alternatives for OLINVYK. Nowithstanding our reduction of commercial support for OLINVYK, we will continue to comply with all regulatory requirements, including post-marketing surveillance and reporting obligations.

Competition

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. While we believe that our technology, knowledge, experience and scientific resources provide us with competitive advantages, we face potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions and governmental agencies and public and private research institutions. OLINVYK and any further product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future. Products in development by other companies may provide efficacy, safety, convenience and other benefits that are not provided by currently marketed therapies. As a result, they may provide significant competition for OLINVYK and any of our additional product candidates for which we obtain marketing approval.

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

The key competitive factors affecting the success of all of our therapeutic product candidates, if approved, are likely to be their efficacy, safety, convenience, price, the level of generic competition and the availability of reimbursement from government and other third-party payors.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. In addition, our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of generic products. Generic products that broadly address these indications are currently on the market for the indications that we are pursuing, and additional products are expected to become available on a generic basis over the coming years. If our product candidates achieve marketing approval, we expect that they will be priced at a significant premium over competitive generic products.

Government Regulation and Product Approval

Government authorities in the United States, at the federal, state and local level, and in other countries extensively regulate, among other things, the research, development, testing, manufacture, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, import and export of pharmaceutical products such as those we are developing. The processes for obtaining regulatory approvals in the United States and in foreign countries, along with subsequent compliance with applicable statutes and regulations, require the expenditure of substantial time and financial resources.

FDA 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. Failure to comply with the applicable United States requirements at any time during the product development process, approval process or after approval, may subject an applicant to a variety of administrative or judicial sanctions, such as the FDA's refusal to approve pending NDAs, withdrawal of an approval, imposition of a

clinical hold, issuance of warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties.

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

- completion of nonclinical 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, covering each clinical site before each trial may be initiated;
- performance of human clinical trials, including adequate and well-controlled clinical trials, in accordance with good clinical practices, or GCP, to establish the safety and efficacy of the proposed drug product for each indication;
- submission of an NDA to the FDA;
- 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 cGMP, and to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity, as well as satisfactory completion of an FDA inspection of selected clinical sites to determine GCP compliance;
- FDA review and approval of an NDA; and
- in certain cases, DEA review and scheduling activities prior to launch.

Nonclinical Studies

Nonclinical studies include laboratory evaluation of drug substance chemistry, toxicity and drug product formulation, as well as animal studies to assess potential safety and efficacy. An IND sponsor must submit the results of the nonclinical 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. Manufacture of drug substance, drug product and the labeling and distribution of clinical supplies must all comply with cGMP standards. Some nonclinical 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 the data submitted in the IND or the proposed clinical trials and places the 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 investigational new drug 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. In addition, an IRB covering each institution

participating in the clinical trial must review and approve the plan for any clinical trial before it commences at that institution, and the IRB must continue to oversee the clinical trial while it is being conducted. Information about certain clinical trials must be submitted within specific timeframes to the National Institutes of Health, or NIH, for public dissemination on their ClinicalTrials.gov website.

Human clinical trials are typically conducted in three sequential phases, which may overlap or be combined. In Phase 1, 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 initial indication of its effectiveness. In Phase 2, the drug typically is administered to a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage. In Phase 3, the drug is administered to an expanded patient population, 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.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if serious adverse events occur. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, or at all. Furthermore, the FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients.

Marketing Approval

Assuming successful completion of the required clinical testing, the results of the nonclinical and clinical studies, 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. In most cases, the submission of an NDA is subject to a substantial application user fee. Under the Prescription Drug User Fee Act, or PDUFA, guidelines that are currently in effect, the FDA has agreed to certain performance goals regarding the timing of its review of a marketing application.

In addition, under the Pediatric Research Equity Act an NDA or supplement 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 also may require a risk evaluation and mitigation strategy, or REMS, to mitigate any identified or suspected serious risks and ensure safe use of the drug. The REMS plan could include medication guides, physician communication plans, assessment plans and elements to assure safe use, such as restricted distribution methods, patient registries or other risk minimization tools. We expect that any oral mu-opioid agonist products may be subject to a REMS, since currently marketed oral opioid products are subject to this requirement. OLINVYK is an IV opioid and is not subject to a REMS.

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. 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.

The FDA typically refers a question regarding a novel drug to an external 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, referred to as a Pre-Approval Inspection, or PAI. 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 will typically inspect one or more clinical trial sites to assure compliance with GCPs.

The testing and approval process for an NDA requires substantial time, effort and financial resources, and each may take several years to complete. Data obtained from nonclinical and clinical testing are not always conclusive and may be susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. The FDA may not grant approval of an NDA on a timely basis, or at all.

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. 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 nonclinical testing in order for the 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. The FDA reviews NDA resubmissions in two or six months depending on the type of information included. An approval letter authorizes commercial distribution and marketing of the drug with specific prescribing information for specific indications. For some products, an additional step of DEA review and scheduling is required.

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, including a boxed warning, require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess a drug's safety after approval, require testing and surveillance programs to monitor the product after commercialization or impose other conditions, including distribution restrictions or other risk management mechanisms under a REMS which can materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-marketing studies or surveillance programs. 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.

Expedited Review and Approval

The FDA has various programs, including Fast Track, Breakthrough Therapy designation, priority review, and accelerated approval, that are intended to expedite or simplify the process for reviewing drugs, and/or provide for the approval of a drug on the basis of a surrogate endpoint. Even if a drug qualifies for one or more of these programs, the FDA may later decide that the drug no longer meets the conditions for qualification or that the time period for FDA review or approval will be shortened. Generally, drugs that are eligible for these programs are those for serious or life-threatening conditions, those with the potential to address unmet medical needs and those that offer meaningful benefits over existing treatments. For example, Fast Track is a process designed to facilitate the development and expedite the review of drugs to treat serious or life-threatening diseases or conditions and fill unmet medical needs. Priority review is designed to give drugs that offer major advances in treatment or provide a treatment where no adequate therapy exists an initial review within six months as compared to a standard review time of ten months.

Although Fast Track and priority review do not affect the standards for approval, the FDA will attempt to facilitate early and frequent meetings with a sponsor of a Fast Track designated drug and expedite review of the application for a drug designated for priority review. Accelerated approval, which is described in Subpart H of 21 Code

of Federal Regulations, or 21 CFR Part 314, provides for an earlier approval for a new drug that is intended to treat a serious or life-threatening disease or condition and that fills an unmet medical need based on a surrogate endpoint. A surrogate endpoint is a clinical measurement or other biomarker used as an indirect or substitute measurement to predict a clinically meaningful outcome. As a condition of approval, the FDA may require that a sponsor of a product candidate receiving accelerated approval perform post-marketing clinical trials.

A Breakthrough Therapy designation is intended to expedite the development and FDA review of drugs for serious or life-threatening conditions or where preliminary clinical evidence indicates that the drug may demonstrate substantial improvement on a clinically significant endpoint(s) over available therapies. A request for Breakthrough Therapy designation should be submitted concurrently with, or as an amendment to an IND.

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 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 user fee requirements, as well as new application fees for supplemental applications with clinical data.

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 clinical trials in pediatric patients or other Phase 4 trials, and surveillance to further assess and monitor the product's safety and effectiveness after commercialization.

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 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-marketing 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 license approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Although physicians, in the practice of medicine, may prescribe approved drugs for unapproved indications, pharmaceutical companies generally are required to promote their drug products only for the approved indications and in accordance with the provisions of the approved label. However, companies may share truthful and not misleading information that is otherwise consistent with a product's approved labeling. 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.

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act, or PDMA, which regulates the distribution of drugs and drug samples at the federal level, and sets minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution.

DEA Regulation

OLINVYK has been classified as a Schedule II controlled substance under the Federal Controlled Substances Act of 1970, or CSA. The CSA establishes registration, security, recordkeeping, reporting, storage, distribution and other requirements administered by the DEA. The DEA is concerned with the control of handlers of controlled substances, and with the equipment and raw materials used in their manufacture and packaging, in order to prevent loss and diversion into illicit channels of commerce.

The DEA regulates controlled substances as Schedule I, II, III, IV or V substances. Schedule I substances by definition have no established medicinal use and may not be marketed or sold in the United States. A pharmaceutical product may be listed as Schedule II, III, IV or V, with Schedule II substances considered to present the highest risk of abuse and Schedule V substances the lowest relative risk of abuse among such substances. Because it is a Schedule II controlled substance, the manufacture, packaging, shipment, storage, sale and use of OLINVYK is subject to a high degree of regulation.

Annual registration is required for any facility that manufactures, packages, distributes, dispenses, imports, exports, or conducts research with any controlled substance. The registration is specific to the particular location, activity and controlled substance schedule.

The DEA typically inspects a facility to review its security measures prior to issuing a registration. Security requirements vary by controlled substance schedule, with the most stringent requirements applying to Schedule I and Schedule II substances. Required security measures include background checks on employees and physical control of inventory through measures such as cages, surveillance cameras and inventory reconciliations. Records must be maintained for the handling of all controlled substances, and periodic reports made to the DEA. Reports must also be made for thefts or losses of any controlled substance, and to obtain authorization to destroy any controlled substance. In addition, special authorization and notification requirements apply to imports and exports.

In addition, a DEA quota system controls and limits the availability and production of controlled substances in Schedule I or II. Distributions of any Schedule I or II controlled substance must also be accompanied by special order forms, with copies provided to the DEA. The DEA may adjust aggregate production quotas and individual production and procurement quotas during the year and across years, and the DEA has substantial discretion in whether or not to make such adjustments. Our contract development and manufacturing organizations (CDMO's) quota of an active ingredient may not be sufficient to meet commercial demand or complete clinical trials. Any delay or refusal by the DEA in establishing our CDMO's quota for controlled substances could delay or stop our clinical trials or product launches, or impact the ability to fill orders of approved products such as OLINVYK.

To meet its responsibilities, the DEA conducts periodic inspections of registered establishments that handle controlled substances. Individual states also regulate controlled substances, and we and our CDMO's will be subject to state regulation with respect to the distribution of controlled substance products.

Federal and State Fraud and Abuse and Data Privacy and Security Laws and Regulations

In addition to FDA restrictions on marketing of pharmaceutical products, federal and state fraud and abuse laws restrict business practices in the biopharmaceutical industry. These laws include anti-kickback and false claims laws and regulations, as well as transparency and data privacy and security laws and regulations.

The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration 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 under Medicare, Medicaid or other federal healthcare programs. The term "remuneration" has been broadly interpreted to include anything of value. The federal Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, formulary managers, and others on the other hand. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly and require strict compliance to offer protection. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the statute has been violated.

The reach of the federal Anti-Kickback Statute was also broadened by the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively PPACA, which, among other things, amended the intent requirement of the federal Anti-Kickback Statute such that a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. In addition, PPACA provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act or the civil monetary penalties statute, which 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. PPACA also created new federal requirements for reporting, by applicable manufacturers of covered drugs of payments and other transfers of value to, as well as ownership interests held by, physicians and teaching hospitals.

The federal criminal and civil false claims laws, including the federal False Claims Act, and civil monetary penalties laws and civil monetary penalties laws, including the federal False Claims Act, prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to 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. A claim includes "any request or demand" for money or property presented to the U.S. government. Pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Companies have been prosecuted for causing false claims to be submitted because of the companies' marketing of products for unapproved, and thus non-reimbursable, uses.

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, created additional federal civil and criminal statutes that prohibit knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private third-party payors 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. Also, many states 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.

The federal Physician Payments Sunshine Act, also known as Open Payments program, 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 specific exceptions, to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to "payments or other transfers of value" made to physicians, as defined by such law, and teaching hospitals and applicable manufacturers and applicable group purchasing organizations to

report annually to CMS ownership and investment interests held by physicians and their immediate family members. Beginning in 2022, applicable manufacturers are also required to report such information regarding payments and transfers of value provided, as well as ownership and investment interests held, during the previous year to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists and certified nurse-midwives.

In addition, we may be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their respective implementing regulations, including the final omnibus rule published on January 25, 2013, imposed specified requirements relating to the privacy, security and transmission of individually identifiable health information on "covered entities" including certain healthcare providers, health plans, and healthcare clearinghouses. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to "business associates," defined as independent contractors or agents of covered entities that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of available statutory exceptions and regulatory safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of such laws. If our operations are found to be in violation of any of the federal or state laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including significant criminal, civil, and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government healthcare programs, integrity oversight and reporting obligations to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. To the extent that any of our products are sold in a foreign country, we may be subject to similar foreign laws and regulations, which may include, for instance, applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws, implementation of corporate compliance programs and reporting of payments or transfers of value to healthcare professionals, and data privacy requirements such as the General Data Protection Regulation (EU) 2016/679.

The Foreign Corrupt Practices Act

The Foreign Corrupt Practices Act, or FCPA, prohibits any U.S. individual or business from paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring such companies to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations. In Europe, and throughout the world, other countries have enacted anti-bribery laws and/or regulations similar to the FCPA. Violations of any of these antibribery laws, or allegations of such violations, could have a negative impact on our business, results of operations and reputation.

Coverage and Reimbursement

The commercial success of our product candidates and our ability to commercialize any approved product candidates successfully will depend in part on the extent to which governmental payor programs at the federal and state levels, including Medicare and Medicaid, private health insurers and other third-party payors provide coverage for and establish adequate reimbursement levels for our product candidates. However, decisions regarding the extent of coverage and amount of reimbursement to be provided are made on a payor-by-payor basis. Government health administration authorities, private health insurers and other organizations generally decide which drugs they will pay for and establish

reimbursement levels for healthcare. In particular, in the United States, private health insurers and other third-party payors often provide reimbursement for products and services based on the level at which the government provides reimbursement through the Medicare or Medicaid programs for such treatments. In the United States, the European Union and other potentially significant markets for our product candidates, government authorities and third-party payors are increasingly attempting to limit or regulate the price of medical products and services, particularly for new and innovative products and therapies, which often has resulted in average selling prices lower than they would otherwise be. Further, the increased emphasis on managed healthcare in the United States and on country and regional pricing and reimbursement controls in the European Union will put additional pressure on product pricing, reimbursement and usage, which may adversely affect our future product sales and results of operations. These pressures can arise from rules and practices of managed care groups, judicial decisions and governmental laws and regulations related to Medicare, Medicaid and healthcare reform, pharmaceutical coverage and reimbursement policies and pricing in general.

Third-party payors are increasingly imposing additional requirements and restrictions on coverage and limiting reimbursement levels for medical products. For example, in the United States, federal and state governments reimburse covered prescription drugs at varying rates generally below average wholesale price. These restrictions and limitations influence the purchase of healthcare services and products. Third-party payors may limit coverage to specific drug products on an approved list, or formulary, which might not include all of the FDA-approved drug products for a particular indication. Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain FDA approvals. Our product candidates may not be considered medically necessary or cost-effective. A payor's decision to provide coverage for a drug product 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 drug development. In addition, for hospital products, a private health insurer or Medicare will typically reimburse a fixed fee for certain procedures, including in-patient surgeries. Pharmaceutical products such as OLINVYK that may be used in connection with the surgery generally will not be separately reimbursed and, therefore, a hospital would have to assess the cost of OLINVYK relative to its benefits. Current or future efforts to limit the level of reimbursement for in-patient hospital procedures could cause a hospital to decide not to use OLINVYK.

The Inflation Reduction Act of 2022 contains substantial drug pricing reforms, including the establishment of a drug price negotiation program within the U.S. Department of Health and Human Services that would require manufacturers to charge a negotiated "maximum fair price" for certain selected drugs or pay an excise tax for noncompliance, the establishment of rebate payment requirements on manufacturers of certain drugs payable under Medicare Parts B and D to penalize price increases that outpace inflation, and requires manufacturers to provide discounts on Part D drugs. Substantial penalties can be assessed for noncompliance with the drug pricing provisions in the Inflation Reduction Act of 2022. The Inflation Reduction Act of 2022 could have the effect of reducing the prices we can charge and reimbursement we receive for our product and our product candidates, if approved, thereby reducing our profitability, and could have a material adverse effect on our financial condition, results of operations and growth prospects. The effect of Inflation Reduction Act of 2022 on our business and the pharmaceutical industry in general is not yet known. Future efforts to reform healthcare or reduce costs under government insurance programs may result in lower reimbursement for our products and product candidates or exclusion of our products and product candidates from coverage. The cost containment measures that healthcare payors and providers are instituting and any healthcare reform could significantly reduce our revenue from the sale of any approved product candidates. We cannot provide any assurances that we will be able to obtain and maintain third-party coverage or adequate reimbursement for our product candidates in whole or in part.

Impact of Healthcare Reform on Coverage, Reimbursement and Pricing

The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that could restrict or regulate post-approval activities relating to our product and product candidates, if approved, and affect our ability to successfully commercialize our product and product candidates, if approved, including implementing cost-containment programs to limit the growth of government-paid healthcare costs,

including price controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs.

The Affordable Care Act was intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms.

Among the provisions of the Affordable Care Act that have been implemented since enactment and are of importance to the successful commercialization of a pharmaceutical product are the following:

- an annual, nondeductible fee on any entity that manufactures, or imports specified branded prescription drugs or biologic agents;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- expansion of healthcare fraud and abuse laws, including the U.S. civil False Claims Act and the Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;
- a Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for a manufacturer's outpatient drugs to be covered under Medicare Part D;
- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- 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;
- expansion of eligibility criteria for Medicaid programs;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- requirements to report certain financial arrangements with physicians and teaching hospitals;
- a requirement to annually report certain information regarding drug samples that manufacturers and distributors provide to physicians; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

There have been significant ongoing judicial, administrative, executive and legislative efforts to modify or eliminate the Affordable Care Act. For example, the Tax Act enacted on December 22, 2017, repealed the shared responsibility payment for individuals who fail to maintain minimum essential coverage under section 5000A of the Internal Revenue Code, commonly referred to as the individual mandate. Other legislative changes have been proposed and adopted since passage of the Affordable Care Act. The Budget Control Act of 2011, among other things, created the Joint Select Committee on Deficit Reduction to recommend proposals in spending reductions to Congress. The Joint Select Committee did not achieve its targeted deficit reduction of an amount greater than $1.2 trillion for the fiscal years 2012 through 2021, triggering the legislation's automatic reductions to several government programs. These reductions included aggregate reductions to Medicare payments to healthcare providers of up to 2.0% per fiscal year, which went into effect in April 2013. Subsequent litigation extended the 2% reduction, on average, to 2030 unless additional Congressional action is taken. The Coronavirus Aid, Relief and Economic Security Act, or the CARES Act, which was

designed to provide financial support and resources to individuals and businesses affected by the COVID-19 pandemic, suspended the 2% Medicare sequester from May 1, 2020 to March 31, 2022. As of July 2, 2022, the 2% sequester resumed. The sequester will remain in place through 2030. On January 2, 2013, the American Taxpayer Relief Act was signed into law, which, among other things, reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

The Affordable Care Act has also been subject to challenges in the courts. On December 14, 2018, a Texas U.S. District Court Judge ruled that the Affordable Care Act is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. On December 18, 2019, the Fifth Circuit U.S. Court of Appeals held that the individual mandate is unconstitutional and remanded the case to the Texas District Court to reconsider its earlier invalidation of the entire Affordable Care Act. On June 17, 2021, the Supreme Court ruled that the plaintiffs lacked standing to challenge the law as they had not alleged personal injury traceable to the allegedly unlawful conduct. As a result, the Supreme Court did not rule on the constitutionality of the ACA or any of its provisions. Further changes to and under the Affordable Care Act remain possible but it is unknown what form any such changes or any law proposed to replace or revise the Affordable Care Act would take, and how or whether it may affect our business in the future. We expect that changes to the Affordable Care Act, the Medicare and Medicaid programs, changes allowing the federal government to directly negotiate drug prices and changes stemming from other healthcare reform measures, especially with regard to healthcare access, financing or other legislation in individual states, could have a material adverse effect on the healthcare industry.

We expect that the Affordable Care Act, as well as other healthcare reform measures that have and may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for our product and product candidates, if approved, and could seriously harm our future revenues. Any reduction in reimbursement from Medicare, Medicaid, or other government programs may result in a similar reduction in payments from private payers. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or successfully commercialize our product and product candidates, if approved.

Exclusivity and Approval of Competing Products

Hatch-Waxman Patent Exclusivity

In seeking approval for a drug through an NDA, applicants are required to list with the FDA each patent with claims that cover the applicant's product or a method of using the product. Upon approval of a drug, each of the patents listed in the application for the drug is then published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential competitors in support of approval of an abbreviated new drug application, or ANDA, or 505(b)(2) NDA. Generally, an ANDA provides for marketing of a drug product that has the same active ingredients in the same strengths, dosage form and route of administration as the listed drug and has been shown to be bioequivalent through *in vitro* and/or *in vivo* testing or otherwise to the listed drug. ANDA applicants are not required to conduct or submit results of nonclinical or clinical tests to prove the safety or effectiveness of their drug product, other than the requirement for bioequivalence testing. Drugs approved in this way are commonly referred to as "generic equivalents" to the listed drug, and can often be substituted by pharmacists under prescriptions written for the original listed drug. 505(b)(2) NDAs generally are submitted for changes to a previously approved drug product, such as a new dosage, dosage form, or indication.

The ANDA or 505(b)(2) NDA applicant is required to certify to the FDA concerning any patents listed for the approved product in the FDA's Orange Book, except for patents covering methods of use for which the ANDA applicant is not seeking approval. Specifically, the applicant must certify with respect to each patent that:

- the required patent information has not been filed;
- the listed patent has expired;

- the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or
- the listed patent is invalid, unenforceable or will not be infringed by the new product.

Generally, the ANDA or 505(b)(2) NDA cannot be approved until all listed patents have expired, except when the ANDA or 505(b)(2) NDA applicant challenges a patent of a listed drug. A certification that the proposed product will not infringe the already approved product's listed patents or that such patents are invalid or unenforceable is called a Paragraph IV certification. If the applicant does not challenge the listed patents or indicate that it is not seeking approval of a patented method of use, the ANDA or 505(b)(2) NDA application will not be approved until all the listed patents claiming the referenced product have expired.

If the ANDA or 505(b)(2) NDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the application has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days after the receipt of notice of the Paragraph IV certification automatically prevents the FDA from approving the ANDA or 505(b)(2) NDA until the earlier of 30 months, expiration of the patent, settlement of the lawsuit or a decision in the infringement case that is favorable to the ANDA applicant.

Hatch-Waxman Non-Patent Exclusivity

Market and data exclusivity provisions under the FDCA also can delay the submission or the approval of certain applications for competing products. The FDCA provides a five-year period of non-patent data exclusivity within the United States to the first applicant to gain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the activity of the drug substance. OLINVYK has been designated as a new chemical entity in the FDA's Orange Book. During the exclusivity period, the FDA may not accept for review an ANDA or a 505(b)(2) NDA submitted by another company that contains the previously approved active moiety. However, an ANDA or 505(b)(2) NDA may be submitted after four years if it contains a certification of patent invalidity or noninfringement. The FDCA also provides three years of marketing exclusivity for an NDA, 505(b)(2) NDA, or supplement to an existing NDA or 505(b)(2) NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant, are deemed by the FDA to be essential to the approval of the application or supplement. Three-year exclusivity may be awarded for changes to a previously approved drug product, such as new indications, dosages, strengths or dosage forms of an existing drug. This three-year exclusivity covers only the conditions of use associated with the new clinical investigations and, as a general matter, does not prohibit the FDA from approving ANDAs or 505(b)(2) NDAs for generic versions of the original, unmodified drug product. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA; however, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the nonclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Pediatric Exclusivity

Pediatric exclusivity is another type of non-patent marketing exclusivity in the United States and, if granted, provides for the attachment of an additional six months of marketing protection to the term of any existing regulatory exclusivity, including the non-patent exclusivity periods described above. This six-month exclusivity may be granted if an NDA sponsor submits pediatric data that fairly respond to a written request from the FDA for such data. The data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, the additional protection is granted. If reports of requested pediatric studies are submitted to and accepted by the FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity or Orange Book listed patent protection cover the drug are extended by six months. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot approve an ANDA or 505(b)(2) application owing to regulatory exclusivity or listed patents. When any of our products is approved, we anticipate seeking pediatric exclusivity when it is appropriate.

Foreign Regulation

To market any product outside of the United States, we would need to comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of our products. For example, in the European Union, we must obtain authorization of a clinical trial application, or CTA, in each member state in which we intend to conduct a clinical trial. Whether or not we obtain FDA approval for a product, we would need to obtain the necessary approvals by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others.

Employees and Human Capital Resources

Investing in, developing, and maintaining human capital is critical to our success. As of December 31, 2023, we had 23 employees, all of whom were located in the United States. We emphasize a number of measures and objectives in managing our human capital assets, including, among others, employee safety and wellness, talent acquisition and retention, employee engagement, development, and training, diversity and inclusion, and compensation and pay equity. None of our employees are represented by a labor union or covered by a collective bargaining agreement. We consider our relationship with our employees to be good.

In April 2024, we announced that OLINVYK remains available for purchase by customers, but that we are reducing commercial support for the product to preserve capital as we conduct a process to explore a range of strategic alternatives for OLINVYK. Following this realignment of resources, as well as other changes, as of the date of this annual report we had 18 employees, all of whom were located in the United States.

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

The success of our business is fundamentally connected to the well-being of our employees. Accordingly, we are committed to their health, safety and wellness. We provide our employees and their families with access to a variety of innovative, flexible and convenient health and wellness programs, including benefits that provide protection and security so they can have peace of mind concerning events that may require time away from work or that impact their financial well-being; that support their physical and mental health by providing tools and resources to help them improve or maintain their health status and encourage engagement in healthy behaviors; and that offer choice where possible so they can customize their benefits to meet their needs and the needs of their families. In response to the COVID-19 pandemic, we implemented significant changes that we determined were in the best interest of our employees, as well as the community in which we operate, and which comply with government regulations, including working from home where appropriate.

Corporate Compliance Program

Our business is subject to extensive regulations. Management has designed and implemented a comprehensive corporate compliance program as part of our commitment to comply fully with applicable criminal, civil and administrative laws, rules and regulations and to maintain the high standards of conduct we expect from all of our employees. We continuously review this compliance program and work to enhance it as and when appropriate. The primary purposes of the compliance program include, among other things:

- Assessing and identifying risks affecting our Company and its products;

- training and educating employees and certain outside professionals who provide services to our Company to promote awareness of legal and regulatory requirements, a culture of compliance, and the necessity of complying with all applicable laws, rules, regulations and requirements;

- developing and implementing compliance policies and procedures and creating controls to support compliance with applicable laws, rules, regulations and requirements and our policies and procedures;

- auditing and monitoring the activities of our operations and business support functions to identify and mitigate risks and potential instances of noncompliance in a timely manner; and

- ensuring that we promptly take steps to resolve any instances of noncompliance and address areas of weakness or potential noncompliance.

We have a Code of Conduct and Business Ethics that guides and binds each of our employees, officers and directors which is available on the "Governance Documents " page of our website, www.trevena.com, under the "Governance" tab. We use an anonymous compliance hotline for employees and outside parties to report potential instances of noncompliance. Our Chief Compliance Officer administers the compliance program and chairs the Company's Compliance Committee. The Chief Compliance Officer reports directly to our Chief Executive Officer and meets regularly with the Chair of the Audit Committee.

Corporate Information

We were incorporated under the laws of the State of Delaware in November 2007. Our principal executive offices are located at 955 Chesterbrook Boulevard, Suite 110, Chesterbrook, PA 19087. Our telephone number is (610) 354-8840 and our internet address is www.trevena.com.

Available Information

Our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and other filings with the United States Securities and Exchange Commission, or the SEC, and all amendments to these filings, are available, free of charge, on our website at www.trevena.com as soon as reasonably practicable following our filing of any of these reports with the SEC. You can also obtain copies free of charge by contacting our Investor Relations department at our office address listed above. The SEC maintains an Internet site that contains reports, proxy, and information statements, and other information regarding issuers that file electronically with the SEC at www.sec.gov. The information posted on or accessible through these websites is not incorporated into this filing.

INFORMATION ABOUT OUR EXECUTIVE OFFICERS

The following table sets forth certain information with respect to our executive officers as of the date of this annual report.

Name	Age	Position
Carrie L. Bourdow	61	President, Chief Executive Officer and Chair of the Board
Mark A Demitrack, M.D.	66	Senior Vice President and Chief Medical Officer
Robert T. Yoder	58	Senior Vice President, Chief Business Officer and Head of Commercial Operations
Barry Shin	52	Executive Vice President, Chief Operating Officer and Chief Financial Officer
Patricia Drake	58	Senior Vice President and Chief Commercial Officer

Carrie L. Bourdow

Ms. Bourdow has served as the President and Chief Executive Officer of our Company and member of our Board of Directors since October 2018 and as Chair of our Board of Directors since November 2023. Prior to her role as Chief Executive Officer, Ms. Bourdow joined our company as our Chief Commercial Officer in May 2015 and was

appointed Executive Vice President and Chief Operating Officer in January 2018. From May 2013 to May 2015, she was Vice President of Marketing at Cubist Pharmaceuticals, Inc. Prior to joining Cubist in 2013, Ms. Bourdow served for more than 20 years at Merck & Co., Inc., where she held positions of increasing responsibility across multiple therapeutic areas. Ms. Bourdow previously served as a member of the Board of Directors of Nabriva Therapeutics plc, a biopharmaceutical company, from June 2027 until July 2023 and she has served as a member of the Board of Directors of Sesen Bio, a biopharmaceutical company, from February 2020 until March 2023. Ms. Bourdow earned her B.A. from Hendrix College and her M.B.A. from Southern Illinois University.

Mark A. Demitrack, M.D.

Dr. Demitrack, a board-certified psychiatrist, joined our company as Senior Vice President and Chief Medical Officer in May 2018. From May 2017 to May 2018, he served as Vice President of Clinical Strategy at Roivant Sciences, Ltd. From July 2003 to May 2017, he served as Vice President and Chief Medical Officer of Neuronetics, Inc., where he led the clinical development of the NeuroStar TMS Therapy System. Prior to this, Dr. Demitrack was Assistant Vice President for Global Medical Affairs in Neuroscience at Wyeth Pharmaceuticals, Inc. where he was responsible for post-marketing clinical development of the Effexor XR brand. Dr. Demitrack also served as Medical Director of the New Antidepressant Team at Lilly Research Laboratories where he led the registration clinical development and the NDA submission program for the antidepressant, duloxetine (Cymbalta). Prior to his industry career, Dr. Demitrack was a faculty member of the Department of Psychiatry at the University of Michigan Medical School, where he directed the Michigan Eating Disorders Program and received federal grant funding in clinical research studying the neuroendocrine pathophysiology of eating disorders and the idiopathic conditions chronic fatigue syndrome and fibromyalgia. Dr. Demitrack received a B.A. in Physics from Columbia University, and his M.D. from the Robert Wood Johnson Medical School in New Jersey. He completed his psychiatry residency training at the University of California-San Francisco and completed a research fellowship in clinical neuroendocrinology at the National Institute of Mental Health. Dr. Demitrack is a Life Fellow of the American Psychiatric Association and a Member of the American College of Neuropsychopharmacology.

Robert T. Yoder

Mr. Yoder was appointed Senior Vice President, Chief Business Officer and Head of Commercial Operations in November 2021. Prior to this role, he served as Senior Vice President and Chief Commercial Officer since December 2018. He joined our company as Vice President of Commercial Operations and Sales in June 2018. Prior to this, he served as Senior Vice President and Head of Global Commercial Operations, Alliance Management and IT at Orexigen Therapeutics, Inc., a biopharmaceutical company, from March 2015 to June 2018. While at Orexigen, Mr. Yoder built the commercial infrastructure with a focus on innovative, efficient, and effective business process and architecture. Additionally, he led external business development efforts that delivered 11 partnership deals spanning 67 countries. Prior to joining Orexigen, Mr. Yoder spent 28 years at Merck & Co., where he held various roles of increasing responsibility across global business operations and commercial functions. In several of these roles, he was responsible for oversight and execution of large-scale initiatives including integration following acquisitions and led a range of organizational design and corporate change initiatives. Mr. Yoder received his B.S. degree in biology from Dickinson College and earned an M.B.A. from Emory University.

Barry Shin

Mr. Shin has served as Executive Vice President, Chief Operating Officer and Chief Financial Officer of our company since February 2024. Prior to this role, he served as Senior Vice President and Chief Financial Officer since June 2019. Mr Shin joined our company with extensive investment banking experience advising biopharmaceutical companies through financing and merger and acquisition, or M&A, transactions. He was Managing Director in the Healthcare Investment Banking Group at Mizuho Securities from May 2017 until he joined the Company. Prior to joining Mizuho Securities, he was a Managing Director in the Healthcare Investment Banking Group of Guggenheim Securities from May 2012 to May 2017. From February 2005 to May 2012, he served in the Healthcare Investment Banking Group of Piper Jaffray. From September 2001 to February 2005, he advised healthcare and technology companies in financing and M&A transactions as a corporate attorney. Mr. Shin received a B.Sc. and joint J.D. / M.B.A. from the University of Toronto.

Patricia Drake

Ms. Drake joined our company as Senior Vice President and Chief Commercial Officer in November 2021. She has held numerous U.S. and global commercial roles in marketing, sales, and strategy and is widely regarded as an influential and inclusive leader with a consistent track record of exceeding financial performance. Prior to joining the Company, she served as Chief Commercial Officer of Sesen Bio. from June 2021 to September 2021. Prior to that, she served in various capacities with Merck & Co., Inc., including as Managing Director and CEO of Merck, Sharp & Dohme (MSD) Finland from January 2019 to May 2021. Ms. Drake also served in Merck's Global Human Health Commercial Strategy Office from November 2017 to December 2018, as Leader of U.S. Market Operations and Strategy Realization from January 2016 to November 2017, as Vice President – Primary Care Sales (Canada) from May 2014 to December 2015, and Hospital Business Unit Leader in Canada where she led the successful launch of multiple commercial products, including Bridion®, a highly successful post-surgical product with over $1 billion worldwide sales in 2020.

ITEM 1A. RISK FACTORS

Our business is subject to numerous risks. You should carefully consider the following risks and all other information contained in this Annual Report on Form 10-K, as well as general economic and business risks, together with any other documents we file with the SEC. If any of the following events actually occur or risks actually materialize, it could have a material adverse effect on our business, operating results and financial condition and cause the trading price of our common stock to decline.

Summary of Risk Factors

- We may not be successful in identifying and implementing any strategic transaction for OLINVYK and any strategic transactions that we may consummate in the future could have negative consequences.
- If we successfully consummate any transaction from our strategic assessment, including, but not limited to, a sale, divestiture of assets and/or licensing of OLINVYK, we may fail to realize all of the anticipated benefits of the transaction, those benefits may take longer to realize than expected, or we may encounter integration difficulties.
- If a strategic transaction for OLINVYK is not consummated, our board of directors may decide to pursue a dissolution and liquidation. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such liquidation as well as the amoubt of cash that will need to be reserved for commitments and contingent liabilities.
- We may become involved in litigation, including securities class action litigation, that could divert management's attention and harm the Company's business and insurance coverage may not be sufficient to cover all costs and damages.
- We have incurred significant losses since our inception. We expect to incur losses over the next several years and may never achieve or maintain profitability.
- Our prospects are highly dependent on sales of OLINVYK and the successful commercialization of our other product candidates. To the extent we are unable to successfully complete development, obtain regulatory approval for or commercialize one or more of our product candidates, or if we experience delays in doing so, our business, financial condition and results of operations may be materially adversely affected, and the price of our common stock may decline.

- We will need substantial additional funding, which may not be available to us on acceptable terms, or at all. If we are unable to raise capital when needed, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts and may not be able to continue as a going concern.

- If we are unable to comply with the applicable continued listing requirements or standards of The Nasdaq Stock Market, including the minimum bid price requirement and minimum stockholders' equity requirement, Nasdaq could delist our common stock.

- Our limited operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

- OLINVYK or any of our other product candidates for which we obtain approval may fail to achieve the degree of market acceptance by physicians, patients, third-party payors, and others in the medical community necessary for commercial success.

- We could face legal or regulatory actions related to the sales, marketing and promotion of OLINVYK to healthcare professionals and healthcare institutions.

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

- If we are not able to obtain, or if there are delays in obtaining regulatory approval of our product candidates, we will not be able to market our product candidates at all, and our ability to generate revenue will be materially impaired.

- OLINVYK has been classified as a Schedule II controlled substance, and the making, use, sale, importation, exportation and distribution of controlled substances are subject to regulation by state, federal and foreign law enforcement and other regulatory agencies which may make the successful commercialization and market acceptance more difficult.

- We are early in our development efforts and have only one product, OLINVYK, for which we have received marketing approval from the FDA. If sales of OLINVYK are unsuccessful, or if we are unable to complete development and commercialize any of our other product candidates, or if we experience significant delays in doing so, our business will be materially harmed.

- Nonclinical and clinical drug development involves a lengthy and expensive process, with an uncertain outcome. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

- We may be unable to obtain regulatory approval for our product candidates under applicable regulatory requirements. The denial or delay of any such approval would delay commercialization of our product candidates and adversely impact our potential to generate revenue, our business and our results of operations.

- We rely, and expect to continue to rely, on third parties to conduct our nonclinical studies and clinical trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials or complying with applicable regulatory requirements.

- We contract with third parties for the manufacture of commercial supply of OLIVNYK and for clinical supply of our other product candidates. This reliance on third parties increases the risk that we will not have sufficient quantities of OLIVNYK or our other product candidates or such quantities at an acceptable cost, which could delay, prevent or impair our development or sales efforts.

- Materials necessary to manufacture our product or product candidates may not be available on commercially reasonable terms, or at all, which may delay the development and commercialization of our product or product candidates.

- If we are unable to obtain and maintain patent protection for our technology and products or if the scope of the patent protection obtained is not 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 products may be impaired.

- In the future, we expect to expand our development, regulatory, manufacturing, sales, marketing, and distribution capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

- We may not have cash available to us in an amount sufficient to enable us to make interest or principal payments on our indebtedness when due.

- We are subject to certain terms and restrictive covenants which, if breached, could have a material adverse effect on our business and prospects.

- We maintain significant inventories of OLINVYK, and in 2023 and 2022 we recorded an inventory valuation adjustment, primarily for slow-moving or obsolete inventory related to OLINVYK, as well as an increase in returns reserve from our wholesalers.

Risks Related to our Strategic Review Process

We may not be successful in identifying and implementing any strategic transaction for OLINVYK and any strategic transactions that we may consummate in the future could have negative consequences.

In April 2024, we announced that we are undertaking a review of strategic alternatives for OLINVYK focused on maximizing stockholder value, including, but not limited to, sale, out-license, divestiture of assets, in-licensing, discontinuation of US commercial sales or other strategic transaction. We expect to devote substantial time and resources to exploring strategic alternatives that our Board of Directors believes will maximize stockholder value. Despite devoting significant efforts to identify and evaluate potential strategic alternatives, there can be no assurance that this strategic review process will result in us pursuing any transaction or that any transaction, if pursued, will be completed on attractive terms or at all. We have not set a timetable for completion of this strategic review process, and our Board of Directors has not approved a definitive course of action. Additionally, there can be no assurances that any particular course of action, business arrangement or transaction, or series of transactions, will be pursued, successfully consummated or lead to increased stockholder value or that we will make any additional cash distributions to our stockholders.

The process of continuing to evaluate these strategic options may be very costly, time-consuming and complex and we have incurred, and may in the future incur, significant costs related to this continued evaluation, such as legal and accounting fees and expenses and other related charges. We may also incur additional unanticipated expenses in connection with this process. A considerable portion of these costs will be incurred regardless of whether any such course of action is implemented or transaction is completed. Any such expenses will decrease the remaining cash available for use in our business.

In addition, potential counterparties in a strategic transaction involving our company may place minimal or no value on our assets and our public listing. Further, should we resume the development of our product candidates, the development and any potential commercialization of our product candidates will require substantial additional cash to fund the costs associated with conducting the necessary preclinical and clinical testing and obtaining regulatory approval. Consequently, any potential counterparty in a strategic transaction involving our company may choose not to spend additional resources and continue development of our product candidates and may attribute little or no value, in such a transaction, to those product candidates.

In addition, any strategic business combination or other transactions that we may consummate in the future could have a variety of negative consequences and we may implement a course of action or consummate a transaction that yields unexpected results that adversely affects our business and decreases the remaining cash available for use in our business or the execution of our strategic plan. Any potential transaction would be dependent on a number of factors that may be beyond our control, including, among other things, market conditions, industry trends, the interest of third parties in a potential transaction with us, obtaining stockholder approval and the availability of financing to third parties in a potential transaction with us on reasonable terms. Any failure of such potential transaction to achieve the anticipated results could significantly impair our ability to enter into any future strategic transactions and may significantly diminish or delay any future distributions to our stockholders.

If we are not successful in setting forth a new strategic path for the Company, or if our plans are not executed in a timely fashion, this may cause reputational harm with our stockholders and the value of our securities may be adversely impacted. In addition, speculation regarding any developments related to the review of strategic alternatives and perceived uncertainties related to the future of the Company could cause our stock price to fluctuate significantly.

Even if we successfully consummate any transaction from our strategic assessment, including, but not limited to, a sale, divestiture of assets and/or licensing of OLINVYK, we may fail to realize all of the anticipated benefits of the transaction, those benefits may take longer to realize than expected, or we may encounter integration difficulties.

Our ability to realize the anticipated benefits of any potential business combination or any other result from our strategic assessment, are highly uncertain. Any anticipated benefits will depend on a number of factors, including our ability to integrate with any future business partner and our ability to generate future stockholder value in the platform we may elect to pursue. The process may be disruptive to our business and the expected benefits may not be achieved within the anticipated time frame, or at all. The failure to meet the challenges involved and to realize the anticipated benefits of any potential transaction could adversely affect our business and financial condition.

If we are successful in completing a strategic transaction for OLINVYK, we may be exposed to other operational and financial risks.

Although there can be no assurance that a strategic transaction will result from the process we have undertaken to identify and evaluate strategic alternatives for OLINVYK, the negotiation and consummation of any such transaction will require significant time on the part of our management, and the diversion of management's attention may disrupt our business.

The negotiation and consummation of any such transaction may also require more time or greater cash resources than we anticipate and expose us to other operational and financial risks, including:

- increased near-term and long-term expenditures;
- exposure to unknown liabilities;
- higher than expected acquisition or integration costs;
- incurrence of substantial debt or dilutive issuances of equity securities to fund future operations;
- write-downs of assets or goodwill or incurrence of non-recurring, impairment or other charges;
- increased amortization expenses;
- difficulty and cost in combining the operations and personnel of any acquired business with our operations and personnel;
- impairment of relationships with key suppliers or customers of any acquired business due to changes in management and ownership;
- inability to retain key employees of our company or any acquired business; and
- possibility of future litigation.

Any of the foregoing risks could have a material adverse effect on our business, financial condition and prospects.

If a strategic transaction is not consummated, our Board of Directors may decide to pursue a dissolution and liquidation. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such liquidation as well as the amount of cash that will need to be reserved for commitments and contingent liabilities.

There can be no assurance that a strategic transaction will be completed. If a strategic transaction is not completed, our Board of Directors may decide to pursue a dissolution and liquidation. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such decision and, with the passage of time the amount of cash available for distribution will be reduced as we continue to fund our operations. In addition, if our Board of Directors were to approve and recommend, and our stockholders were to approve, a dissolution and liquidation, we would be required under Delaware corporate law to pay our outstanding obligations, as well as to make reasonable provision for contingent and unknown obligations, prior to making any distributions in liquidation to our stockholders. As a result of this requirement, a portion of our assets may need to be reserved pending the resolution of such obligations and the timing of any such resolution is uncertain. In addition, we may be subject to litigation or other claims related to a dissolution and liquidation. If a dissolution and liquidation were pursued, our Board of Directors, in consultation with our advisors, would need to evaluate these matters and make a determination about a reasonable amount to reserve. Accordingly, holders of our common stock could lose all or a significant portion of their investment in the event of a liquidation, dissolution or winding up.

Our ability to consummate a strategic transaction depends on our ability to retain our employees required to consummate such transaction.

Our ability to consummate a strategic transaction depends upon our ability to retain our employees required to consummate such a transaction, the loss of whose services may adversely impact the ability to consummate such transaction. The strategic review process is supported by our deep and broad experience at the board, executive management, and supporting staff levels. Our cash conservation activities may yield unintended consequences, such as attrition beyond our reduction in workforce and reduced employee morale, which may cause remaining employees to seek alternative employment. Our ability to successfully complete a strategic transaction depends in large part on our ability to retain certain of our remaining personnel. If we are unable to successfully retain our remaining personnel, we are at risk of a disruption to our exploration and consummation of a strategic alternative as well as business operations.

Any future growth would impose significant added responsibilities on members of management, including the need to identify, recruit, maintain and integrate additional employees. Due to our limited resources, we may not be able to effectively manage our operations or recruit and retain qualified personnel, which may result in weaknesses in our infrastructure and operations, risks that we may not be able to comply with legal and regulatory requirements, and loss of employees and reduced productivity among remaining employees. Our future financial performance and, should we resume development, our ability to develop our product candidates or additional assets will depend, in part, on our ability to effectively manage any future growth or restructuring, as the case may be.

We may become involved in litigation, including securities class action litigation, that could divert management's attention and harm the company's business, and insurance coverage may not be sufficient to cover all costs and damages.

In the past, litigation, including securities class action litigation, has often followed certain significant business transactions, such as the sale of a company or announcement of any other strategic transaction, or the announcement of negative events, such as negative results from clinical trials. These events may also result in investigations by the SEC. We may be exposed to such litigation even if no wrongdoing occurred. Litigation is usually expensive and diverts management's attention and resources, which could adversely affect our business and cash resources and our ability to consummate a potential strategic transaction or the ultimate value our stockholders receive in any such transaction.

Risks Related to Our Financial Position and Capital Needs

We have incurred significant losses since our inception. We expect to incur losses over the next several years and may never achieve or maintain profitability.

Since inception, we have incurred significant operating losses. Our net loss was $40.3 million and $53.7 million for the years ended December 31, 2023 and 2022, respectively. As of December 31, 2023, we had an accumulated deficit of $588.1 million. To date, we have financed our operations primarily through private placements and public offerings of our equity securities and debt borrowings. We have devoted substantially all of our financial resources and efforts to research and development, including nonclinical studies and clinical trials. In August 2020, the FDA granted approval for OLIVNYK as a treatment in the United States for the management of acute pain in adults severe enough to require an intravenous opioid analgesic and for whom alternative treatments are inadequate. We have not generated significant revenue from the sale of OLINVYK, and in April 2024, we announced the reduction of commercial support for OLINVYK. We have suspended marketing and product development efforts with respect to OLINVYK as we evaluate potential strategic and financing alternatives for Trevena. We will continue to sell OLINVYK through our existing sales and distribution channels, but we may not be successful in generating additional sales of OLINVYK.

We expect to continue to incur significant expenses and operating losses over the next several years. Our net losses may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will increase if we:

- are unable to identify strategic alternatives for commercializng OLINVYK or our other product candidates in the United States;
- build out our sales, marketing and distribution capabilities and scale up external manufacturing capabilities to commercialize any product candidates that we choose not to license to a third party and for which we may obtain regulatory approval;
- conduct clinical trials for our other product candidates;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- seek to identify additional product candidates;
- maintain, expand, and protect our intellectual property portfolio;
- hire additional sales, marketing, medical, clinical and scientific personnel; and
- add operational, financial, and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts.

To become and remain profitable, we must succeed in raising substantial additional funding for the Company and developing and commercializing products that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing nonclinical testing and clinical trials of our product candidates, identifying additional product candidates, potentially entering into collaboration and license agreements, obtaining regulatory approval for product candidates, and manufacturing, marketing, and selling OLINVYK and any products or product candidates for which we may obtain regulatory approval. We are only in the preliminary stages of some of these activities and have not begun others. We may never succeed in these activities and, even if we do, our future profitability will depend upon the size of any markets in which our product candidates have received approval, and our ability to achieve sufficient market acceptance, reimbursement from third-party payors and adequate market share for our products in those markets.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses, whether we will have sufficient funding available to or when, or if, we will be able to achieve profitability. If, for example, we are required by the FDA or foreign regulatory authorities to perform studies in addition to those we currently anticipate conducting, or if there are any delays in completing our clinical trials, making necessary regulatory filings, or the development of any of our product candidates, our expenses could increase. Absent substantial additional fundraising, the level and extent of our clinical and, if approved, commercial efforts may lead to a delay in our ability to achieve profitability.

Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, continue our development efforts, diversify our product offerings, or even continue our operations. A decline in the value of our company also could cause you to lose all or part of your investment.

Our prospects are highly dependent on the sales of OLINVYK and the successful commercialization of our other product candidates. To the extent we are unable to successfully complete clinical development, obtain regulatory approval for or commercialize one or more of our product candidates, or if delays in doing so, our business, financial condition and results of operations may be materially adversely affected, and the price of our common stock may decline.

Our future success and ability to generate significant revenue from our product candidates is dependent on our ability to successfully develop, obtain regulatory approval for and commercialize one or more of our product candidates. All of our other product candidates are in earlier stages of development and will require substantial additional investment for manufacturing, preclinical testing, clinical development, regulatory review and approval in one or more jurisdictions. If any of our product candidates encounter safety or efficacy problems, development delays or regulatory issues or other problems, our development plans and business would be materially harmed.

We may not have the financial resources to continue development of our product candidates. Even if clinical trials are completed, we may experience other issues that may delay or prevent regulatory approval of, or our ability to commercialize, our product candidates. Our product candidates will require additional, time-consuming development efforts prior to commercial sale, including preclinical studies, clinical trials and approval by the FDA and applicable foreign regulatory authorities. All product candidates are prone to the risks of failure that are inherent in pharmaceutical product development, including the possibility that such product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities. In addition, we cannot assure stockholders that any such products that are approved will be manufactured or produced economically, successfully commercialized or widely accepted in the marketplace or be more effective than other commercially available alternatives.

We will need substantial additional funding, which may not be available to us on acceptable terms, or at all. If we are unable to raise capital when needed, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts and may not be able to continue as a going concern.

As of December 31, 2023, we had cash and cash equivalents of $33.0 million and restricted cash of $0.5 million. Based upon our current operating plan, we believe that our available cash and cash equivalents will not be sufficient to fund our planned operations and capital expenditure requirements for one year after the date of this filing and therefore management has concluded that substantial doubt exists about our ability to continue as a going concern. Although we plan and budget funding for our operations, it is possible that we may have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. We expect to incur significant expenses in connection with our current operations. Furthermore, we will continue to incur costs associated with operating as a public company and hiring personnel, as needed. Accordingly, we will need to obtain substantial additional funding for these efforts; we would seek to obtain this funding through the sale of equity, the incurrence of debt, and/or other sources, including potential collaborations. Ultimately, we may be unable to raise

additional funds or enter into such other arrangements when needed, on favorable terms, or at all. If we fail to raise additional capital or enter into such arrangements as, and when, needed, we could be forced to:

- significantly delay, scale back, or discontinue our operations, development programs, and/or any current or future commercialization efforts;
- relinquish, or license on unfavorable terms, our rights to technologies or product candidates that we otherwise would seek to develop or commercialize ourselves;
- seek collaborators for one or more of our product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available; or
- may be unable to continue as a going concern and could cease operations altogether.

The extent of our future capital requirements will depend on many factors, including:

- our ability to find strategic alternatives for commercializing OLINVYK in the United States;
- the scope, progress, results and costs of nonclinical development, laboratory testing, and clinical trials for our product candidates, including TRV045 and TRV734;
- the number and development requirements of other product candidates that we pursue;
- the costs, timing, and outcome of regulatory review of any product candidates, both in the United States and in territories outside the United States;
- the costs and timing of any future commercialization activities, including product manufacturing, marketing, sales, and distribution, for any of our product candidates for which we receive marketing approval;
- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- our ability to enter into collaborative agreements for the development and commercialization of our product candidates;
- any product liability or other lawsuits related to our products or operations;
- the expenses needed to attract and retain skilled personnel;
- the costs involved in preparing, filing, and prosecuting patent applications, maintaining and enforcing our intellectual property rights, and defending any intellectual property-related claims, both in the United States and in territories outside of the United States; and
- the impact of any future epidemics and pandemics.

Identifying potential product candidates and conducting nonclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete. Despite these efforts, we may never generate the necessary data or results required to obtain regulatory approval and achieve product sales for our product candidates. In addition, our other product candidates, if approved, may not achieve commercial success or meet our expectations.

Our ability to generate commercial revenue from sales of OLINVYK is unproven, and we do not expect our product candidates to be commercially available for the foreseeable future, if at all. Accordingly, we will need to

continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans. Furthermore, a systemic failure of the banking system in the United States or globally may result in a situation in which we lose our deposits, or access to our deposits, and are unable to obtain financing from other sources which could materially and adversely affect our business and financial condition.

Our limited operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

We are a biopharmaceutical company with a limited operating history. Our activities to date have been limited to, among other things, organizing and staffing our company, business planning, raising capital, developing our product platform, identifying potential product candidates, undertaking nonclinical studies, and conducting clinical trials of our product candidates. With the exception of OLINVYK, our product candidates are in early stages of development. We have not yet demonstrated the ability to generate significant revenue from the sale of OLINVYK. Consequently, any predictions you make about our future success or viability may not be as reliable as they could be if we had a longer and more established operating history.

We have encountered, and will continue to encounter, risks and difficulties frequently experienced by growing companies in a rapidly developing and changing industry, such as the biopharmaceutical industry, including challenges in forecasting accuracy, determining appropriate investments of our limited resources, gaining market acceptance of our products, if approved, managing a complex regulatory landscape and developing new product candidates. Our current operating model may require changes in order for us to scale our operations efficiently. You should consider our business and prospects in light of the risks and difficulties we face as a company focused on developing products in the fields of biopharmaceuticals and biotechnology.

We expect our financial condition and operating results to continue to fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, you should not rely upon the results of any past quarterly or annual periods as indications of future operating performance.

Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited.

We have incurred substantial losses during our history. We do not anticipate generating revenue from sales of products for the foreseeable future, if ever, and we may never achieve profitability. To the extent that we continue to generate tax losses, unused losses generated in tax years ending on or prior to December 31, 2018 will carry forward to offset future taxable income, if any, until such unused losses expire. Unused tax losses generated after December 31, 2018 under the Tax Act will not expire and may be carried forward indefinitely, but will be deductible only to the extent of 80% of current taxable income in any given year. It is uncertain if and to what extent various states will conform to the Tax Act. In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the Code), if a corporation undergoes an “ownership change,” which is generally defined as a greater than 50% change, by value, in its equity ownership over a three year period, the corporation’s ability to use its pre change net operating loss carryforwards and other pre change tax attributes to offset its post change income or taxes may be limited. We have not completed an analysis to determine whether we have experienced an ownership change. In addition, we may experience ownership changes in the future as a result of subsequent shifts in our stock ownership. Similar provisions of state tax law may also apply to limit our use of accumulated state tax attributes. In addition, at the state level, there may be periods during which the use of net operating losses is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. As a result, even if we attain profitability, we may be unable to use all or a material portion of our net operating losses and other tax attributes, which could adversely affect our future cash flows. As of December 31, 2023, we had federal net operating loss carryforwards of approximately $226.5 million that could be limited if we have experienced, or if in the future we experience, an ownership change.

We may not have cash available to us in an amount sufficient to enable us to make interest or principal payments on our indebtedness when due.

An indirect subsidiary ("SPV2"), entered into a royalty-based loan agreement, or the Loan Agreement, with R-Bridge Investment, Four Pte. Ltd., or R-Bridge, pursuant to which we may incur up to $40.0 million of indebtedness. The repayment of all borrowings, interest and other related payments under the Loan Agreement are secured by the Chinese intellectual property related to OLINVYK and associated with our license agreement with Nhwa, and deposit accounts established to hold any amounts received by SPV2 that are required to be used to repay amounts in accordance with the Loan Agreement. Our ability to make any royalty payments from U.S. sales as further provided in the Loan Agreement depends on our future performance, which is subject to regulatory, economic, financial, competitive and other factors beyond our control. We are a biopharmaceutical company that has not yet generated profit from product sales. We expect to continue to incur losses from our infrastructure and personnel to support our commercialization and product development efforts and operations. Accordingly, our business may not generate cash flow from operations in the future sufficient to make capital expenditures necessary to general royalty payments. If we are unable to generate such cash flow, we may be required to adopt one or more alternatives, such as selling assets, restructuring debt or obtaining additional equity capital on terms that may be onerous or highly dilutive. Our ability to refinance our indebtedness will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms. If SPV2 fails to satisfy its debt obligations under the Loan Agreement, it could result in an event of default and, as a result, R-Bridge could accelerate all of its rights and remedies under the Loan Agreement including, but not limited to, foreclosing on the Chinese intellectual property that secures the indebtedness. See Note 7 – Loans Payable to the financial statements included in Part II of this Annual Report on Form 10-K for a more specific description of the Loan Agreement.

We may not satisfy the milestones or conditions set forth in our Loan Agreement with R-Bridge in order to draw down additional funding on our royalty-based loan.

The second tranche of term loans (the "Second Tranche") under our Loan Agreement with R-Bridge, in an amount up to $10.0 million, may only be drawn, subject to the achievement of either a commercial or financing milestone as set forth in the Loan Agreement. We believe the gross proceeds from the private placement in December 2023, in addition to other Permitted Financing, as such term is defined in the Loan Agreement, may satisfy the conditions for us to receive the Second Tranche under the Loan Agreement. However, there can be no assurance when, or if, we will receive the funds under the Second Tranche. Without the achievement of the required commercial or financing milestones and satisfaction of certain customary conditions, we will not be eligible to draw additional funds under the Second Tranche. If we are unable to draw down additional funding under the terms of the Loan Agreement, our business, financial condition and results of operation may be harmed, and we may be required to seek out alternative financing sources which, if available, may have less favorable terms.

We are subject to certain restrictive covenants pursuant to the Loan Agreement which, if breached, could have a material adverse effect on our business and prospects.

The Loan Agreement contains certain customary affirmative covenants, including those relating to: use of proceeds; maintenance of books and records; financial reporting and notification; compliance with laws; and protection of our intellectual property. The Loan Agreement also contains certain customary negative covenants, related to us or SPV2: entering certain fundamental transactions; issuing dividends and distributions (other than certain exceptions, including distributing the loan proceeds to us); incurring additional indebtedness outside of the ordinary course of business; engaging in any business activity other than related to our license agreement relating to OLINVYK with our partner in China, Jiangsu Nhwa Pharmaceutical Co. Ltd, or Nhwa.; and permitting any additional liens on the collateral provided to R-Bridge under the Loan Agreement. As a result, the Loan Agreement may limit our ability to pursue strategic alternatives and react to changes in our business. Our and SPV2's failure to observe or breach these covenants could result in an event of default and, as a result, R-Bridge could accelerate all of the amounts then due by SPV2 under the Loan Agreement, including a premium in certain cases, or otherwise give R-Bridge certain rights over us or SPV2, which would have an adverse effect on our business. In addition, R-Bridge could seek to enforce its respective security interests in certain assets.

We maintain significant inventories of OLINVYK, and in 2023 and 2022 we recorded an inventory valuation adjustment, primarily for slow-moving or obsolete inventory related to OLINVYK, as well as an increase in returns reserve from our wholesalers.

We maintain significant inventories of OLINVYK and evaluate these inventories on a periodic basis for potential slow-moving or obsolete amounts on hand. During 2023, we recognized an inventory valuation adjustment of $0.9 million for OLINVYK inventories of hand, due to uncertainty of commercial activities and future expected OLINVYK sales. During 2023, we also recorded a $0.1 million returns reserve adjustment for OLINVYK to account for expected returns from our wholesalers. The inventory valuation adjustment and returns reserve adjustment were based upon our analysis of current OLINVYK inventory on hand and at our wholesalers, and the remaining shelf-life, in relation to our projected demand for the product.

Inventories are fully reserved as of December 31, 2023 and no additional inventory manufacturing is planned.

Risks Related to Ownership of Our Common Stock

The trading price of the shares of our common stock has been and may continue to be volatile, and you may not be able to resell some or all of your shares at a desired price.

Since our common stock commenced trading in January 2014, our stock price has been highly volatile, with closing stock prices ranging from a high of $339.25 per share to a low of $0.41 per share.

The stock market in general and the market for biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors in our stock may not be able to sell their common stock at or above the price paid for the shares. The market price for our common stock may be influenced by many factors, including:

- sales of OLIVNYK for use in adults for the management of acute pain severe enough to require an intravenous opioid analgesic and for whom alternative treatments are inadequate;
- the status and cost of our post-marketing commitments for OLIVNYK;
- actual or anticipated variations in our operating results;
- changes in financial estimates by us or by any securities analysts who might cover our stock;

- the timing and results of our clinical trials for any of our product candidates;
- the status and cost of development and commercialization of our other product candidates;
- failure or discontinuation of any of our development programs;
- conditions or trends in our industry;
- changes in the structure of healthcare payment systems;
- stock market price and volume fluctuations of comparable companies and, in particular, those that operate in the biopharmaceutical industry;
- announcements by us or our competitors of significant acquisitions, strategic partnerships or divestitures;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- announcements of investigations or regulatory scrutiny of our operations or lawsuits filed against us;
- capital commitments;
- investors' general perception of our company and our business;
- recruitment or departure of key personnel;
- announcements and expectations of additional financing efforts;
- public concern as to, and legislative action with respect to, genetic testing or other research areas of biopharmaceutical companies, the pricing and availability of prescription drugs, or the safety of drugs and drug delivery techniques;
- disruptions caused by man-made or natural disasters or public health pandemics or epidemics or other business interruptions, including, for example, the COVID-19 pandemic;
- economic and political factors, including but not limited to economic and financial crises, wars, terrorism, and political unrest; and
- sales of our common stock, including sales by our directors and officers or specific stockholders.

If we are not able to comply with the applicable continued listing requirements or standards of The Nasdaq Stock Market, Nasdaq could delist our common stock.

Our common stock is currently listed on The Nasdaq Stock Market. In order to maintain that listing, we must satisfy minimum financial and other continued listing requirements and standards, including the Minimum Bid Price Rule (as discussed below) and those regarding director independence and independent committee requirements, minimum stockholders' equity, and certain corporate governance requirements. There can be no assurances that we will be able to comply with the applicable listing standards.

We are required to maintain a minimum bid price of $1.00 per share. On September 1, 2023, we received a notice from Nasdaq indicating that the Company was not in compliance with Nasdaq Listing Rule 5550(a)(2), or the Minimum Bid Price Rule, because our common stock failed to maintain a minimum closing bid price of $1.00 for 30 consecutive business days.

In accordance with Nasdaq Marketplace Rule 5810 (c) (3)(A), the Company was afforded an initial period of 180 calendar days, or until February 28, 2024, to regain compliance with the Minimum Bid Price Rule. On March 1, 2024, the Company received a letter from Nasdaq stating that the Company has not regained compliance with the Minimum Bid Price Rule and is not currently eligible for a second 180-day extension period because the Company does not comply with the $5,000,000 minimum stockholders' equity initial listing requirement for The Nasdaq Capital Market. The Nasdaq letter noted that unless the Company timely requests an appeal of this determination to the Nasdaq Hearings Panel (the "Panel"), the Company's common stock will be scheduled for delisting from The Nasdaq Capital Market. On March 5, 2024, the Company submitted a request for a hearing to appeal Nasdaq's delisting determination. In response to the Company's request for a hearing, on March 5, 2024, the Company received a letter from Nasdaq granting the Company's request for a hearing on appeal and staying the delisting action noted in Nasdaq's letter pending a final decision by the Panel and the expiration of any additional extension period granted by the Panel following the hearing. The Panel hearing is scheduled for May 2, 2024, at 10:00 a.m. via video conference.

In the event that our common stock is delisted from The Nasdaq Stock Market and is not eligible for quotation or listing on another market or exchange, trading of our common stock could be conducted only in the over the counter market or on an electronic bulletin board established for unlisted securities such as the Pink Sheets or the OTC Bulletin Board. In such event, it could become more difficult to dispose of, or obtain accurate price quotations for, our common stock, and there would likely also be a reduction in our coverage by securities analysts and the news media, which could cause the price of our common stock to decline further. Also, it may be difficult for us to raise additional capital if we are not listed on a major exchange.

Such a de-listing would also likely have a negative effect on the price of our common stock and would impair your ability to sell or purchase our common stock when you wish to do so. In the event of a de listing, we may take actions to restore our compliance with The Nasdaq Stock Market's listing requirements, but we can provide no assurance that any such action taken by us would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below The Nasdaq Stock Market minimum bid price requirement or prevent future non-compliance with The Nasdaq Stock Market's listing requirements.

If our common stock were delisted and determined to be a "penny stock," a broker-dealer may find it more difficult to trade our common stock and an investor may find it more difficult to acquire or dispose of our common stock in the secondary market.

If our common stock were removed from listing with The Nasdaq Capital Market, it may be subject to the "penny stock" rules of the Exchange Act. The Exchange Act defines a "penny stock" as an equity security that has a market price per share of less than $5.00, subject to certain exceptions, such as any securities listed on a national securities exchange, which is the exception on which we currently rely.

The penny stock rules require that prior to a transaction involving a penny stock, the broker-dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive the purchaser's written agreement to the transaction. If our common stock were delisted and determined to be a "penny stock," a broker-dealer may find it more difficult to trade our common stock and an investor may find it more difficult to acquire or dispose of our common stock on the secondary market.

We may be subject to securities class action and stockholder derivative litigation.

We have in the past, and may in the future, become subject to class action and stockholder derivative litigation. We and our officers and directors, from time to time, could be subject to such lawsuits. If that were to occur, such suits and any resolution of such suits could result in substantial costs and divert management's attention and resources from our business. This could have a material adverse effect on our business, operating results and financial condition.

Sales of a substantial number of shares of our common stock could cause the market price of our common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. If our stockholders sell, or the market perceives that our stockholders intend to sell, substantial amounts of our common stock in the public market, the market price of our common stock could decline significantly.

In addition, we have filed registration statements on Form S-8 registering the issuance of shares of common stock subject to options or other equity awards issued or reserved for future issuance under our equity incentive plans. Shares registered under these registration statements on Form S-8 are available for sale in the public market subject to vesting arrangements and exercise of existing options, the grant of new options in the future, and the restrictions of Rule 144 in the case of our affiliates.

We are a "smaller reporting company" and, as a result of the reduced disclosure and governance requirements applicable to smaller reporting companies, our common stock may be less attractive to investors.

We are a "smaller reporting company" as defined in Rule 12b-2 promulgated under the Securities Exchange Act of 1934, as amended, or the Exchange Act, and we intend to take advantage of some of the exemptions from reporting requirements that are applicable to other public companies that are not smaller reporting companies, including reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We cannot predict if investors will find our common stock less attractive because we will rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

The issuance of additional stock in connection with financings, acquisitions, investments, our stock incentive plans or otherwise will dilute all other stockholders.

Our Certificate of Incorporation authorizes us to issue up to 200,000,000 shares of common stock and up to 5,000,000 shares of preferred stock with such rights and preferences as may be determined by our Board of Directors. Subject to compliance with applicable rules and regulations, we may seek to expand the number of authorized common shares, and issue our shares of common stock or securities convertible into our common stock from time to time in connection with a financing, acquisition, investment, our stock incentive plans or otherwise. Any such issuance could result in substantial dilution to our existing stockholders and cause the trading price of our common stock to decline.

Provisions in our corporate charter documents and under Delaware law may prevent or frustrate attempts by our stockholders to change our management and hinder efforts to acquire a controlling interest in us, and the market price of our common stock may be lower as a result.

There are provisions in our amended and restated certificate of incorporation and amended and restated bylaws that may make it difficult for a third party to acquire, or attempt to acquire, control of our company, even if a change in control was considered favorable by you and other stockholders. For example, our Board of Directors has the authority to issue up to 5,000,000 shares of preferred stock. The Board of Directors can fix the price, rights, preferences, privileges, and restrictions of the preferred stock without any further vote or action by our stockholders. The issuance of shares of preferred stock may delay or prevent a change in control transaction. As a result, the market price of our common stock and the voting and other rights of our stockholders may be adversely affected. An issuance of shares of preferred stock may result in the loss of voting control to other stockholders.

Our charter documents also contain other provisions that could have an anti-takeover effect, including:

- only one of our three classes of directors will be elected each year;
- stockholders are not entitled to remove directors other than by a 66 2/3% vote and only for cause;
- stockholders are not permitted to take actions by written consent;

- stockholders cannot call a special meeting of stockholders; and
- stockholders must give advance notice to nominate directors or submit proposals for consideration at stockholder meetings.

In addition, we are subject to the anti-takeover provisions of Section 203 of the Delaware General Corporation Law, which regulates corporate acquisitions by prohibiting Delaware corporations from engaging in specified business combinations with particular stockholders of those companies. These provisions could discourage potential acquisition proposals and could delay or prevent a change in control transaction. They could also have the effect of discouraging others from making tender offers for our common stock, including transactions that may be in your best interests. These provisions may also prevent changes in our management or limit the price that investors are willing to pay for our stock.

Because we do not anticipate paying any cash dividends on our common stock in the foreseeable future, capital appreciation, if any, will be your sole source of gains and you may never receive a return on your investment.

You should not rely on an investment in our common stock to provide dividend income. We have not declared or paid cash dividends on our common stock to date and have no plans to pay cash dividends in the foreseeable future. We currently intend to retain our future earnings, if any, to fund the development and growth of our business. Investors seeking cash dividends should not purchase our common stock.

Risks Related to the Development and Commercialization of Our Product Candidates

OLINVYK or any of our product candidates for which we obtain approval may fail to achieve the degree of market acceptance by physicians, patients, third-party payors, and others in the medical community necessary for commercial success.

OLINVYK or any of our product candidates for which we obtain approval may fail to gain sufficient market acceptance by physicians, patients, third-party payors, and others in the medical community. If OLINVYK or our product candidates do not achieve an adequate level of acceptance, we may not generate significant product revenue and we may not attain profitability. The degree of market acceptance of OLINVYK and our product candidates for which we obtain approval will depend on a number of factors, including:

- the efficacy, safety, cost and potential advantages compared to alternative treatments;
- the timing of market introduction, as well as competitive products;
- our ability to offer the product for sale profitably and at competitive prices;
- the convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of sales, marketing, and distribution support;
- the availability of third-party payor coverage and adequate reimbursement;
- the prevalence and severity of any side effects, including any limitations or warnings contained in a product's approved labeling;
- publicity concerning our products or competing products and treatments;

- FDA's, DEA's and HHS's policy initiatives regarding opioids, including enforcement focused on the inappropriate promotion and marketing of opioids;
- the public perception of opioids in general and the ongoing opioid crisis;
- the clinical indications for which the product is approved; and
- any restrictions on the use of our products, both on their own and together with other medications.

We cannot assure you that OLINVYK or any product candidates for which we obtain regulatory approval in the future will achieve market acceptance among physicians, patients, patient advocacy groups, third-party payors or others in the medical community necessary for commercial success. Any failure by OLINVYK or our product candidates that obtain regulatory approval to achieve market acceptance or commercial success could materially adversely affect our business, financial condition, results of operations and prospects.

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

OLINVYK is approved for use in adults for the management of acute pain severe enough to require an intravenous opioid analgesic and for whom alternative treatments are not adequate. OLINVYK competes with generic IV opioid analgesics, such as morphine, hydromorphone and fentanyl. IV opioid analgesics are limited by well-known adverse side effects, such as respiratory depression, nausea, vomiting, constipation, and post-operative ileus, which can be exacerbated by the way these molecules are metabolized or cleared. OLINVYK competes against, or is used in combination with, IV acetaminophen; EXPAREL® (liposomal bupivacaine), marketed by Pacira Pharmaceuticals, Inc.; ZYNRELEF® (bupivacaine and meloxicam) marketed by Heron Therapeutics, Inc; CALDOLOR® (IV ibuprofen), marketed by Cumberland Pharmaceuticals; DSUVIA™ (sublingual sufentanil) marketed by Alora Pharmaceuticals, Inc.; XARACOLL™ (bupivacaine HCL) implant, marketed by Innocoll Holdings plc; and POSIMIR® (bupivacaine solution) marketed by INNOCOLL Biotherapeutic. Together with generic versions of IV NSAIDs such as ketorolac and acetaminophen, and generic versions of local anesthetics such as bupivacaine, these non-opioid analgesics are currently used in combination with opioids in the multimodal management of moderate-to-severe acute pain.

We also are aware of a number of products in mid- and late-stage clinical development that are aimed at improving the treatment of moderate-to-severe acute pain and may compete with OLINVYK. Avenue Therapeutics, Inc. is developing an IV version of generic opioid tramadol for moderate-to-severe acute pain.

Some of these potential competitive compounds are being developed by large, well-financed, and experienced pharmaceutical and biotechnology companies, or have been partnered with such companies, which may give them development, regulatory and marketing advantages over us.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for our product candidates, which could result in our competitors establishing a strong market position before we are able to enter the market. In addition, our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of generic products or lower-cost branded products. Generic products are currently on the market for the OLINVYK indications and the indications that we are pursuing for our product candidates. If our product candidates achieve marketing approval, we expect that they will be priced at a significant premium over competing generic products.

Some of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources, brand recognition and expertise than we do in research and development, manufacturing, nonclinical testing, conducting clinical trials, obtaining regulatory approvals, and selling and marketing approved products. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early-stage companies

also may prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

OLINVYK or any product candidates for which we are able to obtain regulatory approval in the future may become subject to unfavorable pricing regulations, third-party payor coverage and reimbursement policies, or healthcare reform initiatives.

Our ability to sell OLINVYK or commercialize any of our other product candidates, if approved, successfully will depend, in part, on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government payor programs at the federal and state level, including Medicare and Medicaid, private health insurers, managed care plans and other organizations. Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. In addition, for hospital products, a private health insurer or Medicare will typically reimburse a fixed fee for certain procedures, including in-patient surgeries. Pharmaceutical products such as OLINVYK that may be used in connection with the surgery generally will not be separately reimbursed and, therefore, a hospital would have to assess the cost of OLINVYK relative to its benefits. Current or future efforts to limit the level of reimbursement for in-patient hospital procedures could cause a hospital to decide not to use OLINVYK.

A primary trend in the U.S. 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 medications or procedures. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Coverage and reimbursement may not be available for any drug that we or our collaborators commercialize and, even if these are available, the level of reimbursement for a product or procedure may not be satisfactory. Inadequate reimbursement levels may adversely affect the demand for, or the price of, any product candidate for which we or our collaborators obtain marketing approval. Obtaining and maintaining adequate reimbursement for our products may be difficult. We may be required to conduct expensive pharmacoeconomic studies to seek to justify coverage and reimbursement or the level of reimbursement relative to other therapies. If coverage and adequate reimbursement are not available or reimbursement is available only to limited levels, we or our collaborators may not be able to successfully sell OLINVYK or commercialize any of our other product candidates for which marketing approval is obtained.

The Inflation Reduction Act of 2022 contains substantial drug pricing reforms, including the establishment of a drug price negotiation program within the U.S. Department of Health and Human Services that would require manufacturers to charge a negotiated "maximum fair price" for certain selected drugs or pay an excise tax for noncompliance, the establishment of rebate payment requirements on manufacturers of certain drugs payable under Medicare Parts B and D to penalize price increases that outpace inflation, and requires manufacturers to provide discounts on Part D drugs. Substantial penalties can be assessed for noncompliance with the drug pricing provisions in the Inflation Reduction Act of 2022. The Inflation Reduction Act of 2022 could have the effect of reducing the prices we can charge and reimbursement we receive for our product and our product candidates, if approved, thereby reducing our profitability, and could have a material adverse effect on our financial condition, results of operations and growth prospects. The effect of Inflation Reduction Act of 2022 on our business and the pharmaceutical industry in general is not yet known.

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the indications for which the drug is approved by the FDA or analogous regulatory authorities outside the United States. Moreover, eligibility for coverage and reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale, and distribution expenses. Interim reimbursement levels for new drugs, if applicable, also may not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently

restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Private third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our or our collaborators' inability to promptly obtain coverage and adequate reimbursement rates from both government-funded and private payors for any approved drugs that we develop could adversely affect our operating results, our ability to raise capital needed to commercialize drugs and our overall financial condition.

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

There can be no assurance that our product candidates, if they are approved for sale in the United States or in other countries, will be considered medically reasonable and necessary for a specific indication, that they will be considered cost-effective by third-party payors, that coverage or an adequate level of reimbursement will be available, or that third-party payors' reimbursement policies will not adversely affect our ability to profitably sell our product candidates if they are approved for sale.

Product liability lawsuits against us could cause us to incur substantial liabilities and limit sales of OLINVYK or the development or commercialization of our product candidates.

We face an inherent risk of product liability exposure as a result of the commercial sales of OLINVYK in the United States, the testing of our product candidates in human clinical trials, and the commercialization of such product candidates, if approved. Product liability claims might be brought against us by consumers, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with our products. For example, we may be sued if OLINVYK or any product candidate we develop allegedly causes injury or is found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. If we cannot successfully defend ourselves against product liability claims, we will incur substantial liabilities or be required to limit commercialization of our products. Even a successful defense would require significant financial and management resources.

Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or products that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants and potential termination of clinical trial sites or entire clinical programs;
- initiation of investigations by regulatory agencies;
- significant costs to defend the related litigation;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- substantial monetary awards to trial participants or patients;

- loss of revenue;
- exhaustion of any available insurance and our capital resources;
- reduced resources of our management to pursue our business strategy; and
- the inability to commercialize any products that we may develop.

We currently maintain product liability insurance coverage at levels which may not be adequate to cover all liabilities that we may incur. We may need to increase our insurance as we conduct additional clinical trials for our product candidates. We will need to further increase our insurance coverage if we commence commercialization of any of our product candidates for which we obtain marketing approval. Insurance coverage is increasingly expensive, and in the future may be difficult to obtain for our product and product candidates. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. Our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. A successful product liability claim or series of claims brought against us could cause our stock price to fall and, if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business, financial condition, results of operations and prospects.

Concerns around the abuse of opioids, including law enforcement concerns over diversion of opioids and regulatory efforts to combat abuse, impact our ability to generate significant revenues from OLINVYK or any of our other product candidates and may adversely impact external investor perceptions of our business.

Prescription drug abuse and the diversion of opioids is a growing concern and has been referred to as an "opioid crisis" in the United States. Law enforcement and regulatory agencies applied policies that seek to limit the availability or use of opioids. Such efforts may inhibit sales of OLINVYK or our ability to successfully commercialize our product candidates for which we obtain marketing approval. Aggressive enforcement and unfavorable publicity regarding the use or misuse of opioids, including litigation or regulatory activity regarding sales or marketing of opioids, could have a material adverse effect on our business or reputation. Furthermore, a number of governmental entities have brought separate lawsuits against various pharmaceutical companies marketing and selling opioid pain medications, alleging misleading or otherwise improper promotion of opioid drugs to physicians and consumers. These efforts could reduce the potential size of the market for OLINVYK, decrease the revenues we are able to generate from its sale and adversely impact external investor perceptions of our business.

Many state legislatures and the federal government have enacted legislation intended to reduce opioid abuse. In addition, the FDA, DEA, CDC and HHS each have initiatives to address opioid-related overdose, death and dependence. While these initiatives are generally focused on prescribing oral opioids in an outpatient settings, some of these initiatives, and any legislation or regulations resulting from these initiatives, may apply to all opioid drugs, including those like OLINVYK that are administered through an IV in a hospital setting. Many of these changes and others could cause us to expend additional resources in developing and commercializing our products to meet additional requirements.

Risks Related to Regulatory Approval of Our Product Candidates

If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we will not be able to timely commercialize, or to commercialize at all, our product candidates, and our ability to generate revenue will be materially impaired.

Our product candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by the European Medicines Agency and similar regulatory authorities outside the United States. Failure to obtain marketing approval for our product candidates will prevent us from commercializing these product candidates and will significantly limit our ability to generate revenue in the future.

We have limited resources in filing and supporting the applications necessary to gain marketing approvals, and we have relied and expect to continue to rely on third parties to assist us in this process. Securing marketing approval requires the submission of extensive nonclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. Our product candidates may not be effective, may be only moderately effective, or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use. If any of our product candidates receives marketing approval, the accompanying label may limit the approved use of our drug in this way, which could limit sales of the product. The process of obtaining marketing approvals, both in the United States and abroad, is expensive, may take many years if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity, and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application.

OLINVYK has been classified as a Schedule II controlled substance under the Controlled Substances Act. The making, use, sale, importation, exportation and distribution of controlled substances are subject to regulation by state, federal and foreign law enforcement and other regulatory agencies. We anticipate that TRV734, if approved, would also be classified as a Schedule II controlled substance under the Federal Controlled Substances Act of 1970.

Controlled substances are subject to state, federal and foreign laws and regulations regarding their manufacture, use, sale, importation, exportation and distribution. Controlled substances are regulated under the Federal Controlled Substances Act of 1970, or CSA, and regulations of the DEA.

The DEA regulates controlled substances as Schedule I, II, III, IV or V substances. Schedule I substances by definition have a high potential for abuse and no established medicinal use and may not be marketed or sold in the United States. A pharmaceutical product may be listed as Schedule II, III, IV or V, with Schedule II substances considered to present the highest risk of abuse and Schedule V substances the lowest relative risk of abuse among such substances. The FDA has designated OLINVYK® (oliceridine) injection as a Schedule II controlled substance. Consequently, the manufacture, shipment, storage, sale, and use of OLINVYK will be subject to a high degree of regulation.

Various states also independently regulate controlled substances. Though state-controlled substances laws often mirror federal law, because the states are separate jurisdictions, they may separately schedule drugs as well. While some states automatically schedule a drug when the DEA does so, in other states there must be rulemaking or a legislative action. State scheduling may delay commercial sale of any controlled substance drug product for which we obtain federal regulatory approval and adverse scheduling could impair the commercial attractiveness of such product. We or our collaborators must also obtain separate state registrations in order to be able to obtain, handle and distribute controlled substances for clinical trials or commercial sale, and failure to meet applicable regulatory requirements could lead to enforcement and sanctions from the states in addition to those from the DEA or otherwise arising under federal law.

For any of our products classified as controlled substances, we and our suppliers, manufacturers, contractors, customers and distributors are required to obtain and maintain applicable registrations from state, federal and foreign law enforcement and regulatory agencies and comply with state, federal and foreign laws and regulations regarding the manufacture, use, sale, importation, exportation and distribution of controlled substances. There is a risk that DEA regulations may limit the supply of the compounds used in clinical trials for our product candidates and the ability to produce and distribute our products in the volume needed to both meet commercial demand and build inventory to mitigate possible supply disruptions.

Regulations associated with controlled substances govern manufacturing, labeling, packaging, testing, dispensing, production and procurement quotas, recordkeeping, reporting, handling, shipment and disposal. These regulations increase the personnel needs and the expense associated with development and commercialization of product

candidates including controlled substances. The DEA, and some states, conduct periodic inspections of registered establishments that handle controlled substances. Failure to obtain and maintain required registrations or comply with any applicable regulations could delay or preclude us from developing and commercializing our product candidates containing controlled substances and subject us to enforcement action. The DEA may seek civil penalties, refuse to renew necessary registrations or initiate proceedings to revoke those registrations. In some circumstances, violations could lead to criminal proceedings. Because of their restrictive nature, these regulations could limit commercialization of any of our product candidates that are classified as controlled substances.

Failure to obtain marketing approval in international jurisdictions would prevent OLINVYK or our product candidates from being marketed abroad.

To market and sell our products in the European Union, Asia, and many other jurisdictions, we, our current collaborators in South Korea and China for OLINVYK, or any future third-party collaborators must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, it is required that the product be approved for reimbursement before the product can be approved for sale in that country. We or our collaborators may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. However, the failure to obtain approval in one jurisdiction may compromise our ability to obtain approval elsewhere. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our products in any market.

OLINVYK and any product candidate for which we obtain marketing approval could be subject to post-marketing restrictions or withdrawal from the market and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our product candidates, when and if any of them are approved.

OLINVYK and any product candidate for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, advertising, and promotional activities for such product, will be subject to ongoing requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration, and listing requirements, current good manufacturing practice, or cGMP, requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping. Even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, including the requirement to implement a REMS. If any of our product candidates receives marketing approval, the accompanying label may limit the approved use of our drug, which could limit sales of the product.

The FDA also may impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of the product. The FDA closely regulates the post-approval marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in accordance with the provisions of the approved labeling. However, companies may share truthful and not misleading information that is otherwise consistent with a product's FDA approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use and if we do not market our products for only their approved indications, we may be subject to enforcement action for off-label marketing. Violations of the Federal Food, Drug, and Cosmetic Act relating to the promotion of prescription drugs may lead to investigations alleging violations of federal and state healthcare fraud and abuse laws, as well as state consumer protection laws.

Even though the FDA has granted approval of OLINVYK, the scope and terms of the approval may limit the ability to generate substantial sales revenues from OLINVYK either on our own or with a partner. The FDA has approved OLINVYK only for use in adults for the management of acute pain severe enough to require an intravenous

opioid analgesic and for whom alternative treatments are inadequate. The label for OLINVYK also contains a "boxed" warning about addiction, abuse, misuse, life-threatening respiratory depression, neonatal opioid withdrawal syndrome, and risks from concomitant use with benzodiazepines or other central nervous system depressants. This "boxed" warning may discourage physicians from prescribing OLINVYK to patients.

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

- the need to generate additional clinical data in order to provide information to the FDA to sufficiently address any future concerns for OLINVYK or our product candidates for which we may obtain regulatory approval;
- restrictions on such products, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning letters, untitled letters, or Form 483s;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- fines, restitution or disgorgement of profits or revenue;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of our products;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

If any of these actions were to occur, we may have to discontinue commercializing OLINVYK, limit our sales and marketing efforts, conduct further post-approval studies, and/or discontinue or change any other ongoing or planned clinical studies, which in turn could result in significant expense and delay or limit our ability to generate sales revenues. Moreover, the FDA's policies may change and additional government regulations may be enacted that could impose additional post-marketing obligations on any approved products. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained.

Risks Related to the Discovery and Development of Our Product Candidates

We have only one product, OLINVYK, for which we received marketing approval from the FDA. If we are unable to find a commercial partner for OLINVYK, or if we are unable to complete development of our product candidates, or if we experience significant delays in doing so, our business will be materially harmed.

We have only one product, OLINVYK, for which we have received marketing approval by the FDA. To this point, we have invested substantially all of our efforts and financial resources in the identification and development of biased ligands. Our ability to generate product revenue may depend heavily on the successful ability to find a commercial partner of OLINVYK and the development and commercialization, if approved, of our other product candidates. The success of OLINVYK and our development-stage product candidates will depend on several factors, including the following:

- successful completion of nonclinical studies and clinical trials;
- receipt of marketing approvals from applicable regulatory authorities;
- obtaining, maintaining, and protecting our intellectual property portfolio, including patents and trade secrets, and regulatory exclusivity for our product candidates;
- making arrangements with third-party manufacturers for, or establishing, commercial manufacturing capabilities;
- launching commercial sales of our product candidates, if and when approved, whether alone or in collaboration with others;
- acceptance of our product candidates, if and when approved, by patients, the medical community, and third-party payors;
- effectively competing with other therapies;
- obtaining and maintaining healthcare coverage of our products and adequate reimbursement; and
- maintaining a continued acceptable safety profile of our products following approval.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our product candidates, if approved, which would materially harm our business.

Nonclinical and clinical drug development involves a lengthy and expensive process, with an uncertain outcome. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

Clinical testing is expensive, can take many years to complete, and has a high risk of failure. It is impossible to predict when or if any of our product candidates will prove effective or safe in humans or will receive regulatory approval. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete nonclinical studies and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. A failure of one or more clinical trials can occur at any stage of testing. The outcome of nonclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim or topline results of a clinical trial do not necessarily predict final results. Moreover, nonclinical and clinical data often are susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in nonclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products. We may experience numerous unforeseen events during, or as a result of, clinical trials, which could

delay or prevent our ability to receive marketing approval or subsequently to commercialize our product candidates, including:

- regulatory agencies or institutional review boards may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at prospective trial sites;
- we may experience delays in reaching, or fail to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulatory agencies may require us, to conduct additional clinical trials or abandon product development programs;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate, or participants may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we may have to suspend or terminate clinical trials of our product candidates for various reasons, including a finding that the participants are being exposed to unacceptable health risks;
- regulatory agencies or institutional review boards may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our product candidates may be greater than we anticipate;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate; and
- our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulatory agencies or institutional review boards to suspend or terminate the trials.

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

- be delayed in obtaining marketing approval for our product candidates;
- not obtain marketing approval at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;
- be subject to additional post-marketing testing and/or reporting requirements; or
- have the product removed from the market after obtaining marketing approval.

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

We may be unable to obtain regulatory approval for our product candidates under applicable regulatory requirements. The denial or delay of any such approval would delay commercialization of our product candidates and adversely impact our potential to generate revenue, our business and our results of operations.

The research, testing, manufacturing, labeling, licensure, sale, marketing and distribution of biopharmaceutical products are subject to extensive regulation by the FDA and comparable regulatory authorities in the United States and other countries, and such regulations differ from country to country. We are not permitted to market our product candidates in any jurisdiction until they receive the requisite marketing approval from the applicable regulatory authorities of such jurisdictions. To gain approval to market our product candidates, we must provide the FDA and foreign regulatory authorities with nonclinical and clinical data that adequately demonstrate the safety and efficacy of the product for the intended indication applied for in the applicable regulatory filing. The approval process is typically lengthy and expensive, and approval is never certain. Our receipt of regulatory approval in the United States for OLINVYK does not mean that we will be successful in obtaining regulatory approval for our other product candidates.

The FDA or any foreign regulatory authorities can delay, limit or deny approval of our product candidates for many reasons, including:

- the FDA or other equivalent foreign regulatory authorities may disagree with the number, design, size, conduct or implementation of our clinical trials;
- our inability to demonstrate to the satisfaction of the FDA or the equivalent foreign regulatory authority that any of our product candidates is safe and effective for the requested indication;
- the results of our clinical trials may not meet the level of statistical significance or clinical meaningfulness required by the FDA or other equivalent foreign regulatory authorities for marketing approval;
- the FDA or other equivalent foreign regulatory authorities may not accept data generated from our clinical trial sites;
- the FDA or other equivalent foreign regulatory authorities may find the chemistry, manufacturing and controls data insufficient to support the quality of our product candidates;
- the FDA or other equivalent foreign regulatory authorities may identify deficiencies in the manufacturing processes or facilities of our CDMOs;
- the FDA or equivalent foreign regulatory authorities may not approve the formulation, dosing, labeling or specifications; or
- the potential for approval policies or regulations of the FDA or the equivalent foreign regulatory authorities to significantly change in a manner rendering our clinical data insufficient for approval.

Any of these factors, many of which are beyond our control, may result in our failing to obtain regulatory approval to market any of our product candidates, which could materially adversely affect our business, financial condition, results of operations and prospects.

If we experience delays or difficulties in the enrollment of patients in clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.

We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the United States. Some of our competitors have ongoing clinical trials for product candidates that treat the same indications as our product candidates, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates. Patient enrollment is affected by other factors including:

- the severity of the disease under investigation;
- our ability to recruit clinical trial investigators with appropriate competencies and experience;
- the eligibility criteria for the study in question;
- the size of the patient population required for analysis of the trial's primary endpoints;
- the perceived risks and benefits of the product candidate under study;
- availability and efficacy of approved medications for the disease under investigation;
- the efforts to facilitate timely enrollment in clinical trials;
- the patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment; and
- the proximity and availability of clinical trial sites for prospective patients.

These factors can be exacerbated by other situations, such as our inability to enroll a sufficient number of patients for our clinical trials which would result in significant delays and could require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our product candidates, which would cause the value of our company to decline and limit our ability to obtain additional financing.

If serious adverse or unacceptable side effects are identified during the development of our product candidates or following their approval by the FDA or foreign regulatory authorities, we may need to abandon or limit our development of some of our product candidates, limit the commercial profile of an approved label, or it may result in significant negative consequences following marketing approval, if any.

If our product candidates are associated with adverse side effects in clinical trials or have characteristics that are unexpected, we may need to abandon their development or limit development to more narrow uses or subpopulations in which the side effects or other characteristics are less prevalent, less severe, or more acceptable from a risk-benefit perspective. In our industry, many compounds that initially showed promise in early-stage testing have later been found to cause side effects that prevented further development of the compound or significantly limited its commercial opportunity.

OLINVYK and TRV734 are both biased ligands targeted at the MOR. Common adverse reactions for agonists of the MOR include respiratory depression, constipation, nausea, vomiting, and addiction. In rare cases, MOR agonists can cause respiratory arrest requiring immediate medical intervention. The label for OLINVYK contains a "boxed" warning about addiction, abuse, misuse, life-threatening respiratory depression, neonatal opioid withdrawal syndrome,

and risks from concomitant use with benzodiazepines or other central nervous system depressants. This "boxed" warning may discourage physicians from prescribing OLINVYK to patients.

If our clinical trials reveal a high and unacceptable severity and prevalence of side effects, these trials could be suspended or terminated, and the FDA or comparable foreign regulatory authorities could order us to cease further development or deny approval of our product candidates for any or all targeted indications. Drug related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial and could result in potential product liability claims.

Additionally, if we or others later identify undesirable side effects caused by OLINVYK or one or more of our product candidates for which we may obtain marketing approval, a number of potentially significant negative consequences could result, including:

- regulatory authorities may require additional warnings on the label or even withdraw approvals of such product;
- we may be required to recall a product or change the way such product is administered to patients;
- regulatory authorities may require additional warnings on the label, such as a "black box" warning or a contraindication, or issue safety alerts, press releases or other communications containing warnings or other safety information about the product;
- we may be required to implement a REMS, or create a medication guide outlining the risks of such side effects for distribution to patients, if one is not required in connection with regulatory approval;
- additional restrictions may be imposed on the marketing or promotion of the particular product or the manufacturing processes for the product or any component thereof;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm our business, results of operations and prospects.

We may not be successful in our efforts to expand our pipeline of product candidates.

One element of our strategy has been to expand our pipeline of therapeutics based on biased ligands and advance these product candidates through clinical development for the treatment of a variety of indications. Although we continue to assess the future development of our pipeline, without internal discovery research capabilities, we will need to expand our pipeline through other means, including, for example, by in-licensing product candidates for further development. We may not be able to identify, acquire, and develop product candidates that are safe and effective. Even if we are successful in continuing to expand our pipeline, the potential product candidates that we identify or in-license may not be suitable for clinical development, including as a result of being shown to have harmful side effects or other characteristics that indicate that they are unlikely to receive marketing approval and achieve market acceptance. If we do not successfully develop, receive regulatory approval and commercialize product candidates, we will not be able to obtain product revenue in future periods, which would make it unlikely that we would ever achieve profitability.

We may expend our limited resources to pursue a particular product candidate or indication and thereby fail to capitalize on other 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 focus on research programs and product candidates that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with

other product candidates that later prove to have fewer clinical or regulatory risks and/or 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 products. 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 such product candidate.

In the future, we may conduct a substantial portion of the clinical trials for our product candidates outside of the United States and, if approved, we may seek to market our product candidates abroad through third-party collaborators. Accordingly, we will be subject to the risks of doing business outside of the United States.

In the future, we may conduct a substantial portion of our clinical trials outside of the United States and we may seek to market our product candidates for which we obtain approval outside of the United States. We are thus subject to risks associated with doing business outside of the United States. We may choose to partner with third parties that have direct sales forces and established distribution systems, in lieu of our own sales force and distribution systems, which would indirectly expose us to these risks. Our business and financial results in the future could be adversely affected due to a variety of factors associated with conducting development and marketing of our product candidates, if approved, outside of the United States, including:

- efforts to develop an international sales, marketing and distribution organization may increase our expenses, divert our management's attention from the development of product candidates or cause us to forgo other profitable licensing opportunities in these geographies;
- changes in a specific country's or region's political and cultural climate or economic condition;
- unexpected changes in foreign laws and regulatory requirements;
- difficulty of effective enforcement of contractual provisions in local jurisdictions;
- inadequate intellectual property protection in foreign countries;
- differing payor reimbursement regimes, governmental payors or patient self-pay systems and price controls;
- trade protection measures, import or export licensing requirements such as Export Administration Regulations promulgated by the U.S. Department of Commerce and fines, penalties or suspension or revocation of export privileges;
- regulations under the U.S. Foreign Corrupt Practices Act and similar foreign anti-corruption laws;
- the effects of applicable foreign tax structures and potentially adverse tax consequences; and
- significant adverse changes in foreign currency exchange rates which could make the cost of our clinical trials, to the extent conducted outside of the United States, more expensive.

Risks Related to Our Dependence on Third Parties

Our current collaborators are, and any future relationships or collaborations we may enter into may be, important to us. If we are unable to maintain our relationship with any of these collaborations, or if our relationship with these collaborators is not successful, our business could be adversely affected.

We have limited capabilities for product development, sales, marketing, and distribution. As a result, we may in the future determine to collaborate with pharmaceutical and biotechnology companies for the development and potential

commercialization of our product candidates. For example, we entered into license agreements with partners in South Korea and China in 2018 whereby these parties will develop, seek regulatory approval for, and, if successful, commercialize OLINVYK. We face significant competition in seeking appropriate collaborators. Our ability to reach a definitive agreement for collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration, and the proposed collaborator's evaluation of a number of factors. If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates or bring them to market or continue to develop our product platform and our business may be materially and adversely affected.

Any future collaborations we might enter into with third parties, may pose a number of risks, including the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;
- collaborators may elect not to continue development or commercialization programs or may not pursue commercialization of any product candidates that achieve regulatory approval based on clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials, or require a new formulation of a product candidate for clinical testing;
- collaborators could fail to make timely regulatory submissions for a product candidate;
- collaborators may not comply with all applicable regulatory requirements or may fail to report safety data in accordance with all applicable regulatory requirements;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to limit or eliminate efforts and resources to the commercialization of our product candidates;
- a collaborator with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such product or products;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation, or the preferred course of development, might cause delays or termination of the research, development or

commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;

- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;

- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;

- collaborations may be terminated at the convenience of the collaborator and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates; and

- collaborators may be affected by political instability or instability from a regional or global pandemic disease, such as the recent coronavirus outbreak.

If any collaborations we might enter into in the future do not result in the successful development and commercialization of products or if one of our collaborators terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under the collaboration. If we do not receive the funding we expect under these agreements, our development of our product platform and product candidates could be delayed and we may need additional resources to develop our product candidates and our product platform. The risks relating to our product development, regulatory approval and commercialization described in this Annual Report also apply to the activities of our therapeutic program collaborators.

If a future collaborator of ours is involved in a business combination, the collaborator might deemphasize or terminate development or commercialization of any product candidate licensed to it by us. If one of our collaborators terminates its agreement with us, we may find it more difficult to attract new collaborators and our reputation in the business and financial communities could be adversely affected.

We rely, and expect to continue to rely, on third parties to conduct our nonclinical studies and clinical trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials or complying with applicable regulatory requirements.

We rely on third parties, such as contract research organizations, clinical research organizations, clinical data management organizations, medical institutions, and clinical investigators to conduct our nonclinical studies and clinical trials for our product candidates. The agreements with these third parties might terminate for a variety of reasons, including a failure to perform by the third parties. If we need to enter into alternative arrangements, that could delay our product development activities. Some of these third parties may experience shutdowns or other disruptions due to future pandemics, including, but not limited to, the ability to adequately staff a project or effectively and expeditiously enroll patients in a clinical study, and therefore may be unable to provide the level of service that we received in the past.

Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibilities. For example, we will remain responsible for ensuring that each of our nonclinical studies and clinical trials are conducted in accordance with the general investigational plan and protocols for the trial and for ensuring that our nonclinical studies are conducted in accordance with GLP, as appropriate. Moreover, the FDA requires us to comply with standards, commonly referred to as GCPs for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Regulatory authorities enforce these requirements through periodic inspections of trial sponsors, clinical investigators, and trial sites. If we or any of our clinical research organizations fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials complies with GCP regulations. In addition, our

clinical trials must be conducted with product produced under cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. We also are required to register certain clinical trials and post the results of these clinical trials when completed on a government-sponsored public database, ClinicalTrials.gov, within specified timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

The third parties with whom we have contracted to help perform our nonclinical studies or clinical trials also may have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines, or conduct our nonclinical studies or clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates.

If any of our relationships with these third-party contract research organizations or clinical research organizations terminate, we may not be able to enter into arrangements with alternative contract research organizations or clinical research organizations or to do so on commercially reasonable terms. Switching or adding additional contract research organizations or clinical research organizations involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new contract research organization or clinical research organization commences work. As a result, delays could occur that could compromise our ability to meet our desired development timelines. Although we seek to carefully manage our relationships with our contract research organizations and clinical research organizations, there can be no assurance that we will not encounter similar challenges or delays in the future.

We contract with third parties for the manufacture of commercial supply of OLINVYK and for clinical and nonclinical supply of our product candidates. This reliance on third parties increases the risk that we will not have sufficient quantities of OLINVYK or our product candidates or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We have no internal manufacturing capabilities and do not have any manufacturing facilities. We rely, and expect to continue to rely, on third parties for the manufacture of commercial supply of OLINVYK and the manufacture of supply of our product candidates for nonclinical and clinical testing, as well as for commercial manufacture, if any of such product candidates receive marketing approval. This reliance on third parties increases the risk that we will not have sufficient quantities of OLINVYK or our product candidates or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts.

We also expect to rely on third-party manufacturers or third-party collaborators for the manufacture of commercial supply of any other product candidates for which our collaborators or we obtain marketing approval. We may be unable to establish any agreements with third-party manufacturers or to do so on acceptable terms.

Our reliance on third-party manufacturers for commercial supply of OLINVYK and for any additional product candidates for which we obtain regulatory approval entails additional risks, including:

- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party;
- limitations on supply availability resulting from capacity and scheduling constraints of the third parties;
- manufacturing delays if our third-party manufacturers give greater priority to the supply of other products over our product candidates or otherwise do not satisfactorily perform according to the terms of the agreement between us;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how;

- impact on our reputation in the marketplace if manufacturers of our products, once commercialized, fail to meet the demands of our customers; and

- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

The failure of any of our contract manufacturers to maintain high manufacturing standards could result in injury or death of clinical trial participants or patients using products. Such failure could also result in product liability claims, product recalls, product seizures or withdrawals, delays or failures in testing or delivery, cost overruns or other problems that could seriously harm our business or profitability.

The facilities used by our contract manufacturers to manufacture our product candidates (and commercial supply of those product candidates, if approved) must be approved by the FDA pursuant to inspections that will be conducted after we submit an NDA to the FDA. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturers for compliance with current cGMP regulations for manufacture of our product candidates. These regulations cover all aspects of the manufacturing, testing, quality control and recordkeeping relating to our product candidates and any products that we may commercialize. Third-party manufacturers may not be able to comply with the cGMP regulations or similar regulatory requirements outside the United States. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products.

OLINVYK and any product candidates that we may commercialize, if approved, may compete with other product candidates and products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us. Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval. We do not currently have arrangements in place for redundant supply or a second source for bulk drug substance or drug product. If our current contract manufacturers cannot perform as agreed, we may be required to replace such manufacturers. We may incur added costs and delays in identifying, qualifying, and obtaining applicable regulatory approval(s) of any replacement manufacturers.

The DEA restricts the importation of a controlled substance finished drug product when the same substance is commercially available in the United States, which could reduce the number of potential alternative manufacturers for OLINVYK or our other MOR targeted product candidates. In addition, a DEA quota system controls and limits the availability and production of controlled substances and the DEA also has authority to grant or deny requests for quota of controlled substances, which includes the active ingredient in OLINVYK. Supply disruptions could result from delays in obtaining DEA approvals for controlled substances or from the receipt of quota of controlled substances that are insufficient to meet future product demand. The quota system also may limit our ability to build inventory as a method for mitigating possible supply disruptions of OLINVYK.

Our current and anticipated future dependence upon others for the manufacture of our product candidates or products may adversely affect our future profit margins and our ability to commercialize any products that receive marketing approval on a timely and competitive basis.

We also expect to rely on other third parties to store and distribute drug supplies for our clinical trials. Any performance failure on the part of our distributors could delay clinical development or marketing approval of our product candidates or commercialization of our products, producing additional losses and depriving us of potential product revenue.

Our business could be impacted by sanctions imposed on WuXi

Certain U.S. lawmakers have encouraged sanctions and introduced legislation that could affect WuXi AppTec (Hong Kong) Limited ("WuXi Apptec"), and WuXi Apptec's affiliate XenoBiotics Laboratories, Inc. ("XenoBiotics," together with WuXi Apptec "Wuxi") and companies that do business with WuXi. WuXi is our primary manufacturer and supplier of an important starting material for the active pharmaceutical ingredient for OLINVYK. WuXi is also in the process of running certain toxicology and bioanalytic studies associated with TRV045. We, and the pharmaceutical industry generally, depend on China-based partners such as WuXi for integral chemical synthesis, reagents, starting materials, and ingredients. Sanctions against WuXi, and the impact that such sanctions could have on its business, could negatively impact our ability to manufacture the starting material for the active pharmaceutical ingredient for OLINVYK and could cause delays, disruptions and cost increases to our toxicology and bioanalytic studies for TRV045.

Materials necessary to manufacture our product or product candidates may not be available on commercially reasonable terms, or at all, which may delay the development and commercialization of our product or product candidates.

We currently rely on the manufacturers of our product and product candidates to purchase from third-party suppliers the materials necessary to produce the compounds for our nonclinical studies and clinical trials, and we rely, or will rely, on these other manufacturers for commercial distribution of our product candidates for which we may obtain regulatory approval. Suppliers may not sell these materials to our manufacturers at the time we need them or on commercially reasonable terms and all such prices are susceptible to fluctuations in price and availability due to transportation costs, government regulations, price controls and changes in economic climate or other foreseen circumstances. We do not have any control over the process or timing of the acquisition of these materials by our manufacturers. We may enter into agreements to purchase certain materials and provide them to our manufacturers, with all the risks and uncertainties of supply associated with those purchases. If we or our manufacturers are unable to obtain these materials for our nonclinical studies and clinical trials, product testing and potential regulatory approval of our product candidates would be delayed, significantly impacting our ability to develop and commercialize our product candidates. If our manufacturers or we are unable to purchase these materials for commercial distribution of our product or, after regulatory approval has been obtained, our product candidates, the commercial launch of our product and product candidates, if approved, would be delayed or there would be a shortage in supply, which would materially affect our ability to generate revenues from the sale of our product or product candidates.

We rely on clinical data and results obtained by third parties that could ultimately prove to be inaccurate or unreliable.

As part of our strategy to mitigate development risk, we seek to develop product candidates with validated mechanisms of action and we utilize biomarkers to assess potential clinical efficacy early in the development process. This strategy necessarily relies upon clinical data and other results obtained by third parties that may ultimately prove to be inaccurate or unreliable. Further, such clinical data and results may be based on products or product candidates that are significantly different from our product candidates. If the third-party data and results we rely upon prove to be inaccurate, unreliable or not applicable to our product candidates, we could make inaccurate assumptions and conclusions about our product candidates and our research and development efforts could be compromised.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain patent protection for our technology and products or if the scope of the patent protection obtained is not 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 products may be impaired.

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. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our product candidates.

The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Should we enter into collaborations with third parties, we may be required to consult with or cede control to collaborators regarding the prosecution, maintenance and enforcement of our patents. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. For example, European patent law restricts the patentability of methods of treatment of the human body more than 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 a first filing, or in some cases at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which 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 patents or narrow the scope of our patent protection.

The Leahy-Smith America Invents Act, or the Leahy-Smith Act, could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. On September 16, 2011, the Leahy-Smith Act was signed into law. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The United States Patent and Trademark Office continues to develop and implement new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, only became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

Moreover, we may be subject to a third-party preissuance submission of prior art to the United States Patent and Trademark Office, 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, render unenforceable, 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 patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Even if our 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 or licensed patents by developing similar or alternative technologies or products in a non-infringing manner.

The issuance of a patent does not foreclose challenges to its inventorship, scope, validity or enforceability. Therefore, our owned and 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 product candidates might expire before or shortly after such product candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

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

Competitors may infringe our issued patents or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents. In addition, in a patent infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated, rendered unenforceable, or interpreted narrowly.

We may need to license certain intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms.

A third party may hold intellectual property, including patent rights that are important or necessary to the development of our products. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our products, in which case we would be required to obtain a license from these third parties on commercially reasonable terms, or our business could be harmed, possibly materially.

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

Our commercial success depends upon our ability, and the ability of our collaborators, to develop, manufacture, market and sell our 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 United States Patent and Trademark Office. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future.

If we are found to infringe a third party's intellectual property rights, we could be required to 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. 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. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

If we fail to comply with our obligations in our intellectual property licenses and funding arrangements with third parties, we could lose rights that are important to our business.

We are currently party to license agreements for technologies that we use in conducting our drug discovery activities. In the future, we may become party to licenses that are important for product development and commercialization. If we fail to comply with our obligations under current or future license and funding agreements, our counterparties may have the right to terminate these agreements, in which event we might not be able to develop, manufacture or market any product or utilize any technology that is covered by these agreements or may face other

penalties under the agreements. Such an occurrence could materially and adversely affect the value of a product candidate being developed under any such agreement or could restrict our drug discovery activities. Termination of these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or reinstated agreements with less favorable terms, or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology.

We may be subject to claims by third parties asserting that our employees or we 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 universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. 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.

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

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace.

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

In addition to seeking patent protection for our product candidates, we rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We limit disclosure of such trade secrets where possible, but we also seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who do have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors, and other third parties. We also enter into confidentiality 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 harmed.

Risks Related to Legal Compliance Matters

Our current and future relationships with customers and third-party payors in the United States and elsewhere may be subject, directly or indirectly, to applicable anti-kickback, fraud and abuse, false claims, transparency, health information privacy and security and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens and diminished profits and future earnings.

Healthcare providers, physicians and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of OLINVYK and any other product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare providers, third-party payors, and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act, which may constrain the business or financial arrangements and relationships through which we conduct research, sell, market, and distribute OLINVYK and any other drugs for which we obtain marketing approval. In addition, we may be subject to transparency laws and patient privacy regulation by U.S. federal and state governments and by governments in foreign jurisdictions in which we conduct our business. The applicable federal, state and foreign healthcare laws and regulations that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons 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 under federal and state healthcare programs, such as Medicare and Medicaid;

- federal civil and criminal false claims laws and civil monetary penalty laws, including the federal False Claims Act which can be enforced by individuals, on behalf of the government, through civil whistleblower or qui tam actions, and civil monetary penalty laws prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes, among other things, criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose, among other things, obligations on certain healthcare providers, health plans, and healthcare clearinghouses, known as covered entities, as well as their business associates that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- the federal Physician Payments Sunshine Act, also known as Open Payments program, 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 specific exceptions, to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to "payments or other transfers of value" made to physicians, which is defined to include doctors, dentists, optometrists, podiatrists and chiropractors, and teaching hospitals and applicable manufacturers and applicable group purchasing organizations to report annually to CMS ownership and investment interests held by physicians and their

immediate family members. Beginning in 2022, applicable manufacturers are also required to report such information regarding payments and transfers of value provided, as well as ownership and investment interests held, during the previous year to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists and certified nurse-midwives; and

- the Foreign Corrupt Practices Act, or FCPA, which prohibits any U.S. individual or business from paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business; 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 and foreign 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 or otherwise restrict payments that may be made to healthcare providers; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures, or drug pricing; state and local laws that require the registration of pharmaceutical sales representatives; and state and foreign laws, such as the General Data Protection Regulation (EU) 2016/679, governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations may involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, including, without limitation, damages, fines, disgorgement, imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations, which could have a material adverse effect on our business. If any of the physicians or other healthcare providers or entities with whom we expect to do business, including our collaborators, is found not to be in compliance with applicable laws, it may be subject to significant criminal, civil or administrative sanctions, including exclusions from participation in government healthcare programs, which also could materially affect our business.

Healthcare reform measures may increase the difficulty and cost for us to successfully commercialize our product and product candidates, if approved, and affect the prices we may obtain.

The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that could restrict or regulate post-approval activities relating to our product and product candidates, if approved, including implementing cost-containment programs to limit the growth of government-paid healthcare costs, including price controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs.

The Affordable Care Act was intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms.

Among the provisions of the Affordable Care Act that have been implemented since enactment and are of importance to the successful commercialization of a pharmaceutical product are the following:

- an annual, nondeductible fee on any entity that manufactures, or imports specified branded prescription drugs or biologic agents;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- expansion of healthcare fraud and abuse laws, including the U.S. civil False Claims Act and the Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;
- a Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for a manufacturer's outpatient drugs to be covered under Medicare Part D;
- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- 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;
- expansion of eligibility criteria for Medicaid programs;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- requirements to report certain financial arrangements with physicians and teaching hospitals;
- a requirement to annually report certain information regarding drug samples that manufacturers and distributors provide to physicians; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

There have been significant ongoing judicial, administrative, executive and legislative efforts to modify or eliminate the Affordable Care Act. For example, the Tax Act enacted on December 22, 2017, repealed the shared responsibility payment for individuals who fail to maintain minimum essential coverage under section 5000A of the Internal Revenue Code, commonly referred to as the individual mandate. Other legislative changes have been proposed and adopted since passage of the Affordable Care Act. The Budget Control Act of 2011, among other things, created the Joint Select Committee on Deficit Reduction to recommend proposals in spending reductions to Congress. The Joint Select Committee did not achieve its targeted deficit reduction of an amount greater than $1.2 trillion for the fiscal years 2012 through 2021, triggering the legislation's automatic reductions to several government programs. These reductions included aggregate reductions to Medicare payments to healthcare providers of up to 2.0% per fiscal year, which went into effect in April 2013. Subsequent litigation extended the 2% reduction, on average, to 2030 unless additional Congressional action is taken. The Coronavirus Aid, Relief and Economic Security Act, or the CARES Act, which was designed to provide financial support and resources to individuals and businesses affected by the COVID-19 pandemic, suspended the 2% Medicare sequester from May 1, 2020 to March 31, 2022. As of July 2, 2022, the 2% sequester resumed. The sequester will remain in place through 2030. On January 2, 2013, the American Taxpayer Relief Act was signed into law, which, among other things, reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

The Affordable Care Act has also been subject to challenges in the courts. On December 14, 2018, a Texas U.S. District Court Judge ruled that the Affordable Care Act is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. On December 18, 2019, the Fifth Circuit U.S. Court of Appeals held that the individual mandate is unconstitutional and remanded the case to the Texas District Court to reconsider its earlier invalidation of the entire Affordable Care Act. On June 17, 2021, the Supreme Court ruled that the plaintiffs lacked standing to challenge the law as they had not alleged personal injury traceable to the allegedly unlawful conduct. As a result, the Supreme Court did not rule on the constitutionality of the ACA or any of its provisions. Further changes to and under the Affordable Care Act remain possible but it is unknown what form any such changes or any law proposed to replace or revise the Affordable Care Act would take, and how or whether it may affect our business in the future. We expect that changes to the Affordable Care Act, the Medicare and Medicaid programs, changes allowing the federal government to directly negotiate drug prices and changes stemming from other healthcare reform measures, especially with regard to healthcare access, financing or other legislation in individual states, could have a material adverse effect on the healthcare industry.

We expect that the Affordable Care Act, as well as other healthcare reform measures that have and may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for our product and product candidates, if approved, and could seriously harm our future revenues. Any reduction in reimbursement from Medicare, Medicaid, or other government programs may result in a similar reduction in payments from private payers. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or successfully commercialize our product and product candidates, if approved.

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

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

If we fail to comply with environmental, health, and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business.

We are subject to numerous environmental, health, and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health, and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Our failure to comply with these laws and regulations also may result in substantial fines, penalties, or other sanctions.

Risks Related to Employee Matters and Managing Our Growth

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

We are highly dependent on the development, clinical, business development, legal, financial, and commercial expertise of our executive officers. Although we have entered into employment agreements with these individuals, each of them may terminate their employment with us at any time. We do not maintain "key person" insurance for any of our executives or other employees.

Recruiting and retaining qualified management, scientific, clinical, manufacturing, sales and marketing, and other personnel also will be critical to our success. The loss of the services of our executive officers or other key employees or consultants could impede the achievement of our development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees or consultants may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel.

We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific, clinical, and commercial advisors, to assist us in formulating our development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

In the future, we may expand our development, regulatory, manufacturing, sales, marketing, and distribution capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

In the future, we may experience growth in the number of our employees and the scope of our operations, particularly in the areas of drug development, regulatory affairs, manufacturing, sales, marketing, and distribution. To manage potential future growth, we may be required to implement and improve our managerial, operational and financial systems, expand our facilities and recruit and train additional qualified personnel. Due to our limited financial resources, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

Our employees 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 of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with FDA regulations, provide accurate information to the FDA, report financial information or data accurately or disclose unauthorized activities to us. Employee misconduct also could involve the improper use or misrepresentation of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and financial results, including the imposition of significant civil, criminal and administrative penalties, including, without limitation, damages, fines, disgorgement, imprisonment, exclusion from participation in government

healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations, which could have a material adverse effect on our business.

General Risk Factors

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

Until such time, if ever, as we can generate substantial product revenue and positive cash flows from operations, we expect to finance our cash needs through a combination of equity offerings, debt financings, and license and development agreements in connection with any collaborations. We do not have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, either at the time of such capital raise or thereafter, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Preferred equity financing and additional debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, or declaring dividends, or that include covenants requiring us to meet certain obligations, such as minimum cash requirements or net revenue targets.

If we raise additional funds through collaborations, strategic alliances, or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce, or terminate our product development or our current or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

An active trading market for our common stock may not continue to develop or be sustained.

Although our common stock is listed on the Nasdaq, we cannot assure you that an active, liquid trading market for our shares will continue to develop or be sustained. If an active market for our common stock does not continue to develop or is not sustained, it may be difficult for you to sell shares quickly or without depressing the market price for the shares or to sell your shares at all.

If equity research analysts do not continue to publish research or reports or publish unfavorable research or reports about us, our business or our industry, our stock price and trading volume could decline.

The trading market for our common stock is influenced by the research and reports that equity research analysts publish about us and our business. We have only limited research coverage by equity research analysts. Equity research analysts may elect not to initiate or continue to provide research coverage of our common stock, and such lack of research coverage may adversely affect the market price of our common stock. We have no control over the analysts or the content and opinions included in their reports. The price of our stock could decline if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research.

If one or more equity research analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which in turn could cause our stock price or trading volume to decline.

Changes in tax laws or regulations that are applied adversely to us or our customers may have a material adverse effect on our business, cash flow, financial condition or results of operations.

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could adversely affect our business operations and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. For example, the Tax Act enacted many significant changes to the U.S. tax laws. Future guidance from the Internal Revenue Service and other

tax authorities with respect to the Tax Act may affect us, and certain aspects of the Tax Act could be repealed or modified in future legislation. In addition, it is uncertain if and to what extent various states will conform to the Tax Act or any newly enacted federal tax legislation. Changes in corporate tax rates, the realization of net deferred tax assets relating to our operations, the taxation of foreign earnings, and the deductibility of expenses under the Tax Act or future reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one-time charges, and could increase our future U.S. tax expense.

If we fail to maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired.

We are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act of 2002, as amended, or the Sarbanes-Oxley Act, and the rules and regulations of Nasdaq. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal controls over financial reporting. Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. For our fiscal year ended December 31, 2023, we are obligated to perform system and process evaluation and testing of our internal controls over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting in our Annual Report on Form 10-K filing for that year, as required by Section 404(a) of the Sarbanes-Oxley Act.

We incur costs and demands upon management as a result of being a public company.

As a public company listed in the United States, we are incurring, and will continue to incur, significant legal, accounting and other costs. These costs could negatively affect our financial results. In addition, changing laws, regulations and standards relating to corporate governance and public disclosure, including regulations implemented by the SEC and stock exchanges, may increase legal and financial compliance costs and make some activities more time consuming. These laws, regulations and standards are subject to varying interpretations and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. If, notwithstanding our efforts to comply with new laws, regulations and standards, we fail to comply, regulatory authorities may initiate legal proceedings against us and our business may be harmed.

Failure to comply with these rules also might make it more difficult for us to obtain some types of insurance, including directors' and officers' liability insurance, and we might be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our Board of Directors, on committees of our Board of Directors or as members of senior management.

Our business and operations would suffer in the event of system failures.

We utilize information technology systems and networks to process, transmit and store electronic information in connection with our business activities. As use of digital technologies has increased, cyber incidents, including deliberate attacks and attempts to gain unauthorized access to computer systems and networks, have increased in frequency and sophistication. These threats pose a risk to the security of our systems and networks and the confidentiality, availability and integrity of our data. There can be no assurance that we will be successful in preventing cyber-attacks or successfully mitigating their effects.

Despite our implementation of security measures, our internal computer systems and operations and those of our contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, outbreak of regional or global pandemic diseases, such as the recent coronavirus outbreak, terrorism, war, and telecommunication and electrical failures. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption to our product candidate development programs. For example, the loss of data from completed, ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a

loss of or damage to our data or applications, or inappropriate disclosure of personal, confidential or proprietary information, we could incur liability and the further development of any of our product candidates could be delayed or abandoned.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 1C. CYBERSECURITY

Cyber Risk Management and Strategy

We recognize the importance of assessing, identifying, and managing risks from cybersecurity threats. Our approach to cybersecurity risk management is aligned with our risk profile and business.

We have leveraged the support of third-party information technology and security providers, including to perform a risk assessment designed to identify, assess, and manage cybersecurity risks. We provide ongoing training to our employees to identify and understand the risks from cybersecurity threats, Further, we follow a formal, documented process to assess the data protection practices of certain third-party vendors.

Our cybersecurity risk management program is integrated into our overall enterprise risk management program and shares common methodologies, reporting channels, and governance processes that apply across the enterprise risk management program to other legal, compliance, strategic, operational, and financial risk areas.

Our cybersecurity risk management program includes:

- risk assessments designed to help identify material cybersecurity risks to our critical systems, information, products, services, and our broader enterprise information technology ("IT") environment;
- an outsourced security team principally responsible for managing (1) our cybersecurity risk assessment processes, (2) our security controls, and (3) our response to cybersecurity incidents;
- the use of external service providers, where appropriate, to assess, test, or otherwise assist with aspects of our security controls;
- cybersecurity awareness training for our employees, incident response personnel, and senior management. This includes mandatory computer-based training, internal communications, and regular phishing awareness campaigns that are designed to emulate real-world contemporary threats and provide immediate feedback (and, if necessary, additional training or remedial action) to employees.

In addition to the processes, technologies, and controls that we have in place to reduce the likelihood of a material cybersecurity incident (or series of related cybersecurity incidents), our outsourced security team has a written incident response plan outlining how to address cybersecurity events that occur. We have assigned a team comprised of finance and technology personnel to review the plan annually to serve as a framework for the execution of responsibilities across businesses and operational roles. The incident response plan is designed to help us coordinate actions to prepare for, detect, respond to and recover from cybersecurity incidents, and includes processes to triage, assess severity, escalate, contain, investigate, and remediate the incident, as well as to assess the need for disclosure, comply with applicable legal obligations and mitigate the impact to our brand and reputation and on impacted parties.

In addition to the cybersecurity incident response plan, our outsourced team conducts tabletop exercises to enhance our incident response preparedness. They also have processes to oversee and identify material risks from cybersecurity threats associated with our use of third-party service providers. Such processes include conducting due diligence and risk assessment of our current and potential vendors that examine such vendor's cybersecurity protocols and adherence to applicable regulations.

We also maintain business continuity and disaster recovery plans to prepare for and respond to the potential for any disruption in the technology we rely on. Additionally, we maintain insurance coverage that, subject to its terms and conditions, is intended to help us cover certain costs associated with cybersecurity incidents and information system failures.

Although risks from cybersecurity threats have to date not materially affected, and we do not believe they are reasonably likely to materially affect, us or our business strategy, results of operations or financial condition, we could, from time to time, experience threats and security incidents relating to our and our third-party vendors' information systems. For more information, please see the section entitled "Risk Factors" in this Annual Report on Form 10-K.

Governance Related to Cybersecurity Risks

Based on the information available as of the date of this Annual Report, we have no reason to believe any risks from cybersecurity threats, including as a result of any previous cybersecurity incidents, have materially affected or are reasonably likely to materially affect us, including our business strategy, results of operations or financial condition. For additional information, see "Risks Related to Cybersecurity, Data Privacy and IT Systems," in Item 1A, "Risk Factors" in this Annual Report on Form 10-K.

Our Senior Vice President, Chief Business Officer and Head of Commercial Operations is responsible for the strategic leadership and direction of our cybersecurity program. The Senior Vice President, Chief Business Officer and Head of Commercial Operations has nearly 10 years of experience overseeing information technology activities.
Our audit committee has oversight over cybersecurity risks. Our management provides periodic presentations to the audit committee on our cybersecurity program, including updates on cybersecurity risks and related cybersecurity strategy, as applicable. The audit committee provides updates regarding our cybersecurity program to the board of directors when material.

ITEM 2. PROPERTIES

Our principal office is located at 955 Chesterbrook Boulevard, Chesterbrook, Pennsylvania, where we currently lease approximately 8,231 square feet of developed office space on the first floor and 40,565 square feet of developed office space on the second floor. The lease term for this space extends through May 2028. On October 11, 2018, we entered into an agreement with The Vanguard Group, Inc., or Vanguard, whereby Vanguard agreed to sublease the 40,565 square feet of space on the second floor for an initial term of 37 months. On October 2, 2020, Vanguard notified the Company that they exercised the first option to extend the sublease term for three years through November 30, 2024. Vanguard has a second option to extend the sublease term for an additional three years through November 30, 2027. On August 3, 2023, Vanguard exercised its second option to extend its sublease term. The Company and Vanguard agreed to further extend the sublease through May 2028. With the current extension to May 2028, Vanguard's sublease is coterminous with the Company's master lease term. The sublease provides for rent abatement for the first month of the term; thereafter, the rent payable per square foot to us by Vanguard under the sublease is (i) $0.50 less during months 2 through 13 of the sublease, (ii) $1.00 less during months 14 through 109 of the sublease and (iii) in month 110 through 116 of the sublease, $16.50 less than the base rent per square foot payable by us under our master lease with Chesterbrook Partners, L.P. Vanguard also is responsible for paying to us all tenant energy costs, annual operating costs, and annual tax costs attributable to the subleased space during the term of the sublease. Management believes our office facilities are adequate to support our operations at their current levels and for the foreseeable future.

ITEM 3. LEGAL PROCEEDINGS

The Company is not involved in any legal proceeding that it expects to have a material effect on its business, financial condition, results of operations and cash flows.

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 and Holders

Our common stock is traded on the Nasdaq Capital Market under the symbol "TRVN." On March 28, 2024, there were 5 holders of record of our common stock.

Dividends

We have never declared or paid any dividends on our common stock. We anticipate that we will retain all of our future earnings, if any, for use in the operation and expansion of our business and do not anticipate paying cash dividends in the foreseeable future.

Recent Sales of Unregistered Securities

We did not sell any equity securities during the fiscal year ended December 31, 2023 in transactions that were not registered under the Securities Act.

ITEM 6. Selected Financial Data.

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

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and related notes appearing in this Annual Report. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this Annual Report, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis. Please also see the section entitled "Cautionary Note Regarding Forward-Looking Statements."

Overview

We are a biopharmaceutical company focused on developing and commercializing novel medicines for patients affected by central nervous system, or CNS, disorders. Our lead product, OLINVYK® (oliceridine) injection, or OLINVYK, was approved by the United States Food and Drug Administration, or the FDA, in August 2020. In October 2020, we announced that OLINVYK had received scheduling from the U.S. Drug Enforcement Administration, or DEA, and was classified as a Schedule II controlled substance. We initiated commercial launch of OLINVYK in the first quarter of 2021.

In April 2024, we announced that OLINVYK remains available for purchase by customers, but that we are reducing commercial support for the product to preserve capital as we conduct a process to explore a range of strategic alternatives for OLINVYK. Potential alternatives that may be explored or evaluated include, but are not limited to, a sale, license or divestiture of OLINVYK. There can be no assurance regarding the schedule for completion of the strategic review process, that this strategic review process will result in the Company pursuing any transaction or that any transaction, if pursued, will be completed.

OLINVYK is an opioid agonist for use in adults for the management of acute pain severe enough to require an intravenous opioid analgesic and for whom alternative treatments are inadequate. We are also developing a pipeline of

product candidates based on our proprietary product platform, including TRV045 for diabetic neuropathic pain, epilepsy, and seizure disorders; and TRV734 for moderate-to-severe acute and chronic pain and opioid use disorders.

Since our incorporation in late 2007, our operations have included organizing and staffing our company, business planning, raising capital, discovering and developing our product candidates, and establishing our intellectual property portfolio. We have financed our operations primarily through private placements and public offerings of our equity securities and debt borrowings. As of December 31, 2023, we had an accumulated deficit of $588.1 million. Our net loss was $40.3 million and $53.7 million for the years ended December 31, 2023 and 2022, respectively. Our ability to become and remain profitable depends on our ability to generate revenue or sales. We do not expect to generate significant revenue or sales unless and until we or a collaborator successfully commercialize OLINVYK or obtain marketing approval for and successfully commercialize TRV045 or TRV734.

We expect to incur significant expenses and operating losses for the foreseeable future as we continue to make OLINVYK available for purchase by customers and continue the development and clinical trials of our other product candidates. We will need to obtain substantial additional funding in connection with our continuing operations. We will seek to fund our operations through the sale of equity, debt financings or other sources, including potential collaborations. However, we may be unable to raise additional funds or enter into such other agreements when needed on favorable terms, or at all. If we fail to raise capital or enter into such other arrangements as, and when, needed, we may have to significantly delay, scale back or discontinue our operations, development programs, and/or any future commercialization efforts.

Recent Developments

Results of Special General Meeting

On March 21, 2024, the Special Meeting of Stockholders (the "Special Meeting") was convened at 8:30 a.m. Eastern Time. The Special Meeting was adjourned without any business being conducted due to lack of the required quorum. This adjournment will allow additional time for our stockholders to vote on the proposals set forth in the definitive proxy statement filed with the U.S. Securities and Exchange Commission on February 20, 2024 (the "Proxy Statement"). The Special Meeting will reconvene on April 19, 2024, at 8:30 a.m. ET, to be held virtually at www.virtualshareholdermeeting.com/TRVN2024SM. During the current adjournment, we will continue to solicit votes from our stockholders with respect to the proposals set forth in the Proxy Statement. Only stockholders of record, as of the record date of February 9, 2024, are entitled to and are being requested to vote at the Special Meeting, either in person or by proxy. Proxies previously submitted in respect of the Special Meeting will be voted at the adjourned Special Meeting unless properly revoked, and stockholders who have previously submitted a proxy or otherwise voted need not take any action.

R-Bridge Financing

In April 2022, an indirect subsidiary ("SPV2") entered into the Loan Agreement with R-Bridge, pursuant to which we may be eligible to receive up to $40.0 million in term loan borrowings, or the R-Bridge Financing. Term loan borrowings were to be advanced in three tranches. The first tranche of $15.0 million was advanced in April 2022. The second tranche of $10.0 million (the "Second Tranche") was to become available upon achievement of either a commercial or financing milestone as set forth in the Loan Agreement. The third tranche of $15.0 million was advanced in September 2023 upon the first commercial sale of OLINVYK in China.

In December 2023, we notified R-Bridge that we believed we had satisfied the conditions for the Second Tranche based on the achievement of the specified cumulative financing milestone. We are in discussions with R-Bridge with respect to the Second Tranche. However, there can be no assurance when, or if, we will receive the funds under the Second Tranche.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States. The preparation of our 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 our financial statements, as well as the reported revenues and expenses during the reported periods. 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 apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Our significant accounting policies are more fully described in the notes to our audited financial statements for the year ended December 31, 2023 included in this Annual Report on Form 10-K. However, we believe that the following accounting policies are important to understanding and evaluating our reported financial results, and we have accordingly included them in this discussion.

Product Revenue

We account for product revenue in accordance with ASC Topic 606, Revenue from Contracts with Customers (ASC 606). We perform the following five steps to recognize revenue under ASC 606: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. We only recognize revenue when we believe that it is probable that we will collect the consideration to which we are entitled in exchange for the goods or services that will be transferred to the customer.

We sell OLINVYK to wholesalers in the US (collectively, "customers"). These customers subsequently resell our products generally to hospitals, ambulatory surgical centers and other purchasers of OLINVYK. We recognize revenue from OLINVYK sales at the point customers obtain control of the product, which generally occurs upon delivery. The transaction price that is recognized as revenue for products includes an estimate of variable consideration which is described below.

Variable Consideration

We include an estimate of variable consideration in our transaction price at the time of sale when control of the product transfers to the customer. Variable consideration includes distributor chargebacks, prompt payment (cash) discounts, distribution service fees and product returns.

We assess whether or not an estimate of our variable consideration is constrained based on the probability that a significant reversal in the amount of cumulative revenue may occur in the future when the uncertainty associated with the variable consideration is subsequently resolved. Actual amounts of consideration ultimately received may vary from our estimates. If actual results in the future vary from our estimates, we will adjust these estimates, which would affect product sales and earnings in the period such variances become known.

Distributor Chargebacks

When a product is sold to a third party that is subject to a contractual price agreement, the difference between the price paid to us by the wholesaler and the price under the specific contract is charged back to us by the wholesaler. Utilizing this information, we estimate a chargeback percentage for each product and record an allowance for chargebacks as a reduction to revenue when we record our sale of the products. We reduce the chargeback allowance when a chargeback request from a wholesaler is processed. Reserves for chargebacks are included in accounts receivable, net on the consolidated balance sheet.

Product Returns

Generally, our customers have the right to return any unopened product during the eighteen (18) month period beginning six (6) months prior to the labeled expiration date and ending twelve (12) months after the labeled expiration date. We do not currently rely on industry data in our analysis of returns reserve. As we sold OLINVYK and established historical sales over a longer period of time (i.e., two to three years), we placed more reliance on historical purchasing, demand from hospitals and ambulatory surgical centers, return patterns of our customers and the amount of OLINVYK held by wholesalers, when evaluating our reserves for product returns. OLINVYK has a forty-eight (48) month shelf life.

We recognize the amount of expected returns as a refund liability, representing the obligation to return the customer's consideration. Since the returns primarily consist of expired and short dated products that will not be resold, we do not record a return asset for the right to recover the goods returned by the customer at the time of the initial sale (when recognition of revenue is deferred due to the anticipated return). Accrued product return estimates are recorded in accrued expenses and other current liabilities on the consolidated balance sheet.

Research and Development

Research and development costs are charged to expense as incurred. Research and development costs include, but are not limited to, personnel expenses, clinical trial supplies, fees for clinical trial services, manufacturing costs, consulting costs, and allocated overhead.

Costs for certain development activities, such as clinical trials, are recognized based on an evaluation of the progress to completion of specific tasks using data such as subject enrollment, clinical site activations or information provided to us by our vendors with respect to their actual costs incurred. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected in the financial statements as prepaid or accrued research and development expense, as the case may be.

As part of the process of preparing our financial statements, we are required to estimate our expenses resulting from our obligations under contracts with vendors, clinical research organizations and consultants, and under clinical site agreements in connection with conducting clinical trials. 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 under such contracts. Our objective is to reflect the appropriate trial expenses in our financial statements by matching those expenses with the period in which services are performed and efforts are expended. We may account for these expenses according to the progress of the trial as measured by subject progression and the timing of various aspects of the trial. We determine accrual estimates through financial models taking into account discussion with applicable personnel and outside service providers as to the progress or state of consummation of trials, or the services completed. During the course of a clinical trial, we adjust our clinical expense recognition if actual results differ from estimates. We make estimates of our accrued expenses as of each balance sheet date based on the facts and circumstances known to us at that time. Our clinical trial accruals are dependent upon the timely and accurate reporting of contract research organizations and other third-party vendors. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in us reporting amounts that are too high or too low for any particular period. For the years ended December 31, 2023 and 2022, there were no material adjustments to our prior period estimates of accrued expenses for clinical trials.

Stock-Based Compensation

We have equity incentive plans under which various types of equity-based awards including, but not limited to, incentive stock options, non-qualified stock options, and restricted stock unit awards, may be granted to employees, non-employee directors, and non-employee consultants. We also have an inducement plan under which various types of equity-based awards, including non-qualified stock options and restricted stock unit awards, may be granted to new employees.

At December 31, 2023, we have one stock-based compensation plan from which we are actively making grants of stock-based awards, which is more fully described in Note 8 to the financial statements included in Part II of this Annual Report on Form 10-K. We have applied the fair value recognition provisions of Financial Accounting Standards Board Accounting Standards Codification Topic 718, *Compensation — Stock Compensation*, or ASC 718, to account for stock-based compensation for employees.

We recognize compensation expense on a straight-line basis over the requisite service period for all stock-based awards based on the estimated grant-date fair values. For restricted stock unit awards to employees, the fair value is based on the closing price of our common stock on the date of grant. The fair value of stock options is determined using the Black-Scholes option pricing model. We utilize a dividend yield of zero based on the fact that we have never paid cash dividends and have no current intention of paying cash dividends. We elected an accounting policy to record forfeitures as they occur.

See Note 8 to the financial statements included in Part II of this Annual Report on Form 10-K for a discussion of the assumptions we used in determining the grant date fair value of options granted under the Black-Scholes option pricing model, as well as a summary of the stock option activity under our stock-based compensation plan for all years presented.

Loan Payable

In April 2022, an indirect subsidiary ("SPV2") entered into a Loan Agreement with R-Bridge, pursuant to which the Company may be eligible to receive up to $40.0 million in term loan borrowings, or the R-Bridge Financing. Term loan borrowings will be advanced in three tranches. The first tranche of $15.0 million was advanced in April 2022. The second tranche of $10.0 million will become available upon achievement of either a commercial or financing milestone as set forth in the Loan Agreement. The third tranche of $15.0 million was received in August 2023 upon the first commercial sale of OLINVYK in China. Under the relevant accounting guidance, the loan agreement has been accounted for as a debt instrument that will be amortized using the effective interest method over the life of the arrangement. In order to determine the amortization of the liability, we are required to estimate the total amount of future royalty payments to be paid to R-Bridge. Consequently, we impute interest on the unamortized portion of the liability and record interest expense related to the loan agreement accordingly. Due to the significant judgments and factors related to the estimates of future payments under the loan agreement, there are significant uncertainties surrounding the amount and timing of future payments and the related interest expense we recognize. We record non-cash interest expense within our consolidated statements of operations over the term of the loan agreement.

Recent Accounting Pronouncements

None.

Results of Operations

Comparison of Years Ended December 31, 2023 and 2022

(in thousands, except per share data)

	Year Ended December 31,		
	2023	2022	Change
Revenue:			
Product revenue	$ (54)	$ (438)	$ 384
License and royalty revenue	3,179	20	3,159
Total revenue	3,125	(418)	3,543
Operating expenses:			
Cost of goods sold	1,670	3,018	(1,348)
Selling, general and administrative	20,410	34,728	(14,318)
Research and development	16,333	18,211	(1,878)
Total operating expenses	38,413	55,957	(17,544)
Loss from operations	(35,288)	(56,375)	21,087
Other income (expense):			
Change in fair value of warrant liability	2,126	11,180	(9,054)
Other income, net	(4,522)	(7,681)	3,159
Interest income	1,398	451	947
Interest expense	(3,644)	(1,256)	(2,388)
Gain (loss) on foreign currency transactions	(41)	11	(52)
Foreign income tax expense	(318)	—	(318)
Total other income (expense), net	(5,001)	2,705	(7,706)
Net Loss	$ (40,289)	$ (53,670)	$ 13,381
Unrealized loss on marketable securities	—	1	(1)
Comprehensive loss	$ (40,289)	$ (53,669)	$ 13,380

Revenue

We derive our revenue from providing OLINVYK to our customers and activities pursuant to our licensing agreements related to the development and commercialization of OLINVYK in China and South Korea. For the year ended December 31, 2023 and 2022, product revenue includes a return adjustment of $0.1 million and $0.4 million respectively for expected returns from our wholesalers. In April 2024, we announced that OLINVYK remains available for purchase by customers, but that we are reducing commercial support for the product to preserve capital as we conduct a process to explore a range of strategic alternatives for OLINVYK.

As noted, in 2022 we recorded a returns reserve adjustment of $0.4 million for expected returns from our wholesalers. This adjustment was due, in part, to feedback we received in October 2022 from one of our wholesalers indicating that the wholesaler intended to return a significant portion of its supply of OLINVYK. As a result, we evaluated our returns reserves and updated our estimates to reflect this expected return, as well as potential increased probability of returns from our other wholesalers. In the fourth quarter of 2023, we recorded a returns adjustment of $0.1 million for expected returns from our wholesalers. This adjustment was due, in part, on our evaluation of historical purchasing trends, the remaining expiry period of inventory held by our wholesalers and the potential increase in the probability of returns from our wholesalers.

As further background on our methodology with respect to returns reserves, every quarter since our launch of OLINVYK, we review the amounts of OLINVYK held at our wholesalers to evaluate the likelihood of expected product returns. In our analysis, we consider a range of factors including the level of sales from our wholesalers to hospitals, ambulatory surgical centers (ASCs) and other purchasers of OLINVYK, which our wholesalers report to us on a regular basis, as well as any new customer contracts. Based on information from our wholesalers, sales from our wholesalers to

hospitals and ASCs, which we refer to as commercial sell through, have occurred, at a low level, every quarter since our commercial launch in February 2021. Commercial sell through of OLINVYK from our wholesalers to hospitals and ASCs for the year ended December 31, 2023 was approximately $82,000. Commercial sell through from our wholesalers to hospitals and ASCs for the year ended December 31, 2022 was approximately $35,800. While there is a general upward trend compared to the prior period, the overall level of these sales remains low and we do not expect this trend will continue as we reduce commercial support for OLINVYK.

In our returns reserve analysis, we also consider feedback from our wholesalers, group purchasing organizations and users of OLINVYK, as well as additional factors such as new safety data, or clinical or health economic data for OLINVYK that may affect future adoption and sales trends. Examples include OLINVYK data we announced in April 2022 with respect to respiratory physiology, and in July 2022 with respect to cognitive function. More recently in July 2023, we also announced OLINVYK data with respect to reduced cost per admission for hospitals and reduced average length of hospital stay, for OLINVYK-treated patients compared to matched patients treated with other IV opioids. We also consider factors that may negatively affect sales of OLINVYK, such as the price of OLINVYK compared to conventional IV opioids, which are generally generic and available at a lower initial cost relative to OLINVYK, and our reduction in commercial support for OLINVYK that we announced in April 2024. Other factors may include the public perception of opioids in general, as well as the FDA's and HHS' policy initiatives that may limit the promotion and marketing of opioids.

We incorporate these factors as we consider the need for any adjustment for slow-moving or obsolete product on a quarterly basis.

License and royalty revenue for the year ended December 31, 2023 relates to royalties earned on OLINVYK sales by Nhwa in China and the milestone payment that became payable by Nhwa upon regulatory approval of OLINVYK in China. License and royalty revenue recorded for the year ended December 31, 2022 related to materials shipped to Pharmbio to support the development of oliceridine efforts in South Korea.

Gross product revenue, and adjustments applied to calculate net product revenue, are set forth below (in thousands):

	Year Ended December 31,	
	2023	2022
Product revenue, gross	$ 58	$ (50)
GTN Accruals		
Chargebacks and cash discounts	(6)	—
Returns	(8)	—
Other rebates, discounts and adjustments	(6)	(1)
Total GTN Accruals	(20)	(1)
Product revenue	38	(51)
Adjustments to prior period accruals		
Returns reserve	(153)	(383)
Other GTN accrual adjustments	61	(4)
Product revenue, net	$ (54)	$ (438)

Cost of goods sold

Cost of goods sold for product revenue includes product costs, third party logistics costs, shipping costs, and indirect overhead costs which are recorded as period costs in the period incurred.

The following table provides information regarding cost of goods sold during the periods indicated, including percent changes (dollar amounts in thousands):

	Year Ended December 31,		
	2023	2022	% Increase (Decrease)
Cost of goods sold	$ 1,670	$ 3,018	-45%

Cost of goods sold decreased by $1.3 million, or 45% for the year ended December 31, 2023 compared to the same period in 2022, primarily due to a $0.9 million and $2.1 million non-cash valuation adjustment recoded in 2023 and 2022, respectively, for slow-moving or obsolete inventory due to the uncertainty of commercial activities and future expected OLINVYK sales.

Selling, general and administrative expense

Selling, general and administrative expenses consist principally of salaries and related costs for personnel in our executive, finance, commercial, and other administrative areas, including expenses associated with stock-based compensation and travel. Other selling, general and administrative expenses include professional fees for legal, field sales organization, medical affairs, market research, consulting, and accounting services.

Selling, general and administrative expenses decreased by $14.3 million, or 41%, for the year ended December 31, 2023 compared to the same period in 2022, primarily related to a reduction in full time employees, a reduction in marketing activities and termination in early 2022 of our contract sales force agreement.

Research and development expense

Research and development expenses consist primarily of costs incurred for research and the development of our product candidates, including costs associated with the regulatory approval process. In addition, research and development expenses include salaries and related costs for our research and development personnel and stock-based compensation expense and travel expenses for such individuals. Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size, complexity and duration of later-stage clinical trials.

Research and development costs are expensed as incurred and are tracked by discovery program and subsequently by product candidate once a product candidate has been selected for development. We record costs for some development activities, such as clinical trials, based on an evaluation of the progress to completion of specific tasks using data such as patient enrollment, clinical site activations or information provided to us by our vendors.

Research and development expenses decreased by $1.9 million, or 10% in 2023 as compared to 2022. The following table summarizes our research and development expenses (in thousands):

	Year Ended December 31,	
	2023	2022
TRV045	$ 9,472	$ 6,130
OLINVYK	610	3,230
TRV250	11	612
TRV027	127	409
Personnel-related costs	3,384	5,518
Other research and development	2,729	2,312
	$ 16,333	$ 18,211

The decrease in research and development expenses during the year ended December 31, 2023 was primarily driven by increased spend to advance TRV045 offset by decreased spend on OLINVYK post-approval clinical studies in respiratory physiology, cognitive function and gastrointestinal tolerability, lower personnel costs and decreased spending on TRV027 and TRV250.

Change in Fair Value Warrant Liability

Total Change in Fair Value Warrant Liability decreased by $9.1 million, or 81%, during the year ended December 31, 2023 compared to the same period in 2022, primarily due to a $9.1 million gain on the change in fair value of our liability classified warrants in 2022 and $4.6 million of expense in 2023 for issuances of inducement warrants associated with the December Financing.

Interest Expense

Interest expense increased $2.4 million, or 190%, during the year ended December 31, 2023 compared to the same period in 2022, primarily due to an increase in interest expense related to the debt issuance associated with our royalty financing obligation with R-Bridge.

Other income, net

Other income, net, increased $3.2 million, or 41% during the year ended December 31, 2023 compared to the same period in 2022, primarily due to the recording of $7.0 million for the excess fair value of warrant liabilities over the proceeds received in connection with the Company's equity offerings in July 2022 and November 2022.

Liquidity and Capital Resources

We have historically funded substantially all of our operations through the sale and issuance of our equity securities, debt securities and borrowings under debt facilities. We have also received an aggregate of $12.1 million pursuant to licensing agreements for the development and commercialization of OLINVYK in China and South Korea.

At December 31, 2023, we had an accumulated deficit of $588.1 million, working capital of $27.7 million, cash and cash equivalents of $33.0 million and restricted cash of $0.5 million. In November 2020, we filed a $250.0 million shelf registration statement, which includes our at-the-market ("ATM") program with H.C Wainwright & Co., LLC. ("HCW") (" HCW ATM Program"), of which there was approximately $33.7 million of available capacity as of December 31, 2023.

Our primary use of cash is to fund operating expenses, which consist of research and development expenditures, commercialization expenditures, and other selling, general and administrative expenditures. We anticipate these expenses to decrease in 2024 as we reduce commercial support of OLINVYK, while we continue to make OLINVYK available for purchase by customers and continue to advance our other product candidates. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in accounts payable and accrued expenses. Net cash used in operating activities was $33.0 million and $51.5 million for the years ended December 31, 2023 and 2022, respectively. We incurred net losses of $40.3 million and $53.7 million for those same periods.

Our success is dependent on finding a commercial partner for OLINVYK and obtaining adequate capital to fund operating losses until we become profitable. We expect that our existing balance of cash and cash equivalents as of December 31, 2023 is not sufficient to fund operations for one year after the date of this filing and therefore management has concluded that substantial doubt exists about our ability to continue as a going concern.

Cash Flows

The following table summarizes our cash flows (in thousands):

	December 31,	
	2023	2022
Net cash (used in) provided by:		
Operating activities	$ (33,035)	$ (51,477)
Investing activities	(41)	18
Financing activities	26,311	23,505
Net decrease in cash, cash equivalents and restricted cash	$ (6,765)	$ (27,954)

Net cash used in operating activities

Net cash used in operating activities was $33.0 million for the year ended December 31, 2023 as compared to $51.5 million for the year ended December 31, 2022. Net cash used in operating activities for the year ended December 31, 2023 includes a $40.3 million net loss as compared to $53.7 million for the prior period. The net loss was $13.4 million lower due to a $14.3 million decrease in selling, general and administrative expenses from the reduction of OLINVYK commercial activities and field-based headcount, lower cost of goods sold of $1.3 million due to a lower non-cash inventory reserve adjustment, and lower research and development costs of $1.9 million, as well as $3.0 million in license revenue.

Net cash (used in) provided by investing activities

Net cash used in investing activities was less than $0.1 million for the year ended December 31, 2023, primarily related to capital expenditures related to cybersecurity and technology updates.

Net cash provided by financing activities

Net cash provided by financing activities was $26.3 million for the year ended December 31, 2023. Net cash provided by financing activities for the year ended December 31, 2023 was primarily due to net proceeds of $14.8 million from debt issuance upon the first commercial sale of OLINVYK in China per the royalty-based loan agreement, net proceeds of $8.1 million from the HCW ATM Program, and $3.5 million from the December 2023 equity offering.

Net cash provided by financing activities was $23.5 million for the year ended December 31, 2022 primarily due to net proceeds of $13.9 million from debt issuance, and $9.7 million from the July 2022 and November 2022 equity offerings and issuance of warrants.

Leases

The Company currently leases approximately 8,231 square feet of developed office space on the first floor and 40,565 square feet of developed office space on the second floor in Chesterbrook Pennsylvania. The lease term for this space extends through May 2028. On October 11, 2018, the Company entered into an agreement with The Vanguard Group, Inc., or Vanguard, whereby Vanguard agreed to sublease the 40,565 square feet of space on the second floor for an initial term of 37 months. On October 2, 2020, Vanguard notified the Company that they exercised the first option to extend the sublease term for three years through November 30, 2024. Vanguard has a second option to extend the sublease term for an additional three years through November 30, 2027. On August 3, 2023, Vanguard exercised its second option to extend its sublease term. The Company and Vanguard agreed to further extend the sublease through May 2028. With the current extension to May 2028, Vanguard's sublease is coterminous with the Company's master lease term. The sublease provides for rent abatement for the first month of the term; thereafter, the rent payable per square foot to us by Vanguard under the sublease is (i) $0.50 less during months 2 through 13 of the sublease, (ii) $1.00 less during months 14 through 109 of the sublease and (iii) in month 110 through 116 of the sublease, $16.50 less than the base rent per square foot payable by us under our master lease with Chesterbrook Partners, L.P. Vanguard also is responsible for paying to the Company all tenant energy costs, annual operating costs, and annual tax costs attributable

to the subleased space during the term of the sublease. In 2024, we expect to pay approximately $1.4 million for our operating lease obligations. Future rent streams of $1.2 million to be collected in less than one year and $3.5 million to be collected between one and three years are not offset against operating lease obligations. See "Item 8 – Financial Statements and Supplementary Data – Note 9 – Commitments and Contingencies" in Part II of this Form 10-K for information about our operating lease obligations, including maturities of such obligations.

R-Bridge Financing

In April 2022, our wholly-owned subsidiary Trevena SPV2 LLC ("SPV2") entered into a royalty-based loan agreement (the "Loan Agreement") pursuant to which we may be eligible to receive up to $40.0 million in term loan borrowings. Term loan borrowings will be advanced in three tranches. The first tranche of $15.0 million was advanced in April 2022. The second tranche of $10.0 million will become available upon achievement of either a commercial or financing milestone as set forth in the Loan Agreement. The third tranche of $15.0 million became available upon the first commercial sale of OLINVYK in China which occurred in August 2023 and the Company elected to receive such proceeds.

In December 2023, we notified R-Bridge that we believed that we had satisfied the conditions for the second tranche of $10 million based on the achievement of the financing milestone. We are in discussions with R-Bridge with respect to the second tranche. However, there can be no assurance when, or if, we will receive the second tranche.

The term loans bear interest at a rate per annum equal to 7.00% and will mature on the earlier of (i) the fifteen (15) year anniversary of the closing date in March 2022 and (ii) the date on which the license agreement with Nhwa expires. Repayment of any borrowings and related interest will be made quarterly beginning June 30, 2022. Repayment will be in the form of (i) a 4.0% royalty payment on net sales of OLINVYK in the United States and (ii) proceeds from royalties from our license agreement with Nhwa. As a result of Nhwa obtaining Chinese approval of OLINVYK in May 2023, royalties from net sales of OLINVYK in the United States are capped at $10.0 million in accordance with the Loan Agreement. Upon a change in control or in the event the Company elects to repay any outstanding borrowings prior to their contractual maturity, the Company is required to pay a control premium equal to the greater of (i) principal and interest and (ii) $10.0 million or $20.0 million depending on the timing in which the triggering event occurs as further provided in the Loan Agreement.

In April 2022, the Company placed $2.0 million into an interest reserve account in connection with the Loan Agreement. Payments of interest under the Loan Agreement are made quarterly from the royalty on the Company's net sales of OLINVYK in the United States and proceeds from royalties from our license agreement with Nhwa. On each interest payment date, if the royalty payments received do not equal the total interest due for the respective quarter, the interest payment due will be paid from the interest reserve account. This interest reserve account was classified as restricted cash in our consolidated balance sheet at December 31, 2022. During the second quarter of 2023, the Company agreed to transfer the remaining funds, approximately $1.0 million, to R-Bridge to prepay future interest payments.

Repayments of all borrowings, interest and other related payments, under the Loan Agreement are secured by substantially all of the assets associated with the license agreement with Nhwa, the Chinese intellectual property related to OLINVYK, and deposit accounts established to hold amounts received on account for repayment of the borrowings and related interest under the Loan Agreement. The Loan Agreement contains certain customary affirmative and negative covenants and contains customary defined events of default, upon which any outstanding principal and unpaid interest shall be due on demand. At December 31, 2023, there were no events of default pursuant to the Loan Agreement and we were in compliance with all covenants.

In connection with the first tranche borrowings in April 2022, the Company issued a warrant to R-Bridge to purchase 200,000 shares of the Company's common stock at an initial exercise price of $20.50 per share and will be exercisable for a period of three years. The Company concluded the warrant was a freestanding equity-classified instrument to which the proceeds from the first tranche was allocated across the debt and warrant on a relative fair value basis. In addition, the Company incurred lender fees and third-party costs of $0.5 million each and were netted against the proceeds allocated to the debt and warrant. Fees netted against debt proceeds represent a debt discount and are amortized into interest expense using the effective interest method. During the year ended December 31, 2023, the

Company recognized interest expense of $3.6 million, of which $0.1 million pertained to the amortization of the debt discount.

The accounting for the Loan Agreement requires the Company to make certain estimates and assumptions, particularly about future royalties under the license agreement with Nhwa and sales of OLINVYK in the United States and China. Such estimates and assumptions are utilized in determining the expected repayment term, amortization period of the debt discount, accretion of interest expense and classification between current and long-term portions of amounts outstanding. The Company amortizes the debt discount into interest expense over the expected term of the arrangement using the interest method based on projected cash flows. Similarly, the Company classifies as current debt for the Loan Agreement, amounts that are expected to be repaid during the succeeding twelve months after the reporting period end. However, the repayment of amounts due under the Loan Agreement is variable because the cash flows to be utilized for periodic payments is a function of amounts received by the Company with respect to the royalties and net product sales.

Accordingly, the estimates of the magnitude and timing of amounts to be available for debt service are subject to significant variability and thus, subject to significant uncertainty. Therefore, these estimates and assumptions are likely to change, which may result in future adjustments to the portion of the debt that is classified as a current liability, the amortization of debt discount and the accretion of interest expense. Other amounts that may become due and payable under the Loan Agreement, including amounts shared between the parties with respect to cash flows received in excess of pre-defined thresholds, are recognized as additional interest expense when they become probable and estimable. The amount of principal to be repaid in each of the five succeeding years is not fixed and determinable.

Capital Raise

On December 28, 2023, we closed an offering for the issuance and sale of 2,779,906 shares of common stock (or pre-funded warrants in lieu thereof) of the Company and warrants to purchase up to an aggregate of 2,779,906 shares of common stock of the Company, at a purchase price of $0.70 per share (or pre-funded warrant in lieu thereof) and associated warrant in a private placement, for gross proceeds to the Company of approximately $1.9 million (the “private placement”).

Pursuant to a previously announced definitive agreement with respect to the immediate exercise for cash of certain existing warrants to purchase up to an aggregate of 2,934,380 shares of common stock issued in July 2022 and November 2022, the holder of such warrants exercised such warrants for cash at a reduced exercise price of $0.70 per share, in exchange for unregistered warrants to purchase up to 5,868,760 shares of common stock (the “induced warrant exercise” and, collectively with the private placement, the “offerings”).

The warrants issued in the offerings have an exercise price of $0.70 per share, will be exercisable commencing on the effective date of stockholder approval of the issuance of the shares issuable upon exercise of such warrants and will expire five years thereafter.

The aggregate gross proceeds to the Company from the offerings were approximately $4 million, before deducting placement agent fees and other offering expenses. The Company intends to use the net proceeds from the offerings for general corporate and working capital purposes.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements, as defined by applicable SEC regulations.

Operating and Capital Expenditure Requirements

We have not achieved profitability since our inception, and we expect to continue to incur net losses and negative cash flows from operations for the foreseeable future. We expect our cash expenditures to continue to be significant in the near term as we continue to make OLINVYK available for purchase by customers, and continue to develop TRV045. Over the next twelve months, we anticipate that our total operating expenses will decrease compared to the previous twelve months.

We believe that our cash and cash equivalents as of December 31, 2023, together with interest thereon, will not be sufficient to fund our operating expenses and capital expenditure requirements for one year after the date of this filing and as a result, there is substantial doubt about our ability to continue as a going concern through the year from the date of this filing. Our anticipated operating expenses involve significant risks and uncertainties and are dependent on our current assessment of the extent and costs of activities required to support our operations and advance our other product candidates. In the future, we anticipate that we will need to raise substantial additional financing to fund our operations. To meet these requirements, we may seek to sell equity or convertible securities in public or private transactions that may result in significant dilution to our stockholders. We may offer and sell shares of our common stock under the existing registration statement or any registration statement we may file in the future. If we raise additional funds through the issuance of convertible securities, these securities could have rights senior to those of our common stock and could contain covenants that restrict our operations.

Ultimately, there can be no assurance that we will be able to obtain additional equity or debt financing on terms acceptable to us, if at all. Our future capital requirements will depend on many factors, including:

- our ability to successfully find a commercial partner for OLINVYK and commercialize our other product candidates;
- our ability to generate sales and other revenues from OLINVYK or any of our other product candidates, once approved, including setting an acceptable price for and obtaining adequate coverage and hospital formulary acceptance of such products;
- the size and growth potential of the markets for OLINVYK and our ability to serve those markets;
- the scope, progress, results and costs of researching and developing our product candidates or any future product candidates, both in the United States and in territories outside the United States;
- the number and development requirements of any other product candidates that we may pursue;
- our ability to enter into collaborative agreements for the development and/or commercialization of our product candidates, including for OLINVYK;
- the costs, timing, and outcome of any regulatory review of OLINVYK and any future product candidates, both in the United States and in territories outside the United States;
- the costs, timing, and extent of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval;
- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- any product liability or other lawsuits related to our products or us;
- the expenses needed to attract and retain skilled personnel; and
- the costs involved in preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending our intellectual property-related claims, both in the United States and in territories outside the United States.

Please see “Risk Factors” for additional risks associated with our substantial capital requirements.

Other Commitments

In the course of normal business operations, we have agreements with contract service providers to assist in the performance of our research and development and manufacturing activities. We can elect to discontinue the work under these agreements at any time. We also could enter into additional collaborative research, contract research, manufacturing and supplier agreements in the future, which may require upfront payments and even long-term commitments of cash.

We have no material non-cancelable purchase commitments with contract manufacturers or service providers as we have generally contracted on a cancelable basis.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not required.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

REPORT OF MANAGEMENT

Management's Report on Financial Statements

Our management is responsible for the preparation, integrity and fair presentation of information in our financial statements, including estimates and judgments. The financial statements presented in this Annual Report on Form 10-K have been prepared in accordance with accounting principles generally accepted in the United States of America. Our management believes the financial statements and other financial information included in this Annual Report on Form 10-K fairly present, in all material respects, our financial condition, results of operations and cash flows as of and for the periods presented in this Annual Report on Form 10-K. The financial statements have been audited by Ernst & Young LLP, an independent registered public accounting firm, as stated in their report, which is included herein.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Our internal control system was designed to provide reasonable assurance to our management and Board of Directors regarding the preparation and fair presentation of published financial statements. Internal control over financial reporting is defined in Rule 13a-15(f) or 15d-15(f) promulgated under the Exchange Act as a process designed by, or under the supervision of, our principal executive and principal financial officers and effected by our Board of Directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

- pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect our transactions and dispositions of our assets;
- provide reasonable assurance that our transactions are recorded as necessary to permit preparation of our financial statements in accordance with accounting principles generally accepted in the United States of America, and that our receipts and expenditures are being made only in accordance with authorization of our management and our directors; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of our assets that could have a material effect on our financial statements.

Our management, including our Chief Executive Officer and Chief Operating Officer and Chief Financial Officer, do not expect that our internal control over financial reporting will prevent or detect all errors and all fraud. A control system, no matter how well designed and implemented, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues within a company are detected. The inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple errors or mistakes. Controls can also be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of the controls. 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 cost-effective control system, misstatements due to error or fraud may occur and may not be detected.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2023. In making this assessment, our management used the criteria based on the framework set forth by the Committee of Sponsoring Organizations of the Treadway Commission in "Internal Control—Integrated Framework" (2013). Based on the assessments of our internal control over financial reporting, our management, including our Chief Executive Officer and Chief Financial Officer, believe that, as of December 31, 2023, our internal control over financial reporting was effective based on those criteria.

Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors of Trevena, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Trevena, Inc. (the Company) as of December 31, 2023 and 2022, the related consolidated statements of operations and comprehensive loss, stockholders' (deficit) equity and cash flows for each of the two years in the period ended December 31, 2023, 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, 2023 and 2022, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2023, in conformity with U.S. generally accepted accounting principles.

The Company's Ability to Continue as a Going Concern

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 financial statements, the Company has suffered recurring losses from operations and has stated that substantial doubt exists about the Company's ability to continue as a going concern. Management's evaluation of the events and conditions and management's plans regarding 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 financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's 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 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 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 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 financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of the critical audit matter 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 matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Loan Payable

Description of the Matter	As described in Note 7 to the consolidated financial statements, the Company, through a subsidiary, entered into a loan agreement with R-Bridge Investment Four Pte. Ltd. (R-Bridge) in April 2022. Pursuant to the loan agreement, the Company received gross proceeds of $30 million in exchange for the obligation to make principal and interest payments to R-Bridge based on a percentage of net sales of OLINVYK in the United States and proceeds from royalties from the Company's license agreement with Jiangsu Nhwa Pharmaceutical Co. Ltd. on sales of OLINVYK in China. The Company recorded borrowings under the loan agreement on the consolidated balance sheet at a carrying value of $30.8 million as of December 31, 2023 and imputed interest expense associated with this loan during 2023 using the effective interest rate method. The effective interest rate is calculated based on the rate that would enable the loan to be repaid in full over the anticipated life of the agreement. The effective interest rate on the loan may vary during the term of the loan depending on a number of factors, including the level and timing of forecasted net sales of OLINVYK and the resulting repayment to R-Bridge. The Company utilizes the prospective method to account for the loan, under which a new effective interest rate is determined at each balance sheet date based on the Company's current estimates of the amount and timing of expected future payments. Auditing the loan payable involved complex and subjective auditor judgment due to the estimation uncertainty involved in determining the effective interest rate. The Company's effective interest rate model includes estimated revenue projections which are sensitive to significant assumptions including the estimated market demand for OLINVYK.
How We Addressed the Matter in Our Audit	To test the loan payable, our audit procedures included, among others, confirming certain loan provisions directly with R-Bridge, testing the significant assumptions used to develop the estimates and evaluating the completeness and accuracy of the underlying data used by the Company in its effective interest rate model. We recalculated the current year interest expense based on the Company's model, and performed sensitivity analyses to evaluate the changes in the effective interest rate, and associated interest expense, that would result from changes in the significant assumptions.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2007.

Philadelphia, Pennsylvania
April 1, 2024

TREVENA, INC.

Consolidated Balance Sheets
(in thousands, except share and per share data)

	December 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 32,975	$ 38,320
Inventories	-	906
Prepaid expenses and other current assets	2,230	1,782
Total current assets	35,205	41,008
Restricted cash	540	1,960
Property and equipment, net	1,195	1,488
Right-of-use lease assets	3,665	4,224
Total assets	$ 40,605	$ 48,680
Liabilities and stockholders' (deficit) equity		
Current liabilities:		
Accounts payable, net	$ 2,303	$ 2,372
Accrued expenses and other current liabilities	4,239	5,461
Lease liabilities	1,012	899
Total current liabilities	7,554	8,732
Loan payable, net	30,809	13,430
Leases, net of current portion	4,424	5,436
Warrant liability	5,475	5,483
Total liabilities	48,262	33,081
Stockholders' (deficit) equity:		
Preferred stock—$0.001 par value; 5,000,000 shares authorized, none issued or outstanding at December 31, 2023 and 2022	—	—
Common stock—$0.001 par value; 200,000,000 shares authorized at December 31, 2023 and 2022; 17,289,104 and 7,744,692 shares issued and outstanding at December 31, 2023 and 2022, respectively	17	8
Additional paid-in capital	580,387	563,362
Accumulated deficit	(588,061)	(547,772)
Accumulated other comprehensive income	—	1
Total stockholders' (deficit) equity	(7,657)	15,599
Total liabilities and stockholders' (deficit) equity	$ 40,605	$ 48,680

See accompanying notes to consolidated financial statements.

TREVENA, INC.

Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share data)

	Year Ended December 31,	
	2023	2022
Revenue:		
Product revenue	$ (54)	$ (438)
License and royalty revenue	3,179	20
Total revenue	3,125	(418)
Operating expenses:		
Cost of goods sold	1,670	3,018
Selling, general and administrative	20,410	34,728
Research and development	16,333	18,211
Total operating expenses	38,413	55,957
Loss from operations	(35,288)	(56,375)
Other income (expense):		
Change in fair value of warrant liability	2,126	11,180
Other expense, net	(4,522)	(7,681)
Interest income	1,398	451
Interest expense	(3,644)	(1,256)
(Loss) gain on foreign currency exchange	(41)	11
Foreign income tax expense	(318)	—
Total other income (expense), net	(5,001)	2,705
Net Loss	(40,289)	(53,670)
Unrealized gain on marketable securities	—	1
Comprehensive loss	$ (40,289)	$ (53,669)
Per share information:		
Net loss per share of common stock, basic and diluted	$ (3.16)	$ (7.59)
Weighted average common shares outstanding, basic and diluted	12,735,010	7,072,362

See accompanying notes to consolidated financial statements.

TREVENA, INC.
Consolidated Statements of Stockholders' (Deficit) Equity
(in thousands, except share data)

	Stockholders' Equity							
	Preferred Stock		Common Stock					
	Number of Shares	$0.001 Par Value	Number of Shares	$0.001 Par Value	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' (Deficit) Equity
Balance, January 1, 2022	—	$ —	6,618,093	$ 7	$ 558,724	$ (494,102)	$ —	$ 64,629
Stock-based compensation expense	—	—	—	—	3,676	—	—	3,676
Issuance of common stock warrants in connection with loan payable	—	—	—	—	603	—	—	603
Issuance of Common Stock in connection with equity offering	—	—	765,000	1	(1)	—	—	—
Issuance of common stock upon vesting of RSUs, net of shares withheld for employee taxes	—	—	41,599	—	(37)	—	—	(37)
Issuance of preferred stock	2,000	397	—	—	—	—	—	—
Conversion of preferred stock to common stock	(2,000)	(397)	320,000	—	397	—	—	397
Unrealized gain on marketable securities	—	—	—	—	—	—	1	1
Net loss	—	—	—	—	—	(53,670)	—	(53,670)
Balance, December 31, 2022	—	$ —	7,744,692	$ 8	$ 563,362	$ (547,772)	$ 1	$ 15,599
Stock-based compensation expense	—	—	—	—	2,930	—	—	2,930
Exercise of pre-funded warrants and related reclassification of warrant liability	—	—	1,849,380	2	2,001	—	—	2,003
Issuance of common stock upon exercise of warrant and related reclassifcation of warrant liability	—	—	1,700,000	1	3,874	—	—	3,875
Issuance of warrants in connection with offering	—	—	—	—	161	—	—	161
Issuance of common stock, net of issuance costs	—	—	5,843,328	6	8,061	—	—	8,067
Issuance of common stock upon vesting of RSUs, net of shares withheld for employee taxes	—	—	151,704	—	(2)	—	—	(2)
Unrealized loss on marketable securities	—	—	—	—	—	—	(1)	(1)
Net loss	—	—	—	—	—	(40,289)	—	(40,289)
Balance, December 31, 2023	—	$ —	17,289,104	$ 17	$ 580,387	$ (588,061)	$ —	$ (7,657)

See accompanying notes to consolidated financial statements.

TREVENA, INC.

Statements of Cash Flows
(in thousands)

	Year Ended December 31,	
	2023	2022
Operating activities:		
Net loss	$ (40,289)	$ (53,670)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	334	382
Stock-based compensation	2,930	3,676
Noncash interest expense on loan	1,634	128
Inventory valuation adjustment	896	2,070
Value of warrants issued for exercise inducement	4,674	—
Change in fair value of warrant liability	(2,126)	(11,180)
Returns reserve adjustment	107	383
Fair value of warrants in excess of proceeds	—	7,147
Accretion of bond discount on marketable securities	—	(46)
Change in right-of-use asset	559	482
Changes in operating assets and liabilities:		
Accounts receivable, prepaid expenses and other assets	522	1,209
Inventories	10	(624)
Operating lease liabilities	(887)	(758)
Accounts payable, accrued expenses and other liabilities	(1,399)	(676)
Net cash used in operating activities	(33,035)	(51,477)
Investing activities:		
Purchases of property and equipment	(41)	(28)
Maturities of marketable securities	—	33,000
Purchases of marketable securities	—	(32,954)
Net cash used in investing activities	(41)	18
Financing activities:		
Proceeds from issuance of common stock, net of issuance costs	8,066	—
Payment of employee withholding taxes on vested restricted stock units	(2)	(37)
Proceeds from the sale of common stock, warrants and pre-funded warrants	1,426	7,997
Exercise of Prefunded Warrants and warrants	2,056	—
Finance lease payments	(12)	(8)
Proceeds from exercise of pre-funded warrants	2	—
Proceeds from issuance of convertible Series A and Series B preferred stock and warrants, net of issuance costs	—	1,647
Proceeds from loan payable	14,775	13,906
Net cash provided by financing activities	26,311	23,505
Net decrease in cash, cash equivalents and restricted cash	(6,765)	(27,954)
Cash, cash equivalents and restricted cash—beginning of period	40,280	68,234
Cash, cash equivalents and restricted cash—end of period	$ 33,515	$ 40,280
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 801	$ 604
Allocation of loan payable proceeds to common stock warrants	$ —	$ 603
Preferred stock proceeds allocated to warrant liability	$ —	$ (603)
Reclassification of warrant liability upon exercise of pre-funded warrants	$ 2,001	$ —
Conversion of Series A and Series B preferred stock to common stock	$ —	$ (397)

See accompanying notes to consolidated financial statements.

TREVENA, INC.

Notes to Consolidated Financial Statements

December 31, 2023

1. Organization and Description of the Business

Trevena, Inc., or the Company, is a biopharmaceutical company focused on the development and commercialization of novel medicines for patients affected by central nervous system, or CNS, disorders. The Company operates in one segment and has its principal office in Chesterbrook, Pennsylvania.

Since commencing operations in 2007, the Company has devoted substantially all of its financial resources and efforts to commercialization and research and development, including nonclinical studies and clinical trials. The Company has never been profitable. In late 2017, the Company submitted a new drug application, or NDA, for OLINVYK® (OLINVYK) injection, or OLINVYK, to the United States Food and Drug Administration, or the FDA. In August 2020, the FDA approved the NDA for OLINVYK and the Company initiated commercial launch of OLINVYK in the first quarter of 2021.

Since the Company's inception, the Company has incurred losses and negative cash flows from operations. At December 31, 2023, the Company had an accumulated deficit of $588.1 million. The Company's net loss was $40.3 million and $53.7 million for the years ended December 31, 2023 and 2022, respectively. The Company follows the provisions of Financial Accounting Standards Board, or FASB, Accounting Standards Codification, or ASC, Topic 205-40, *Presentation of Financial Statements—Going Concern*, or ASC 205-40, which requires management to assess the Company's ability to continue as a going concern for one year after the date the financial statements are issued. The Company expects that its existing balance of cash and cash equivalents as of December 31, 2023 is not sufficient to fund operations for one year after the date of this filing and therefore management has concluded that substantial doubt exists about the Company's ability to continue as a going concern. Management's plans to mitigate this risk include raising additional capital through equity or debt financings, or through strategic transactions. Management's plans also include the deferral of certain operating expenses unless and until additional capital is received. However, there can be no assurance that the Company will be successful in raising additional capital or that such capital, if available, will be on terms that are acceptable to the Company, or that the Company will be successful in deferring certain operating expenses. As a result, management concluded that such plans do not alleviate the substantial doubt. If the Company is unable to raise sufficient additional capital or defer sufficient operating expenses, the Company may be compelled to reduce the scope of its operations and planned capital expenditures.

Effective as of 5:01 p.m. ET on November 9, 2022 (the "Effective Time"), the Company filed a Certificate of Amendment to its Certificate of Incorporation with the Secretary of State of the State of Delaware to effect a 25-for-1 reverse stock of the Company's common stock (the "Reverse Stock Split"), and the Company's common stock began trading on a split-adjusted basis on the Nasdaq Capital Market ("Nasdaq") when the market opened on November 10, 2022. As a result of the Reverse Stock Split, each 25 shares of the Company's common stock immediately prior to the Effective Time were combined into one validly issued, fully paid and non-assessable share of the Company's common stock. No fractional shares were issued in connection with the Reverse Stock Split, and cash paid to stockholders for potential fractional shares was insignificant. All of the shares and per share amounts discussed in this Annual Report on Form 10-K have been adjusted to reflect the effect of the Reverse Stock Split.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America, or U.S. GAAP. Any reference in these notes to applicable guidance is meant to refer to the authoritative United States generally accepted accounting principles as found in the ASC and Accounting Standards Updates, or ASUs, of the FASB. The Company's functional currency is the U.S. dollar.

Principles of Consolidation

In connection with the loan agreement disclosed in Note 7, the Company established three wholly owned subsidiaries, Trevena Royalty Corporation, Trevena SPV1 LLC and Trevena SPV2 LLC to facilitate the financing. The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries as of December 31, 2023. All intercompany accounts and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Management used significant estimates in the following areas, among others: stock-based compensation expense, the determination of the fair value of stock-based awards, the fair value of common stock warrants, the accounting for research and development costs, accrued expenses, the recoverability of the Company's net deferred tax assets and related valuation allowance, and the amortization of the debt expenses. The financial data and other information disclosed in these notes are not necessarily indicative of the results to be expected for any future year or period. The Company bases its estimates on historical experience and also on assumptions that it believes are reasonable, however, actual results could significantly differ from those results.

Cash and Cash Equivalents

The Company considers all highly liquid investments that have maturities of three months or less when acquired to be cash equivalents. Cash equivalents are valued at cost, which approximates their fair market value. The Company maintains a portion of its cash and cash equivalent balances in money market mutual funds that may invest substantially all of their assets in U.S. government agency securities and U.S. Treasury securities.

Restricted Cash

The Company maintains $0.5 million as collateral under a letter of credit for the Company's facility lease obligations in Chesterbrook, Pennsylvania. The Company has recorded this deposit and accumulated interest thereon as restricted cash on its balance sheet.

In April 2022, the Company placed $2.0 million into an interest reserve account in connection with the royalty based loan agreement (the "Loan Agreement") with R-Bridge Investment Four Pte. Ltd. ("R-Bridge"). Payments of interest under the Loan Agreement are made quarterly from certain royalties on the Company's net sales of OLINVYK in the United States and proceeds from royalties from the Company's license agreement with Jiangsu Nhwa Pharmaceuticals Co. Ltd., or Nhwa. On each interest payment date, if the royalty payments received do not equal the total interest due for the respective quarter, the interest payment due will be paid from the interest reserve account. As of December 31, 2023, there is no interest reserve account balance.

Fair Value of Financial Instruments

The carrying amount of the Company's financial instruments, which include cash and cash equivalents, restricted cash, accounts payable and accrued expenses approximate their fair values, given their short-term nature. Additionally, the Company believes the carrying value of the loan payable approximates its fair value as the interest rate

is reflective of the rate the Company could obtain on debt with similar terms and conditions. Certain of the Company's common stock warrants are carried at fair value, as disclosed in Note 3.

The Company has evaluated the estimated fair value of financial instruments using available market information and management's estimates. The use of different market assumptions and/or estimation methodologies could have a significant effect on the estimated fair value amounts. See Note 3 for additional information.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk are primarily cash, cash equivalents, and restricted cash. The Company's investment policy includes guidelines on the quality of the institutions and financial instruments and defines allowable investments that the Company believes minimizes the exposure to concentration of credit risk. The Company has no off-balance sheet concentrations of credit risk such as foreign currency exchange contracts, option contracts or other hedging arrangements.

Product Revenue

Product revenue is recognized at the point in time when our performance obligations with our customers have been satisfied. At contract inception, we determine if the contract is within the scope of ASC Topic 606 and then evaluate the contract using the following five steps: (i) identify the contract with the customer; (ii) identify the performance obligations; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations; and (v) recognize revenue at the point in time when the Company satisfies a performance obligation.

OLINVYK is sold to wholesalers in the US (collectively, "customers"). These customers subsequently resell the OLINVYK generally to hospitals, ambulatory surgical centers and other purchasers of OLINVYK. We recognize revenue from OLINVYK sales at the point customers obtain control of the product, which generally occurs upon delivery.

Revenue is recorded at the transaction price, which is the amount of consideration we expect to receive in exchange for transferring products to a customer. We determine the transaction price based on fixed consideration in our contractual agreements, which includes estimates of variable consideration which is described below. The transaction price is allocated entirely to the performance obligation to provide pharmaceutical products. In determining the transaction price, a significant financing component does not exist since the timing from when we deliver product to when the customers pay for the product is less than one year and the customers do not pay for product in advance of the transfer of the product.

Variable Consideration

The Company includes an estimate of variable consideration in its transaction price at the time of sale when control of the product transfers to the customer. Variable consideration includes distributor chargebacks, prompt payment (cash) discounts, distribution service fees and product returns.

The Company assesses whether or not an estimate of its variable consideration is constrained and has determined that the constraint does not apply, since it is probable that a significant reversal in the amount of cumulative revenue will not occur in the future when the uncertainty associated with the variable consideration is subsequently resolved. The Company's estimates for variable consideration are adjusted as required at each reporting period for specific known developments that may result in a change in the amount of total consideration it expects to receive.

Distributor Chargebacks

When a product that is subject to a contractual price agreement is sold to a third party, the difference between the price paid to the Company by the wholesaler and the price under the specific contract is charged back to the Company by the wholesaler. Utilizing this information, the Company estimates a chargeback percentage for each product and records an allowance for chargebacks as a reduction to revenue when the Company records sales of the

products. We reduce the chargeback allowance when a chargeback request from a wholesaler is processed. Reserves for distributor chargebacks are included in accounts receivable, net on the consolidated balance sheet.

Prompt Payment (Cash) Discounts

The Company provides customers with prompt payment discounts which may result in adjustments to the price that is invoiced for the product transferred, in the case that payments are made within a defined period. The Company's prompt payment discount reserves are based on actual net sales and contractual discount rates. Reserves for prompt payment discounts are included in accounts receivable, net on the consolidated balance sheet.

Distribution Service Fees

The Company pays distribution service fees to its customers based on a fixed percentage of the product price. These fees are not in exchange for a distinct good or service and therefore are recognized as a reduction of the transaction price. The Company reserves for these fees based on actual net sales, contractual fee rates negotiated with the customer and the mix of the products in the distribution channel that remain subject to fees. Reserves for distribution service fees are included in accounts receivable, net on the consolidated balance sheet.

Product Returns

Generally, the Company's customers have the right to return any unopened product during the eighteen (18) month period beginning six (6) months prior to the labeled expiration date and ending twelve (12) months after the labeled expiration date. The Company does not currently rely on industry data in its analysis of returns reserve. As the Company sold OLINVYK and established historical sales over a longer period of time (i.e., two to three years), the Company placed more reliance on historical purchasing, demand and return patterns of its customers when evaluating its reserves for product returns. OLINVYK has a forty-eight (48) month shelf life.

The Company recognizes the amount of expected returns as a refund liability, representing the obligation to return the customer's consideration. Since the returns primarily consist of expired and short dated products that will not be resold, the Company does not record a return asset for the right to recover the goods returned by the customer at the time of the initial sale (when recognition of revenue is deferred due to the anticipated return). Accrued product return estimates are recorded in accrued expenses and other current liabilities on the consolidated balance sheet.

License Revenues

Our licensing agreements typically include payment to us of one or more of the following: nonrefundable, up-front license fees; regulatory and commercial milestone payments; payments for manufacturing supply services; materials shipped to support development; and royalties on net sales of licensed products.

We also assess whether there is an option in a contract to acquire additional goods or services. An option gives rise to a performance obligation only if the option provides a material right to the customer that it would not receive without entering into that contract. Factors that we consider in evaluating whether an option represents a material right include, but are not limited to: (i) the overall objective of the arrangement, (ii) the benefit the collaborator might obtain from the arrangement without exercising the option, (iii) the cost to exercise the option (e.g. priced at a significant and incremental discount) and (iv) the likelihood that the option will be exercised. With respect to options determined to be performance obligations, we recognize revenue when those future goods or services are transferred or when the options expire.

Our licensing revenue arrangements may include the following:

Up-front License Fees: If a license is determined to be distinct from the other performance obligations identified in the arrangement, we recognize revenues from nonrefundable, up-front fees allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are bundled with other promises, we utilize judgment to assess the nature of the combined performance obligation to

determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, up-front fees. We evaluate the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

Milestone Payments: At the inception of an agreement that includes regulatory or commercial milestone payments, we evaluate whether each milestone is considered probable of being achieved and estimate the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within our control or the control of the licensee, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. At each reporting period, we assess the probability of achievement of each milestone under our current agreements.

Research and Development Activities: Under our current collaboration and license arrangements, if we are entitled to reimbursement for costs for services that we provided, such reimbursement would be recorded as an offset to research and development expenses.

Royalties: If we are entitled to receive sales-based royalties from our collaborator, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, we recognize revenue at the later of (i) when the related sales occur, provided the reported sales are reliably measurable, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

Manufacturing Supply and Research Services: Arrangements that include a promise for future supply of drug substance or drug product for either clinical development or commercial supply at the licensee's discretion are generally considered as options. We assess if these options provide a material right to the licensee and if so, they are accounted for as separate performance obligations.

We receive payments from our licensees based on schedules established in each contract. Upfront payments are recorded as deferred revenue upon receipt and may require deferral of revenue recognition to a future period until we perform our obligations under these arrangements. Amounts are recorded as accounts receivable when our right to consideration is unconditional. We do not assess whether a contract has a significant financing component if the expectation at contract inception is such that the period between payment by the licensees and the transfer of the promised goods or services to the licensees will be one year or less.

Property and Equipment

Property and equipment consists of computer and laboratory equipment, software, office equipment, furniture, manufacturing equipment and leasehold improvements and is recorded at cost. Maintenance and repairs that do not improve or extend the lives of the respective assets are expensed to operations as incurred. Upon disposal, retirement or sale, the related cost and accumulated depreciation are removed from the accounts and any resulting gain or loss is included in the results of operations. Property and equipment are depreciated on a straight-line basis over their estimated useful lives. The Company uses a life of three years for computer equipment and five years for laboratory equipment, office equipment, furniture, manufacturing equipment and software. Leasehold improvements are amortized over the shorter of the lease term or the estimated useful life of the asset.

The Company reviews long-lived assets when events or changes in circumstances indicate the carrying value of the assets may not be recoverable. Recoverability is measured by comparison of the book values of the assets to future net undiscounted cash flows that the assets are expected to generate. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the book value of the assets exceed their fair value, which is measured based on the projected discounted future net cash flows arising from the assets. No impairment losses were recorded during the years ended December 31, 2023 or 2022.

Leases

At the commencement of a lease, the Company recognizes a liability to make lease payments and an asset representing the right to use the underlying asset during the lease term. The lease liability is measured at the present value of lease payments over the lease term, including variable fees that are known or subject to a minimum floor. The lease liability includes lease component fees, while non-lease component fees are expensed as incurred for all asset classes. When a contract excludes an implicit rate, the Company utilizes an incremental borrowing rate based on information available at the lease commencement date including lease term and geographic region. The initial valuation of the right-of-use, or ROU, asset includes the initial measurement of the lease liability, lease payments made in advance of the lease commencement date, and initial direct costs incurred by the Company and excludes lease incentives.

Leases with an initial term of 12 months or less are classified as short-term leases and are not recorded on the balance sheet. The lease expense for short-term leases is recognized on a straight-line basis over the lease term. The Company tests for impairment of the ROU assets whenever circumstances indicate that the carrying amount of the asset may not be recoverable.

Common Stock Warrants

Freestanding warrants that are related to the purchase of common stock are classified as liabilities and recorded at fair value regardless of the timing of the redemption feature or the redemption price or the likelihood of redemption. These warrants are subject to re-measurement at each balance sheet date and any change in fair value is recognized as a component of change in fair value of warrant liability in the statements of operations and comprehensive loss. The Company will continue to adjust the liability for changes in fair value until the earlier of the exercise or expiration of the warrants. The warrants are classified as Level 3 liabilities as of December 31, 2023 and 2022.

In addition, in connection with entering into loan agreements, the Company has issued warrants to purchase shares of the Company's common stock. These detachable warrant instruments qualify for equity classification and have been allocated upon the relative fair value of the base instrument and the warrant. See Note 7 and Note 8 for additional information.

Research and Development

Research and development costs are charged to expense as incurred. Research and development costs include, but are not limited to, personnel expenses, clinical trial supplies, fees for clinical trial services, manufacturing costs, consulting costs, and allocated overhead.

Costs for certain development activities, such as clinical trials, are recognized based on an evaluation of the progress to completion of specific tasks using data such as subject enrollment, clinical site activations or information provided to the Company by its vendors with respect to their actual costs incurred. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected in the financial statements as prepaid or accrued research and development expense, as the case may be.

As part of the process of preparing its financial statements, the Company is required to estimate its expenses resulting from its obligations under contracts with vendors, clinical research organizations and consultants, and under clinical site agreements in connection with conducting clinical trials. 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 under such contracts. The Company's objective is to reflect the appropriate trial expenses in its financial statements by matching those expenses with the period in which services are performed and efforts are expended. The Company may account for these expenses according to the progress of the trial as measured by subject progression and the timing of various aspects of the trial. The Company determines accrual estimates through financial models taking into account discussion with applicable personnel and outside service providers as to the progress or state of consummation of trials, or the services completed. During the course of a clinical trial, the Company adjusts its clinical expense recognition if actual results differ from its estimates. The Company makes estimates of its accrued expenses as of each balance sheet date based on the facts and circumstances known to it at that time. The

Company's clinical trial accruals are dependent upon the timely and accurate reporting of contract research organizations and other third-party vendors. Although the Company does not expect its estimates to be materially different from amounts actually incurred, its understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in it reporting amounts that are too high or too low for any particular period. For the years ended December 31, 2023 and 2022, there were no material adjustments to the Company's prior period estimates of accrued expenses for clinical trials.

Stock-Based Compensation

The Company has equity incentive plans under which various types of equity-based awards including, but not limited to, incentive stock options, non-qualified stock options, and restricted stock unit awards, may be granted to employees, non-employee directors, and non-employee consultants. At December 31, 2023, the Company had three stock-based compensation plans, which are more fully described in Note 8. The Company also has an inducement plan under which various types of equity-based awards, including non-qualified stock options and restricted stock awards, may be granted to new employees.

The Company has applied the fair value recognition provisions of Financial Accounting Standards Board Accounting Standards Codification Topic 718, Compensation — Stock Compensation, to account for stock-based compensation for employees. The Company recognizes compensation expense for all stock-based awards based on the estimated grant-date fair values. For restricted stock unit awards to employees, the fair value is based on the closing price of the Company's common stock on the date of grant. The value of the portion of the award that is ultimately expected to vest is recognized as expense on a straight-line basis over the requisite service period.

The fair value of stock options is determined using the Black-Scholes option pricing model. The Company utilizes a dividend yield of zero based on the fact that the Company has never paid cash dividends and has no current intention of paying cash dividends. The Company elected an accounting policy to record forfeitures as they occur. For stock awards that vest based on performance conditions (e.g., achievement of certain milestones), expense is recognized when it is probable that the conditions will be met. See Note 8 for a discussion of the assumptions used by the Company in determining the grant date fair value of options granted under the Black-Scholes option pricing model, as well as a summary of the stock option activity under the Company's stock-based compensation plan for all years presented.

Income Taxes

Income taxes are recorded in accordance with ASC Topic 740, *Income Taxes*, or ASC 740, which provides for deferred taxes using an asset and liability approach. The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or tax returns. Deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Valuation allowances are provided, if based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

The Company accounts for uncertain tax positions in accordance with the provisions of ASC 740. When uncertain tax positions exist, the Company recognizes the tax benefit of tax positions to the extent that the benefit will more likely than not be realized. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position, as well as consideration of the available facts and circumstances. To date, the Company has not taken any uncertain tax position or recorded any reserves, interest or penalties.

Comprehensive Income (Loss)

Comprehensive income (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.

Basic and Diluted Net Loss Per Share of Common Stock

The Company's basic net loss per share is calculated by dividing the net loss by the weighted average number of shares of common stock outstanding for the period. The diluted net loss per common share is computed by giving effect to all potential dilutive common stock equivalents outstanding for the period. Because the impact of these items is anti-dilutive during periods of net loss, there was no difference between basic and diluted net loss per share of common stock for all periods presented.

3. Fair Value of Financial Instruments

ASC Topic 820, *Fair Value Measurement,* or ASC 820, establishes a fair value hierarchy for instruments measured at fair value that distinguishes between assumptions based on market data (observable inputs) and the Company's own assumptions (unobservable inputs). Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the inputs that market participants would use in pricing the asset or liability and are developed based on the best information available in the circumstances.

ASC 820 identifies fair value as the exchange price, or exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As a basis for considering market participant assumptions in fair value measurements, ASC 820 establishes a three-tier fair value hierarchy that distinguishes among the following:

Level 1—Valuations based on unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access.

Level 2—Valuations based on quoted prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active and models for which all significant inputs are observable, either directly or indirectly.

Level 3—Valuations based on inputs that are unobservable and significant to the overall fair value measurement.

To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

The following table presents the Company's cash, cash equivalents, restricted cash, and warrant liability as of December 31, 2023 and 2022 (in thousands):

Description:	December 31, 2023	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Unobservable Inputs (Level 3)
Assets:				
Cash	$ 3,159	$ 3,159	$ —	$ —
Money Market Funds	29,816	29,816	—	—
Restricted Cash	540	540	—	—
Total assets measured and recorded at fair value	$ 33,515	$ 33,515	$ —	$ —
Liabilities:				
Warrant Liability	5,475	—	—	5,475
Total liabilities measured and recorded at fair value	$ 5,475	$ —	$ —	$ 5,475

Description:	December 31, 2022	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Unobservable Inputs (Level 3)
Assets:				
Cash	$ 9,651	$ 9,651	$ —	$ —
Money Market Funds	28,669	28,669	—	—
Restricted Cash	1,960	1,960	—	—
Total assets measured and recorded at fair value	$ 40,280	$ 40,280	$ —	$ —
Liabilities:				
Warrant Liability	5,483	—	—	5,483
Total liabilities measured and recorded at fair value	$ 5,483	$ —	$ —	$ 5,483

(1) The fair value of Level 1 securities is estimated based on quoted prices in active markets for identical assets or liabilities.

The Company did not transfer any financial instruments into or out of Level 3 classification, during the year ended December 31, 2023 and 2022.

The common stock warrants issued in connection with the Company's equity raise in December 2023 were classified as liabilities at the time of issuance due to certain cash settlement adjustment features that were not deemed to be indexed to the Company's stock. The warrant liability is remeasured each reporting period with the change in fair value recorded to other income (expense) in the consolidated statement of operations and comprehensive loss until the warrants are exercised, expired, reclassified or otherwise settled. The fair value of the warrant liability was estimated using a Black-Scholes Option Pricing Model. The significant assumptions used in preparing the option pricing model for valuing the Company's warrants to purchase shares of common stock included (i) volatility of 128.28 %, (ii) risk free interest rate 3.84%, (iii) strike price $0.70 per share, (iv) fair value of the Company's common stock at the time of issuance and again at each reporting period, and (v) expected life of 5.32 years. The Company classifies investments available to fund current operations as current assets on its balance sheets. As of December 31, 2023 and 2022, the Company did not hold any investment securities exceeding a one-year maturity.

Accretion of bond discount on marketable securities is included in other income as a separate component of other income (expense) on the statement of operations and comprehensive loss. Interest income on marketable securities is recorded as interest income on the statement of operations and comprehensive loss.

The Company recognizes transfers between levels of the fair value hierarchy as of the end of the reporting period. There were no transfers between Level 2 and Level 3 during the years ended December 31, 2023 or 2022.

4. Inventories

Inventories are valued at the lower of cost or net realizable value. Cost is determined using the first-in, first-out method for all inventories. Inventory includes the cost of API, raw materials and third-party contract manufacturing and packaging services. Indirect overhead costs associated with production and distribution are recorded as period costs in the period incurred. Costs of drug product to be consumed in any current or future clinical trials will continue to be recognized as research and development expense.

The Company periodically evaluates the carrying value of inventory on hand using the same lower of cost or net realizable value approach as that used to initially value the inventory. Valuation adjustments may be required for slow-moving or obsolete inventory or in any situations where market conditions have caused net realizable value to fall below the carrying cost of the inventory.

	December 31, 2023	December 31, 2022
Finished goods	$ 896	$ 3,111
Inventory Valuation Adjustment	(896)	(2,205)
Total Inventories	$ -	$ 906

The Company recorded an inventory valuation adjustment of $0.9 million and $2.1 million during the year ended December 31, 2023 and December 31, 2022, respectively. The valuation adjustments recorded were to account for slow moving or obsolete inventory due to uncertainty of commercial activities and future expected OLINVYK sales..

5. Property and Equipment, net

Property and equipment consisted of the following (in thousands):

	Estimated Useful Life in Years	December 31, 2023	December 31, 2022
Computers and software	3 - 5	$ 449	$ 408
Office equipment and furniture	5	224	721
Manufacturing equipment	5	10	10
Leasehold improvements	10	3,082	3,082
Leased assets	5	29	29
Total property and equipment		3,794	4,250
Less accumulated depreciation and amortization		(2,599)	(2,762)
Property and equipment, net		$ 1,195	$ 1,488

Depreciation and amortization expense was $0.3 million and $0.4 million for the years ended December 31, 2023 and 2022.

6. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following (in thousands):

	December 31,	
	2023	2022
Compensation and benefits	$ 2,093	$ 1,965
Commercial expenses	43	93
Legal expenses	423	381
Clinical trial expenses	38	1,421
Pharmaceutical development expenses	398	201
Credit balances due to customers		67
Accrued interest	—	522
Other accrued expenses and other current liabilities	1,244	811
Total accrued expenses and other current liabilities	$ 4,239	$ 5,461

7. Loan Payable

In April 2022, the Company, through its wholly owned subsidiary Trevena SPV2 LLC ("SPV2"), entered into a royalty-based loan agreement (the "Loan Agreement") with R-Bridge, pursuant to which the Company may be eligible to receive up to $40.0 million in term loan borrowings (the "R-Bridge Financing"). Term loan borrowings will be advanced in three tranches. The first tranche of $15.0 million was advanced in April 2022. The second tranche of $10.0 million will become available upon achievement of either a commercial or financing milestone as set forth in the Loan Agreement. The third tranche of $15.0 million became available upon the first commercial sale of OLINVYK in China which occurred in August 2023 and the Company elected to receive such proceeds..

The following table summarizes the impact of the Loan Agreement on the Company's consolidated balance sheet as follows (in thousands):

	December 31, 2023
Principal and accreted interest	$ 32,232
Unamortized debt discount	(1,423)
Loans payable, net	$ 30,809

The term loans bear interest at a rate per annum equal to 7.00% and will mature on the earlier of (i) the fifteen (15) year anniversary of the closing date in March 2022 and (ii) the date on which the license agreement with Nhwa expires. Repayment of any borrowings and related interest will be made quarterly beginning June 30, 2022. Repayment will be in the form of (i) a 4.0% royalty payment on the Company's net sales of OLINVYK in the United States and (ii) proceeds from royalties from the Company's license agreement with Nhwa. As a result of Nhwa obtaining Chinese approval of OLINVYK in May 2023, royalties from net sales of OLINVYK in the United States are capped at $10.0 million in accordance with the Loan Agreement. Upon a change in control or in the event the Company elects to repay any outstanding borrowings prior to their contractual maturity, SPV2 is required to pay a control premium equal to the greater of (i) principal and interest and (ii) $10.0 million or $20.0 million depending on the timing in which the triggering event occurs as further provided in the Loan Agreement.

In April 2022, the Company placed $2.0 million into an interest reserve account in connection with the Loan Agreement. Payments of interest under the Loan Agreement are made quarterly from the royalty on the Company's net sales of OLINVYK in the United States and proceeds from royalties from the Company's license agreement with Nhwa. On each interest payment date, if the royalty payments received do not equal the total interest due for the respective quarter, the interest payment due will be paid from the interest reserve account. The interest reserve account was classified as restricted cash on the Company's balance sheet at December 31, 2022. During the second quarter of 2023, the Company agreed to transfer the remaining funds, approximately $1.0 million, to R-Bridge to prepay future interest

payments. As of December 31, 2023, there was $0.0 million of prepaid interest on the Company's consolidated balance sheet.

Repayments of all borrowings, interest and other related payments, under the Loan Agreement are secured by substantially all of the assets associated with the license agreement with Nhwa, the Chinese intellectual property related to OLINVYK, and deposit accounts established to hold amounts received on account for repayment of the borrowings and related interest under the Loan Agreement. The Loan Agreement contains certain customary affirmative and negative covenants and contains customary defined events of default, upon which any outstanding principal and unpaid interest shall be due on demand. At December 31, 2023, there were no events of default pursuant to the Loan Agreement and the Company was in compliance with all covenants. Interest expense is imputed based on the estimated loan repayment period, which takes into consideration the probability and timing of obtaining regulatory approval in China and the potential future revenue in the United States and China. Changes in estimates are recognized prospectively and may have a material impact on liability balance. As of December 31, 2023, the effective interest rate was 14%.

In connection with the first tranche borrowings in April 2022, the Company issued a warrant to R-Bridge to purchase 200,000 shares of the Company's common stock at an initial exercise price of $20.50 per share and that is exercisable for three years. The Company concluded the warrant was a freestanding equity-classified instrument to which the proceeds from the first tranche was allocated across the debt and warrant on a relative fair value basis. In addition, the Company incurred lender fees and third-party costs of $0.5 million each and were netted against the proceeds allocated to the debt and warrant. Fees netted against debt proceeds represent a debt discount and are amortized into interest expense using the effective interest method. During the twelve months ended December 31, 2023, the Company recognized interest expense of $3.6 milion, of which $0.1 million pertained to the amortization of the debt discount.

The accounting for the Loan Agreement requires the Company to make certain estimates and assumptions, particularly about future royalties under the license agreement with Nhwa and sales of OLINVYK in the United States and China. Such estimates and assumptions are utilized in determining the expected repayment term, amortization period of the debt discount, accretion of interest expense and classification between current and long-term portions of amounts outstanding. The Company amortizes the debt discount into interest expense over the expected term of the arrangement using the interest method based on projected cash flows. Similarly, the Company classifies as current debt for the Loan Agreement, amounts that are expected to be repaid during the succeeding twelve months after the reporting period end. However, the repayment of amounts due under the Loan Agreement is variable because the cash flows to be utilized for periodic payments is a function of amounts received by the Company with respect to the royalties and net product sales.

Accordingly, the estimates of the magnitude and timing of amounts to be available for debt service are subject to significant variability and thus, subject to significant uncertainty. Therefore, these estimates and assumptions are likely to change, which may result in future adjustments to the portion of the debt that is classified as a current liability, the amortization of debt discount and the accretion of interest expense. Other amounts that may become due and payable under the Loan Agreement, including amounts shared between the parties with respect to cash flows received in excess of pre-defined thresholds, are recognized as additional interest expense when they become probable and estimable. The amount of principal to be repaid in each of the five succeeding years is not fixed and determinable.

8. Stockholders' (Deficit) Equity

Under its Certificate of Incorporation, the Company was authorized to issue up to 200,000,000 shares of common stock as of December 31, 2023 and December 31, 2022. The Company also was authorized to issue up to 5,000,000 shares of preferred stock as of December 31, 2023 and December 31, 2022. The Company is required, at all times, to reserve and keep available out of its authorized but unissued shares of common stock sufficient shares to effect the conversion of the shares of the preferred stock and all outstanding stock options and warrants.

ATM Programs

On April 17, 2019, the Company entered into a Common Stock Sales Agreement with H.C. Wainwright & Co., LLC, or Wainwright, pursuant to which the Company may offer and sell through Wainwright, from time to time at the Company's sole discretion, shares of its common stock, having an aggregate offering price of up to $50.0 million, or the HCW ATM Program. Sales of the shares of common stock are deemed to be "at-the-market offerings," as defined in Rule 415 under the Securities Act. In December 2020, the Company and Wainwright entered into Amendment No. 1 to Common Stock Sales Agreement, or the Amendment, to amend the Common Stock Sales Agreement to, among other things, update the reference to the registration statement pursuant to which the shares of common stock may be sold and to include an additional $50.0 million of shares of common stock in the HCW ATM Program. For the year ended December 31, 2023, the Company issued and sold approximately 5.8 million shares of common stock under the HCW ATM Program. The net offering proceeds to the Company in 2023 for sales under the HCW ATM Program were approximately $8.1 million after deducting related expenses, including commissions. As of December 31, 2023, there was approximately $33.7 million remaining available for future issuances under the HCW ATM Program.

Registered Direct Offerings and Concurrent Warrant Issuances

In July 2022, the Company announced a targeted registered direct financing of 72 shares of the Company's Series A convertible preferred stock, or the Series A Preferred, and 8 shares of the Company's Series B convertible preferred stock, or Series B Preferred. The shares of preferred stock issued in this offering are convertible into an aggregate of 320,000 shares of the Company's common stock. The Series A Preferred has voting rights equal to the number of shares of common stock into which the Series A Preferred is convertible. The Series B Preferred has voting rights, only with respect to a proposal to effect a reverse split of the Company's common stock, equal to 1,000,000 votes per share of Series B Preferred, provided that any votes cast by the Series B Preferred with respect to the reverse split proposal must be counted by the Company in the same proportion as the shares of common stock and Series A Preferred voted on such proposal. The shares of preferred stock were convertible at the option of the holder at any time following the date of issuance. In August 2022 the shares of preferred stock were converted into shares of common stock.

In connection with this registered direct offering, the Company also issued warrants to purchase 320,000 shares of common stock (each, a "Common Stock Warrant") (together with the Series A Preferred and Series B Preferred, the "Preferred Stock Transaction"). The Common Stock Warrants have an exercise price of $6.575 per share, will be exercisable beginning on the later of six months following the date of issuance and the effective date of a reverse stock split of our common stock in an amount sufficient to permit the exercise in full of the Common Stock Warrants and will expire five and one-half years following the date of issuance. The Common Stock Warrants are classified as a liability. The Company evaluates its warrants to determine if the contracts qualify as liabilities in accordance with ASC 480-10, Distinguishing Liabilities from Equity and ASC 815, Derivatives and Hedging. The Common Stock Warrants, valued using the Black Scholes valuation model, were initially recorded at their issuance date fair value and are remeasured on each subsequent balance sheet date with changes in fair value recorded as a component of other income (expense), net.

The net proceeds from the Preferred Stock Transaction were allocated as follows:

Common Stock Warrant liability	$	1,519
Series A and Series B Preferred Stock		481
Gross Proceeds	$	2,000

The net proceeds related to the Preferred Stock Transaction were approximately $1.6 million. Approximately $0.4 million of issuance costs were incurred and allocated on a pro rata basis to the Common Stock Warrant liability and the Series A and Series B Preferred Stock, respectively. Approximately $0.3 million was allocated to the Common Stock Warrant liability and recorded in selling, general and administrative expenses. The Series A and Series B Preferred Stock were recorded net of approximately $0.1 million of issuance costs.

The fair value of the Common Stock Warrant liability was determined using Level 3 inputs and was estimated using the Black-Scholes valuation model. The assumptions used to estimate the fair value were as follows:

	December 31, 2023	December 31, 2022
Expected term of warrants (in years)	—	4.6
Risk-free interest rate	— %	4.0 %
Expected volatility	— %	108.9 %
Dividend yield	— %	— %

The following is a roll forward of the July 2022 Offering common stock warrant liability (in thousands):

Balance, December 31, 2022	$ 259
Change in fair value	(146)
Incremental value for inducement	86
Exercise of common stock warrants	(199)
Balance, December 31, 2023	$ —

November 2022 Equity Offering and Warrant issuance

In November 2022, the Company completed a registered direct offering with a single institutional investor whereby the Company sold (i) 765,000 shares of common stock, (ii) pre-funded warrants to purchase 1,849,380 shares of common stock with an exercise price of $0.001 per share and (iii) warrants to purchase an aggregate of 2,614,380 shares of common stock at an initial exercise price of $2.95 per share. The warrants are exercisable immediately on the date of issuance and will expire five years after the date of issuance. The pre-funded warrants are exercisable immediately on the date of issuance and will remain outstanding until this warrant is exercised in full. The Company received $7.6 million in net cash proceeds after deducting underwriter fees and other third-party costs. The pre-funded warrants and warrants are liability classified as they contain certain cash settlement adjustment features that were outside of the Company's control or not deemed to be indexed to the Company's stock, respectively.

Due to the nominal exercise price of the prefunded warrants, the fair value is equal to the intrinsitc value. The fair value of the Common Stock Warrant liability was determined using Level 3 inputs and was estimated using the Black-Scholes valuation model. The assumptions used to estimate the fair value were as follows:

	December 31, 2023	December 31, 2022
Expected term of warrants (in years)	—	4.9
Risk-free interest rate	— %	4.0 %
Expected volatility	— %	106.1 %
Dividend yield	— %	— %

The following is a roll forward of the November 2022 Offering common stock warrant liability (in thousands):

	Warrant Liability
Balance, December 31, 2022	$ 5,224
Change in fair value	(2,084)
Incremental value for inducement	484
Exercise of pre-funded common stock warrants	(2,001)
Exercise of common stock warrants	(1,623)
Balance, December 31, 2023	$ —

December 2023 Equity Offering and Warrant issuance

On December 28, 2023, the Company and a single investor entered into a securities purchase agreement whereby the Company issued 2,779,906 pre-funded warrants with an initial exercise price of $0.001 per share for $0.70 per warrant, which are exercisable immediately and do not expire. In addition, the investor received 2,779,906 common stock warrants with an initial exercise price of $0.70 per share, which are exercisable for five years beginning on the date in which the Company obtains shareholder approval to issue the underlying shares of common stock associated with the warrants.

Concurrent with the securities purchase agreement above, the Company and the investor entered into an inducement agreement whereby the Company agreed to reduce the exercise price of 2,934,380 warrants held by the investor from prior equity offerings. The weighted average exercise price of the outstanding warrants was $3.35 per share and was reduced to $0.70 per share in exchange for the investor agreeing to immediately exercise the warrants. Of the warrants exercised, 1,234,380 are being held in abeyance for the benefit of the holder due to certain beneficial ownership limitations and these shares are not considered issued or outstanding in our consolidated balance sheet. In addition to reducing the exercise price, the Company issued 5,868,760 common stock warrants to the investor with an initial exercise price of $0.70 per share, which are exercisable for five years beginning on the date in which the Company obtains shareholder approval to issue the underlying shares of common stock associated with the warrants. The fair value of the warrants to purchase 5,868,760 shares of common stock and the change in fair value of the warrants resulting from the reduction in the exercise price totaling $4.2 million was accounted for as equity issuance costs in the consolidated statement of operations.

The Company received $3.5 million in total, after deducting underwriter fees and other third-party costs, as a result of the sale of pre-funded warrants and exercise of the warrants as part of the inducement.

The warrants issued did not meet the requirements to be indexed to equity and equity classified and, as such, are classified as liabilities at fair value with changes in fair value recorded within other income (expense), net on the consolidated statements of operations and comprehensive loss.

The fair value of the Common Stock Warrant liability was $5.4 million at issuance and $5.5 million at December 31, 2023, as a result of a change in fair value of $0.1 million and was determined using Level 3 inputs and was estimated using the Black-Scholes valuation model. The assumptions used to estimate the fair value were as follows:

	December 31, 2023	December 28, 2023
Expected term of warrants (in years)	5.3	5.3
Risk-free interest rate	3.8 %	3.8 %
Expected volatility	128.26 %	128.26 %
Dividend yield	— %	— %

Warrants

As of December 31, 2023, the Company had the following common stock warrants outstanding:

	Classification	Warrants	Exercise Price	Expiration Date
December 2023 Offering Pre-Funded Warrants	Equity	2,779,906	$0.001	Until exercised
December 2023 Offering Warrants	Liability	8,648,666	0.70	5 years from shareholder approval
R-Bridge warrants	Equity	200,000	20.50	4/14/2025
Other warrants	Equity	11,014	31.25 - 265.48	1/29/2024 - 3/31/2027
		11,639,586		

Equity Incentive Plans

In 2008, the Company adopted the 2008 Equity Incentive Plan, as amended on February 29, 2008, January 7, 2010, July 8, 2010, December 10, 2010, June 23, 2011 and June 17, 2013, collectively, the 2008 Plan, that authorized the Company to grant restricted stock and stock options to eligible employees, directors and consultants to the Company.

In 2013, the Company adopted the 2013 Equity Incentive Plan, as amended on May 14, 2014, collectively, 2013 Plan. The 2013 Plan became effective upon the Company's entry into the underwriting agreement related to its IPO in January 2014 and, as of such date, no further grants were permitted under the 2008 Plan. The 2013 Plan provides for the grant of incentive stock options, nonqualified stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance-based stock awards and other forms of equity compensation (collectively, stock awards), all of which may be granted to employees, including officers, non-employee directors and consultants of the Company. Additionally, the 2013 Plan provides for the grant of cash and stock-based performance awards. The 2013 Plan contains an "evergreen" provision, pursuant to which the number of shares of common stock available for issuance under the plan automatically increases on January 1 of each year beginning in 2015.

On June 15, 2023 , upon recommendation of the Compensation Committee of the Board of Directors, our Board of Directors adopted, and our stockholders subsequently approved, the Trevena, Inc. 2023 Equity Incentive Plan (the "2023 Plan"). The 2023 Plan replaced the 2013 Plan, and no further awards will be granted under the 2013 Plan as of the effective date of the 2023 Plan. The 2023 Plan provides for, among other things, the grant of incentive stock options, nonqualified stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance-based stock awards and other forms of equity compensation, all of which may be granted to employees, including officers, non-employee directors and consultants of the Company. The 2023 Plan also provides for the rescission, cancellation or recoupment of grants, in whole or in part, or other similar action in accordance with the terms of any company clawback or similar policy or any applicable law related. Unlike the 2013 Plan, there is no evergreen provision in the 2023 Plan. The terms and conditions of awards granted previously under the 2013 Plan will not be affected by the adoption and approval of the 2023 Plan.

On December 15, 2016, the Company adopted the Trevena, Inc. Inducement Plan, or the Inducement Plan, effective January 1, 2017, pursuant to which the Company reserved 20,000 shares of the Company's common stock for issuance under the Inducement Plan. The Plan provides for nonqualified stock options and restricted stock unit awards. The only persons eligible to receive grants of awards under the Inducement Plan are individuals who satisfy the standards for inducement grants under Nasdaq Marketplace Rule 5635(c)(4) and the related guidance under Nasdaq IM 5635-1, including individuals who were not previously an employee or director of the Company or are following a bona fide period of non-employment, in each case as an inducement material to such individual's agreement to enter into employment with the Company.

Under all of the Company's equity incentive plans, the amount, terms of grants and exercisability provisions are determined by the Board of Directors or its designee. The term of the options may be up to 10 years, and options are exercisable in cash or as otherwise determined by the board of directors or its designee. Vesting generally occurs over a period of not greater than four years. For performance-based stock awards, the Company recognizes expense when achievement of the performance condition is probable, over the requisite service period.

The estimated grant-date fair value of the Company's stock-based awards is amortized on a straight-line basis over the awards' service periods. Stock-based compensation expense recognized was as follows (in thousands):

	Year Ended December 31,	
	2023	2022
Research and development	$ 602	$ 806
Selling, general and administrative	2,328	2,871
Cost of goods sold	—	(1)
Total stock-based compensation	$ 2,930	$ 3,676

Stock Options

A summary of stock option activity and related information from January 1, 2022 through December 31, 2023 follows:

	Options Outstanding		
	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)
Balance, January 1, 2022	497,977	$ 66.64	7.11
Granted	39,998	11.47	
Exercised	—	—	
Forfeited/Cancelled	(186,266)	87.83	
Balance, December 31, 2022	351,709	$ 49.15	6.94
Granted	130,150	1.01	
Exercised	—	—	
Forfeited/Cancelled	(78,375)	38.51	
Balance, December 31, 2023	403,484	$ 35.68	6.81
Vested or expected to vest at December 31, 2023	403,484	$ 35.68	6.81
Exercisable at December 31, 2023	260,668	$ 48.05	5.68

The aggregate intrinsic value of the options exercisable as of December 31, 2023 was zero, based on the difference between the Company's closing stock price of $0.72 and the exercise price of each stock option.

The Company uses the Black-Scholes option-pricing model to estimate the fair value of stock options at the grant date. The Black-Scholes model requires the Company to make certain estimates and assumptions, including estimating the fair value of the Company's common stock, assumptions related to the expected price volatility of the Company's stock, the period during which the options will be outstanding, the rate of return on risk-free investments and the expected dividend yield for the Company's stock.

The per-share weighted average grant date fair value of the options granted to employees and directors during the years ended December 31, 2023 and 2022 was estimated at $0.82 and $8.88 per share, respectively, on the date of grant using the Black-Scholes option-pricing model with the following weighted average assumptions:

	December 31,	
	2023	2022
Expected term of options (in years)	5.7	5.7
Risk-free interest rate	3.9 %	2.7 %
Expected volatility	110.3 %	98.0 %
Dividend yield	— %	— %

The weighted average valuation assumptions were determined as follows:

- Risk-free interest rate: The Company based the risk-free interest rate on the interest rate payable on U.S. Treasury securities in effect at the time of grant for a period that is commensurate with the assumed expected option term.
- Expected term of options: Due to its lack of sufficient historical data, the Company estimates the expected life of its employee stock options using the "simplified" method, as prescribed in Staff Accounting Bulletin No. 107.
- Expected stock price volatility: The Company estimates the expected volatility based on the actual historical volatility of the Company's stock price using daily closing prices over a period equal to the expected term of the associated award.
- Expected annual dividend yield: The Company estimated the expected dividend yield based on consideration of its historical dividend experience and future dividend expectations. The Company has not historically declared or paid dividends to stockholders. Moreover, it does not intend to pay dividends in the future, but instead expects to retain any earnings to invest in the continued growth of the business. Accordingly, the Company assumed an expected dividend yield of 0.0%.

The Company elects to record forfeitures upon occurrence, rather than utilizing an estimate.

As of December 31, 2023, there was $1.3 million of total unrecognized compensation expense related to unvested stock options that will be recognized over the weighted average remaining period of 1.21 years.

Restricted Stock Units

RSU-related expense is recognized on a straight-line basis over the vesting period. Upon vesting, these awards may be settled on a net-exercise basis to cover any required withholding tax with the remaining amount converted into an equivalent number of shares of common stock.

There were 60,653 shares of common stock withheld for employee taxes as a result of the vested RSUs during the year ended December 31, 2023 whose value was based on the Company's closing stock price on the applicable vesting date. The shares withheld for taxes are again available for issuance under the plan.

The following is a summary of changes in the status of non-vested RSUs from January 1, 2022 through December 31, 2023:

	Number of Awards		Weighted Average Grant Date Fair Value
Non-vested at January 1, 2022	236,737	$	26.97
Granted	233,987		1.83
Vested	(55,800)		27.19
Forfeited/Cancelled	(48,147)		30.55
Non-vested at December 31, 2022	366,777	$	10.43
Granted	1,530,882		0.99
Vested	(212,279)		7.45
Forfeited/Cancelled	(82,792)		5.73
Non-vested at December 31, 2023	1,602,588	$	2.05

For the years ended December 31, 2023 and 2022, the Company recorded $1.5 million and $1.5 million, respectively, in stock-based compensation expense related to RSUs, which is reflected in the statements of operations and comprehensive loss.

As of December 31, 2023, there was $2.9 million of total unrecognized compensation expense related to unvested RSUs that will be recognized over the weighted average remaining period of 2.35 years.

Shares Available for Future Grant

At December 31, 2023, the Company has the following shares available to be granted:

	2023 Plan	Inducement Plan
Available at December 31, 2022	404,807	12,000
Authorized	1,287,958	—
Granted	(1,661,032)	—
Shares withheld for taxes not issued	60,563	—
Forfeited/Cancelled	161,167	—
Available at December 31, 2023	253,463	12,000

Shares Reserved for Future Issuance

At December 31, 2023, the Company has reserved the following shares of common stock for issuance:

Stock options outstanding under 2013 Plan	292,734
Stock options outstanding under 2023 Plan	102,750
Restricted stock units outstanding under 2013 Plan	1,602,588
Stock options outstanding under Inducement Plan	8,000
Warrants outstanding	11,639,586
Total shares of common stock reserved for future issuance	13,645,658

9. Commitments and Contingencies

Leases

The Company leases office space in Chesterbrook, Pennsylvania and equipment. The Company's principal office is located at 955 Chesterbrook Boulevard, Chesterbrook, Pennsylvania, where the Company currently leases approximately 8,231 square feet of developed office space on the first floor and 40,565 square feet of developed office space on the second floor. The lease term for this space extends through May 2028. On October 11, 2018, the Company entered into an agreement with The Vanguard Group, Inc., or Vanguard, whereby Vanguard agreed to sublease the 40,565 square feet of space on the second floor for an initial term of 37 months. On October 2, 2020, Vanguard notified the Company that they exercised the first option to extend the sublease term for three years through November 30, 2024. Vanguard had a second option to extend the sublease term for an additional three years through November 30, 2027. On August 3, 2023, Vanguard exercised its second option to extend its sublease term. The Company and Vanguard agreed to further extend the sublease through May 2028. With the current extension to May 2028, Vanguard's sublease is coterminous with the Company's master lease term. The sublease provides for rent abatement for the first month of the term; thereafter, the rent payable per square foot to us by Vanguard under the sublease is (i) $0.50 less during months 2 through 13 of the sublease, (ii) $1.00 less in month 14 through 109 of the sublease, and (iii) in month 110 through 116 of the sublease, $16.50 less than the base rent per square foot payable by the us under our master lease with Chesterbrook Partners, L.P. Vanguard also is responsible for paying to the Company all tenant energy costs, annual operating costs,

and annual tax costs attributable to the subleased space during the term of the sublease. Rent expense and associated sublease income are recorded in the Company's statements of operations and comprehensive loss as other income (expense).

Supplemental balance sheet information related to leases was as follows (in thousands):

	December 31, 2023	December 31, 2022
Operating leases:		
Operating lease right-of-use assets	$ 3,665	$ 4,224
Other current lease liabilities	1,002	890
Operating lease liabilities	4,417	5,419
Total operating lease liabilities	$ 5,419	$ 6,309
Finance leases:		
Property and equipment, at cost	$ 29	$ 29
Accumulated depreciation	(13)	(4)
Property and equipment, net	16	25
Other current lease liabilities	10	9
Other long-term liabilities	7	17
Total finance lease liabilities	$ 17	$ 26

The components of lease expense were as follows (in thousands):

	Year Ended December 31,	
	2023	2022
Operating lease costs:		
Operating lease expense	$ 1,458	$ 1,308
Other income	(1,392)	(1,330)
Total operating lease costs	$ 66	$ (22)
Finance lease costs:		
Amortization of right-of-use assets	10	7
Interest on lease liabilities	2	1
Total finance lease costs	$ 12	$ 8

Supplemental cash flow information related to leases was as follows (in thousands):

	Year Ended December 31,	
	2023	2022
Cash paid for amounts included in the measurement of lease liabilities		
Operating cash flows from operating leases	$ (452)	$ (295)
Financing cash flows from finance leases	(12)	(8)

Our lease liabilities will mature, as follows (in thousands):

	Operating Leases	Financing Leases
2024	1,450	11
2025	1,474	7
2026	1,499	—
2027	1,523	—
2028 and beyond	640	—
Total minimum lease payments	$ 6,586	$ 18
Less: imputed interest	(1,167)	(1)
Lease liability	$ 5,419	$ 17

Per the terms of our sublease, we expect the following inflows (in thousands):

	Sublease
2024	1,158
2025	1,178
2026	1,198
2027	1,166
2028	254
Total minimum lease payments	$ 4,954

Weighted average lease term and discount rates are as follows:

	Year Ended December 31,	
	2023	2022
Weighted average remaining lease term (years)		
Operating leases	4	5
Finance leases	2	3
Weighted average discount rate		
Operating leases	9.2%	9.2%
Finance leases	6.5%	6.5%

10. Product Revenue

Performance Obligation

The Company's performance obligation is the supply of finished pharmaceutical products to its customers. The Company's customers consist of major wholesale distributors. The Company's customer contracts generally consist of both a master agreement, which is signed by the Company and its customer, and a customer submitted purchase order, which is governed by the terms and conditions of the master agreement.

Revenue is recognized when the Company transfers control of its products to the customer, which occurs at a point-in-time, upon delivery.

The Company offers standard payment terms to its customers and has elected the practical expedient to not adjust the promised amount of consideration for the effects of a significant financing, since the period between when the Company transfers the product to the customer and when the customer pays for that product is one year or less. Taxes collected from customers relating to product revenue and remitted to governmental authorities are excluded from revenues. The consideration amounts due from customers as a result of product revenue are subject to variable consideration.

The Company offers standard product warranties which provide assurance that the product will function as expected and in accordance with specifications. Customers cannot purchase warranties separately and these warranties do not give rise to a separate performance obligation. The Company permits the return of product under certain circumstances, mainly upon at or near product expiration, instances of shipping errors or where product is damaged in transit. The Company accrues for the customer's right to return as part of its variable consideration. See below for further details.

Sales-Related Deductions

The following table presents a rollforward of the major categories of sales-related deductions included in trade receivable allowances for the year ended December 31, 2023 (in thousands):

	Sales Discounts	Chargebacks	Fee for Service
Balance, January 1, 2023	$ 1	30	36
Provision related to sales recorded in the period	1	5	5
Credits / payments during the period	(1)	(9)	(16)
Adjustments related to prior period sales	1	(7)	(16)
Balance, December 31, 2023	$ 2	$ 19	$ 9

As of December 31, 2023, the Company's outstanding accounts receivable of $30,000 was offset by the trade receivable allowances presented above.

11. License Revenue

License and Commercialization Agreement with Pharmbio Korea Inc.

In April 2018, the Company entered into an exclusive license agreement with Pharmbio Korea Inc., or Pharmbio, for the development and commercialization of OLINVYK for the management of moderate to severe acute pain in South Korea. Under the terms of the agreement, the Company received an upfront, non-refundable cash payment of $3.0 million (less applicable withholding taxes of $0.5 million) in June 2018, and will receive a cash commercial milestone of up to $0.5 million if OLINVYK is approved in South Korea and tiered royalties on product sales in South Korea ranging from high single digits to 20%, less applicable withholding taxes. As part of the agreement, the Company also granted Pharmbio an option to manufacture OLINVYK, on a non-exclusive basis, for the development and commercialization of the product in South Korea, subject to a separate arrangement to be entered into if Pharmbio exercises the option. The license agreement is terminable by Pharmbio for any reason upon 180 days written notice.

In accordance with the terms of the agreement, Pharmbio is solely responsible for all development and regulatory activities in South Korea. The parties have formed a Joint Development Committee with equal representation from the Company and Pharmbio to provide overall coordination and oversight of the development of OLINVYK in South Korea. The parties also agreed to form a Joint Manufacturing and Commercialization Committee at least six months prior to the anticipated date of regulatory approval of OLINVYK in South Korea to provide overall coordination and oversight of the manufacture and commercialization of OLINVYK in South Korea.

License Agreement with Jiangsu Nhwa Pharmaceutical Co. Ltd.

In April 2018, the Company also entered into an exclusive license agreement with Jiangsu Nhwa Pharmaceutical Co. Ltd., or Nhwa, for the development and commercialization of OLINVYK for the management of moderate to severe acute pain in China. Under the terms of this agreement, the Company received an upfront, non-refundable cash payment of $2.5 million (less applicable withholding taxes of $0.3 million) in July 2018. In August 2020, the Company received a milestone payment of $3.0 million (less applicable withholding taxes of $0.3 million), that became payable by Nhwa upon FDA approval of OLINVYK. In May 2023, the Company received a milestone payment of $3.0 million (less applicable withholding taxes $0.3 million), that became payable by Nhwa upon regulatory

approval of OLINVYK in China. The Company is eligible to receive up to an additional $6.0 million of commercialization milestone payments based on product sales levels in China, and a ten percent royalty on all net product sales in China, less applicable withholding taxes. In the third quarter of 2023, Nhwa launched OLINVYK, recognized net product sales in China and reported royalties on those sales to the Company. This royalty is required to be used by the Company to repay its obligations under the Loan Agreement. As part of the license agreement with Nhwa, the Company also granted Nhwa an option to manufacture OLINVYK, on an exclusive basis in China, for the development and commercialization of the product in China. In the second quarter of 2018, Nhwa elected to exercise this manufacturing option. The license agreement is terminable by Nhwa for any reason upon 180 days written notice.

In accordance with the terms of the agreement, Nhwa is solely responsible for all development and regulatory activities in China. The parties have formed a Joint Development Committee with equal representation from the Company and Nhwa to provide overall coordination and oversight of the development of OLINVYK in China. The parties also formed a Joint Manufacturing and Commercialization Committee to provide overall coordination and oversight of the manufacture and commercialization of OLINVYK in China.

For the year ended December 31, 2023 and 2022, license and royalty revenue in the accompanying statements of operations and comprehensive loss is comprised of the following:

	Year Ended December 31,	
	2023	2022
Pharmbio Korea Inc.	$ —	$ 20
Jiangsu Nhwa Pharmaceutical Co. Ltd.	3,000	—
Total license revenues	$ 3,000	$ 20
Jiangsu Nhwa Pharmaceutical Co. Ltd.	179	—
Total royalty revenues	$ 179	$ —
Total license and royalty revenues	$ 3,179	$ 20

License revenue recorded for the year ended December 31, 2023 related to the milestone payment that became payable by Nhwa upon regulatory approval of OLINVYK in China. License revenue recorded for the year ended December 31, 2022 related to materials shipped to PharmBio to support the development of oliceridine efforts in South Korea.

Royalty revenue recorded for the year ended December 31, 2023, relates to royalties earned on OLINVYK sales by Nhwa in China and payable to R-Bridge.

12. Net Loss Per Common Share

The following table sets forth the computation of basic and diluted net loss per share for the periods indicated (in thousands, except share and per share data):

	Year Ended December 31,	
	2023	2022
Basic and diluted net loss per common share calculation:		
Net loss	$ (40,289)	$ (53,670)
Weighted average common shares outstanding	12,735,010	7,072,362
Net loss per share of common stock - basic and diluted	$ (3.16)	$ (7.59)

The pre-funded warrants to purchase common shares issued in connection with the December 2023 offering are included in the calculation of basic and diluted net loss per share as the exercise price of $0.001 per share is non-

substantive and virtually assured. The pre-funded warrants are more fully described in Note 8. Further, the shares held in abeyance also described in Note 8, are included in the calculation of basic and diluted net loss per share.

The following outstanding securities at December 31, 2023 and 2022 have been excluded from the computation of diluted weighted shares outstanding, as they would have been anti-dilutive:

	December 31,	
	2023	2022
Options outstanding	403,484	346,367
RSUs outstanding	1,602,588	366,777
Warrants outstanding	8,859,680	3,145,394
Total	10,865,752	3,858,538

13. Income Taxes

The income tax provision for the years ended December 31, 2023 and 2022 are as follows (in thousands):

	December 31,	
	2023	2022
Current:		
State	$ —	$ —
Federal	—	—
Foreign	318	—
Total	318	—
Deferred		
State	—	—
Federal	—	—
Foreign	—	—
Total	—	—
Total income tax provision (benefit)	$ 318	$ —

Deferred tax assets and liabilities reflect the net effects of net operating losses, or NOLs, and tax credit carryovers and temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Realization of the deferred tax assets is contingent on future taxable income and based upon the level of historical losses, management has concluded that the deferred tax assets do not meet the more-likely-than-not threshold for realizability. Accordingly, a full valuation allowance continues to be recorded against the Company's deferred tax assets as of December 31, 2023 and 2022. The Company’s valuation allowance increased by $9.2 million and decreased by $7.5 million for the years ended December 31, 2023 and 2022, respectively. The decrease in the valuation allowance for 2022 was due to a reduction in state income tax rates.

Significant components of the Company's net deferred tax assets as of December 31, 2023 and 2022 are as follows (in thousands):

	December 31, 2023	December 31, 2022
Deferred tax assets:		
NOLs	$ 55,817	$ 46,490
Research and development credits	16,839	16,309
Research and development expenses capitalized for tax purposes	80,046	80,648
Equity-based compensation	2,200	2,257
Deferred rent	437	520
Depreciation	369	365
Other temporary differences	1,338	1,192
Total deferred tax assets	157,046	147,781
Deferred tax liabilities:		
Prepaid expenses	(506)	(436)
Total deferred tax liabilities	(506)	(436)
Net deferred tax assets	156,540	147,345
Less valuation allowance	(156,540)	(147,345)
Net deferred tax asset	$ —	$ —

A reconciliation of income tax expense computed at the statutory federal income tax rate to income taxes as reflected in the financial statements is as follows:

	December 31, 2023	December 31, 2022
Percent of pre-tax income:		
U.S. federal statutory income tax rate	21.0 %	21.0 %
Foreign withholding taxes	(0.8) %	— %
Permanent Differences	(1.4) %	1.3 %
State taxes, net of federal benefit	3.2 %	4.8 %
Research and development credit	1.3 %	1.5 %
Reduction of state tax rate	— %	(37.7) %
Stock compensation	(1.2) %	(3.2) %
Other	0.1 %	(1.7) %
Change in valuation allowance	(23.0) %	14.0 %
Effective income tax rate	(0.8) %	— %

As of December 31, 2023, the Company had U.S. federal and state NOLs of $226.5 million and $209.1 million, respectively, that begin to expire starting in 2027. As of December 31, 2023, the Company had federal research and development tax credit carryforwards of $16.8 million that begin to expire in 2027. Net operating loss and tax credit carryforwards may become subject to annual limitations 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 by Sections 382 and 383 of the Internal Revenue Code as well as similar state provisions. This could limit the amount of tax attributes that can be utilized annually to offset future taxable income or tax liabilities.

The Tax Cuts and Jobs Act of 2017 (TCJA) amended IRC Section 174 to require capitalization of all research and developmental (R&D) costs incurred in tax years beginning after December 31, 2021. These costs are required to be amortized over five years if the R&D activities are performed in the U.S., or over 15 years if the activities were performed outside the U.S. The Company capitalized approximately $15.7 million of R&D expenses incurred as of December 31, 2023.

During 2022, Pennsylvania enacted law that reduces the corporate net income tax rate through a phased in timeline starting in 2023 through each successive year through 2031 from its current 9.99% rate down to 4.99% by 2031. The Company adjusted its deferred tax balances as of December 31, 2022 for the effect of the anticipated tax rates that are phased in during 2023-2031. The total adjustment amounted to a deferred tax expense of $25.7 million which was offset by a full valuation allowance.

The Company files income tax returns in the U.S., the Commonwealth of Pennsylvania and various other states. Tax years for 2020 and thereafter are open and potentially subject to examination by the federal and state taxing authorities. The Company is currently not under examination by the Internal Revenue Service or any other jurisdictions for any tax years. To the extent the Company utilizes any tax attributes from a tax period that may otherwise be closed due to statute expiration, the Internal Revenue Service, state tax authorities, or other governing parties may still adjust the tax attributes upon their examination of the future period in which the attribute was utilized. There are no uncertain tax positions recorded for any federal or state positions. The Company's policy is to record interest and penalties related to tax matters in income tax expense.

14. Employee Benefit Plan

The Company sponsors a 401(k) defined contribution plan for its employees. Employee contributions are voluntary. The Company matches employee contributions in an amount equal to 100% of the first 3% of eligible compensation and 50% of the next 2% of eligible compensation, and such employer contributions are immediately vested. During each of the years ended December 31, 2023 and 2022, the Company provided matching contributions of $0.2 and $0.3 million.

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

An evaluation was performed under the supervision and with the participation of our management, including our Chief Executive Officer, or CEO, and our Chief Financial Officer, or CFO, of the effectiveness of our disclosure controls and procedures, as such term is defined under Rule 13a-15(e) promulgated under the Exchange Act as of December 31, 2021.

Based on that evaluation, our management, including our CEO and CFO, concluded that as of December 31, 2023 our disclosure controls and procedures were effective to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the Securities and Exchange Commission and that such information is accumulated and communicated to the Company's management, including our CEO and CFO, as appropriate to allow timely decisions regarding required disclosure.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting during our most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Management's Report on Internal Control Over Financial Reporting

Management's Report on Internal Control Over Financial Reporting is included in Part II, Item 8 of this Annual Report on Form 10-K and incorporated into this Item 9A by reference.

ITEM 9B. OTHER INFORMATION

None.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information concerning our executive offers required by this Item 10 is provided under the caption "Information about our Executive Officers" in Part I, Item 1 of this Annual Report on Form 10-K. All other information required by this Item 10 is incorporated herein by reference to the information responsive thereto contained in our definitive proxy statement related to the 2024 annual meeting of stockholders, to be filed within 120 days after the end of the year covered by this Annual Report on Form 10-K.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this Item 11 is incorporated by reference to the information responsive thereto contained in our definitive proxy statement related to the 2024 annual meeting of stockholders, to be filed within 120 days after the end of the year covered by this Annual Report on Form 10-K.

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

Securities Authorized for Issuance under Equity Compensation Plans

The following table provides certain information with respect to all of our equity compensation plans in effect as of December 31, 2023:

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights	Weighted Average Exercise Price of Outstanding Options, Warrants and Rights	Number of Securities Remaining Available for Issuance Under Equity Compensation Plans
Equity compensation plans approved by stockholders	1,998,072	$ 35.51	253,463
Equity compensation plans not approved by stockholders	8,000	44.50	12,000
Total	2,006,072	$ 35.54	265,463

(1) Includes 9,032 shares of our common stock issuable under our 2013 Employee Stock Purchase Plan, or the 2013 ESPP.

(2) Includes 253,463 shares of our common stock available for issuance under our 2023 Equity Incentive Plan.

(3) On December 15, 2016, our Board of Directors adopted the Trevena, Inc. Inducement Plan, or the Inducement Plan, which became effective on January 1, 2017, pursuant to which we reserved 20,000 shares of our common stock for issuance under the Inducement Plan. As of December 31, 2023, 12,000 shares remain eligible for issuance under the Inducement Plan.

Other

The other information required by Item 12 is incorporated by reference to the information responsive thereto contained in our definitive proxy statement related to the 2024 annual meeting of stockholders, to be filed within 120 days after the end of the year covered by this Annual Report on Form 10-K.

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

The information required by Item 13 is incorporated by reference to the information responsive thereto contained in our definitive proxy statement related to the 2024 annual meeting of stockholders, to be filed within 120 days after the end of the year covered by this Annual Report on Form 10-K.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by Item 14 is incorporated by reference to the information responsive thereto contained in our definitive proxy statement related to the 2024 annual meeting of stockholders, to be filed within 120 days after the end of the year covered by this Annual Report on Form 10-K.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

(a) DOCUMENTS FILED AS PART OF THIS REPORT

The following is a list of our financial statements and supplementary data included in this Annual Report on Form 10-K under Item 8 of Part II hereof:

1. FINANCIAL STATEMENTS AND SUPPLEMENTAL DATA

Report of Ernst & Young LLP, Independent Registered Public Accounting Firm (PCAOB ID:42).	88
Consolidated Balance Sheets as of December 31, 2023 and 2022.	90
Consolidated Statements of Operations and Comprehensive Loss for the years ended December 31, 2023 and 2022.	91
Consolidated Statements of Stockholders' Equity for the Period From January 1, 2022 to December 31, 2023.	92
Consolidated Statements of Cash Flows for the years ended December 31, 2023 and 2022.	93
Notes to Consolidated Financial Statements for the years ended December 31, 2023 and 2022.	94

(b) EXHIBITS

The following is a list of exhibits filed as part of this Annual Report on Form 10-K. Where so indicated by footnote, exhibits that were previously filed are incorporated by reference. For exhibits incorporated by reference, the location of the exhibit in the previous filing is indicated.

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on February 5, 2014).
3.2	Certificate of Amendment of Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to Registrant's Current Report on Form 8-K, filed with the SEC on May 21, 2018).
3.3	Certificate of Amendment of Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to Registrant's Current Report on Form 8-K, filed with the SEC on November 9, 2022).
3.4	Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to Registrant's Current Report on Form 8-K, filed with the SEC on August 1, 2022)
3.5	Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock (incorporated by reference to Exhibit 3.2 to Registrant's Current Report on Form 8-K, filed with the SEC on August 1, 2022).
3.6	Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K, filed with the SEC on February 5, 2014).
3.7	Amendment No. 1 to Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.3 to Registrant's Current Report on Form 8-K, filed with the SEC on August 1, 2022)
4.1	Reference is made to Exhibits 3.1 and 3.3.
4.2	Specimen stock certificate evidencing shares of Common Stock of the Registrant (incorporated by reference to Exhibit 4.2 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-191643), originally filed with the SEC on October 9, 2013).
4.3	Form Warrant issued by Trevena, Inc. to Oxford Finance LLC, Pacific Western Bank and Three Point Capital, LLC (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on December 23, 2015).
4.4	Warrant to purchase shares of Series B preferred stock issued to Comerica Bank, dated December 9, 2011 (incorporated by reference to Exhibit 10.3 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-191643), originally filed with the SEC on October 9, 2013).
4.5	Form of Warrant issued by Trevena, Inc. to H.C. Wainwright & Co., LLC or its designees (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on February 1, 2019).
4.6	Description of the Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934 (incorporated by reference to Exhibit 4.6 to the Registrant's Annual Report on Form 10-K, filed with the SEC on March 12, 2020
4.7	Form of Warrant (incorporated by reference to Exhibit 4.1 to Registrant's Current Report on Form 8-K,filed with the SEC on August 1, 2022).
4.8	Form of Pre-Funded Warrant (incorporated by reference to Exhibit 4.1 to Registrant's Current Report on Form 8-K, filed with the SEC on November 18, 2022).
4.9	Form of Warrant (incorporated by reference to Exhibit 4.2 to Registrant's Current Report on Form 8-K, filed with the SEC on November 18, 2022).
4.10	Form of Pre-Funded Warrant (incorporated by reference to Exhibit 4.1 to Registrant's Current Report on Form 8-K, filed with the SEC on December 28, 2023)
4.11	Form of Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.2 to Registrant's Current Report on Form 8-K, filed with the SEC on December 28, 2023)

4.12	Form of New Warrant (incorporated by reference to Exhibit 4.3 to Registrant's Current Report on Form 8-K, filed with the SEC on December 28, 2023)
10.1	Amended and Restated Investor Rights Agreement, dated as of May 3, 2013, by and among the Registrant and certain of its stockholders (incorporated by reference to Exhibit 10.5 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-191643), filed with the SEC on October 9, 2013).
10.2	Form of Registration Rights Agreement (incorporated by reference to Exhibit 10.2 to Registrant's Current Report on Form 8-K, filed with the SEC on December 28, 2023)
10.3	Agreement of Lease between Chesterbrook Partners, LP and Trevena, Inc. for 955 Chesterbrook Blvd., Suite 200, Wayne, PA, dated as of December 9, 2016 (incorporated by reference to Exhibit 10.12 to the Registrant's Annual Report on Form 10-K filed with the SEC on March 8, 2017).
10.4	First Amendment dated June 12, 2017 to Agreement of Lease between Chesterbrook Partners, LP and Trevena, Inc. for 955 Chesterbrook Blvd., Suite 200, Chesterbrook, PA as of December 9, 2016 (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed with the SEC on August 3, 2017).
10.5	Sublease Agreement dated as of October 11, 2018 by and between The Vanguard Group, Inc. and Trevena, Inc. (incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on November 8, 2018).
10.6+	2008 Equity Incentive Plan, as amended to date (incorporated by reference to Exhibit 10.9 to the Registrant's Registration Statement on Form S 1, as amended (File No. 333 191643), filed with the SEC on October 9, 2013).
10.7+	Form of Stock Option Agreement under 2008 Equity Incentive Plan (incorporated by reference to Exhibit 10.10 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-191643), filed with the SEC on October 9, 2013).
10.8+	2013 Equity Incentive Plan (incorporated by reference to Exhibit 99.1 to the Registrant's Registration Statement on Form S 8 (File No. 333 195957), filed with the SEC on May 14, 2014).
10.9+	Form of Stock Option Grant Notice and Stock Option Agreement under 2013 Equity Incentive Plan (incorporated by reference to Exhibit 10.12 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-191643), filed with the SEC on October 9, 2013).
10.10+	Form of Stock Option Grant Notice and Stock Option Agreement under 2013 Equity Incentive Plan (incorporated by reference to Exhibit 10.5 to Registrant's Quarterly Report on Form 10-Q, filed with the SEC on May 7, 2015).
10.11+	Form of Restricted Stock Grant Notice and Restricted Stock Unit Award Agreement under 2013 Equity Incentive Plan (incorporated by reference to Exhibit 10.13 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-191643), filed with the SEC on October 9, 2013).
10.12+	Trevena, Inc. Inducement Plan, effective January 1, 2017 (incorporated by reference to Exhibit 10.1 to Registrant's Current Report on Form 8-K, filed with the SEC on December 19, 2016).
10.13+	Form of Stock Option Grant Notice and Stock Option Agreement used in connection with the Trevena, Inc. Inducement Plan (incorporated by referenced to Exhibit 10.2 to Registrant's Current Report on Form 8-K, filed with the SEC on December 19, 2016).
10.14+	Form of Restricted Stock Unit Grant Notice and Restricted Stock Unit Award Agreement used in connection with Trevena, Inc. Inducement Plan (incorporated by reference to Exhibit 10.3 to Registrant's Current Report on Form 8-K, filed with the SEC on December 19, 2016).
10.15+	Trevena, Inc. Incentive Compensation Plan, effective as of January 1, 2015 (incorporated by reference to Exhibit 10.1 to Registrant's Current Report on Form 8-K, filed with the SEC on January 5, 2015).
10.16+	Trevena, Inc. Non-Employee Director Compensation Policy, effective as of January 1, 2016 (incorporated by reference to Exhibit 10.1 to Registrant's Current Report on Form 8-K, filed with the SEC on December 11, 2015).
10.17+	Trevena, Inc. Non-Employee Director Compensation Policy, effective as of February 28, 2018 (incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed with the SEC on March 2, 2018).
10.18+	2013 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.15 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-191643), filed with the SEC on October 9, 2013).

10.19	Trevena, Inc. 2023 Equity Incentive Plan (incorporated by reference to Appendix A to the Company's definitive proxy statement, dated April 28, 2023, for the Company's 2023 Annual Meeting of Stockholders.)
10.20#	Form of Stock Option Grant Notice and Stock Option Agreement under 2023 Equity Incentive Plan
10.21#	Form of Restricted Stock Grant Notice and Restricted Stock Unit Award Agreement under 2023 Equity Incentive Plan
10.22+	Form of Indemnity Agreement with executives and directors (incorporated by reference to Exhibit 10.16 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-191643), filed with the SEC on October 9, 2013).
10.23#	Amended and Restated Executive Employment Agreement dated as of May 1, 2020, by and between Trevena, Inc. and Carrie L. Bourdow.
10.24+	Amended and Restated Executive Employment Agreement dated as of May 1, 2020 by and between Trevena, Inc. and Mark A. Demitrack (incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on May 7, 2020).
10.25+	Amended and Restated Executive Employment Agreement dated as of May 1, 2020 by and between Trevena, Inc. and Robert T. Yoder (incorporated by reference to Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on May 7, 2020).
10.26+	Amended and Restated Executive Employment Agreement dated as of May 1, 2020 by and between Trevena, Inc. and Barry Shin (incorporated by reference to Exhibit 10.5 to Registrant's Quarterly Report on Form 10-Q, filed with the SEC on May 7, 2020).
10.27#	First Amendment to Amended and Restated Executive Employment Agreement dated as of May 1, 2020, by and between Trevena, Inc. and Carrie L. Bourdow.
10.28	First Amendment to Loan and Security Agreement, dated April 13, 2015, by and among Trevena, Inc., as borrower, Oxford Finance LLC, as collateral agent and lender, and Square 1 Bank, as lender (incorporated by reference to Exhibit 10.1 to Registrant's Current Report on Form 8-K, filed with the SEC on April 13, 2015).
10.29	Second Amendment to Loan and Security Agreement dated December 23, 2015, by and among Trevena, Inc., as borrower, Oxford Finance LLC, as collateral agent and lender, and Pacific Western Bank (as the successor to Square 1 Bank), as lender (incorporated by reference to Exhibit 10.1 to Registrant's Current Report on Form 8-K, filed with the SEC on December 23, 2015).
10.30	Third Amendment to Loan and Security Agreement dated December 30, 2016, by and between Trevena, Inc., as borrower, Oxford Finance LLC, as collateral agent and lender, and Pacific Western Bank (as successor to Square 1 Bank), as lender (incorporated by reference to Exhibit 10.1 to Registrant's Current Report on Form 8-K, filed with the SEC on January 4, 2017).
10.31	Fourth Amendment and Consent to Loan and Security Agreement dated as of October 11, 2018 by and between Oxford Finance LLC, Pacific Western Bank, and Trevena, Inc. (incorporated by reference to Exhibit 10.2 to Registrant's Quarterly Report on Form 10-Q, filed with the SEC on November 8, 2018).
10.32*	Master Commercial Supply Agreement dated October 20, 2017 by and between Alcami Corporation and Trevena, Inc. (incorporated by reference to Exhibit 10.45 to Registrant's Annual Report on Form 10-K/A, filed with the SEC on June 14, 2018).
10.33*	Development and Supply Agreement by and between Pfizer, Inc. and Trevena, Inc. dated as of December 15, 2016 (incorporated by reference to Exhibit 10.46 to Registrant's Annual Report on Form 10-K/A, filed with the SEC on June 14, 2018).
10.34	Amendment No. 2 to Development and Supply Agreement by and between Pfizer, Inc. and Trevena, Inc., dated December 2, 2019 (incorporated by reference to Exhibit 10.1 to Registrant's Current Report on Form 8-K, filed with the SEC on December 9, 2019).
10.35	Common Stock Sales Agreement, dated April 17, 2019, by and between Trevena, Inc. and H.C. Wainwright & Co., LLC (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on April 17, 2019).
10.36	Amendment No, 1 to Common Stock Sales Agreement, dated December 31, 2020, by and between Trevena, Inc. and H.C. Wainwright & Co., LLC (incorporated by reference to Exhibit 10.1 to Registrant's Current Report on Form 8-K, filed with the SEC on December 31, 2020).
10.37	Loan Agreement, dated March 30, 2022, by and among R-Bridge Investment Four Pte. Ltd., as lender,

	and Trevena SPV2 LLC, as borrower (incorporated by reference to Exhibit 10.1 to Registrant's Current Report on Form 10-Q, filed with the SEC on May 11, 2022).
10.38	Revenue Interest Purchase Agreement, dated March 30, 2022, by and among Trevena, Inc., as seller, and Trevena SPV2 LLC, as Company (incorporated by reference to Exhibit 10.2 to Registrant's Current Report on Form 10-Q, filed with the SEC on May 11, 2022).
10.39	Contribution and Serving Agreement, dated March 30, 2022, by and among Trevena, Inc., as contributor, and Trevena SPV2 LLC, as Company (incorporated by reference to Exhibit 10.3 to Registrant's Current Report on Form 10-Q, filed with the SEC on May 11, 2022).
10.40	Form of Securities Purchase Agreement (incorporated by reference to Exhibit 10.1 to Registrant's Current Report on Form 8-K, filed with the SEC on August 1, 2022).
10.41	Form of Securities Purchase Agreement (incorporated by reference to Exhibit 10.1 to Registrant's Current Report on Form 8-K, filed with the SEC on November 18, 2022).
10.42	Form of Securities Purchase Agreement (incorporated by reference to Exhibit 10.1 to Registrant's Current Report on Form 8-K, filed with the SEC on December 28, 2023)
10.43	Form of Inducement Letter (incorporated by reference to Exhibit 10.3 to Registrant's Current Report on Form 8-K, filed with the SEC on December 28, 2023)
23.1#	Consent of Independent Registered Public Accounting Firm.
31.1#	Certification of the Principal Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.
31.2#	Certification of the Principal Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.
32.1#	Certification of the Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2#	Certification of the Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
97#	Trevena Inc. Clawback Policy
101#	The following financial information from this Annual Report on Form 10-K for the periods ended December 31, 2023 and 2022, formatted in Inline XBRL (eXtensible Business Reporting Language): (i) Balance Sheets as of December 31, 2023 and 2022, (ii) Statements of Operations and Comprehensive Loss for the years ended December 31, 2023 and 2022, (iii) Statement of Redeemable Convertible Preferred Stock and Stockholders' Equity as of December 31, 2023 and 2022, (iv) Statements of Cash Flows for the years ended December 31, 2023 and 2022 and (v) Notes to Financial Statements, tagged as blocks of text.
104#	Cover Page Interactive Data File – The cover page interactive data file does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.

Filed herewith.

+ Indicates management contract or compensatory plan.

* Portions of this exhibit, indicated by asterisks, have been omitted and separately filed with the Securities and Exchange Commission pursuant to a request for confidential treatment that has been granted by the Securities and Exchange Commission.

SIGNATURES

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

Date: April 1, 2024

TREVENA, INC.
By: /s/ Carrie L. Bourdow

Carrie L. Bourdow
President, Chief Executive Officer & Chair of the Board of Directors
(Principal Executive Officer)

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

Signature	Title	Date
/s/ Carrie L. Bourdow Carrie L. Bourdow	President, Chief Executive Officer & Chair of the Board of Directors (Principal Executive Officer)	April 1, 2024
/s/ Barry Shin Barry Shin	Executive Vice President, Chief Operating Officer & Chief Financial Officer (Principal Financial and Accounting Officer)	April 1, 2024
/s/ Scott Braunstein Scott Braunstein, M.D.	Lead Independent Director	April 1, 2024
/s/ Mark Corrigan, M.D. Mark Corrigan, M.D.	Director	April 1, 2024
/s/ Marvin H. Johnson, Jr. Marvin H. Johnson, Jr.	Director	April 1, 2024
/s/ Jake R. Nunn Jake R. Nunn	Director	April 1, 2024
/s/ Anne M. Phillips Anne M. Phillips, M.D.	Director	April 1, 2024
/s/ Barbara Yanni Barbara Yanni	Director	April 1, 2024

TREVENA, INC.
2023 EQUITY INCENTIVE PLAN

OPTION AGREEMENT
(INCENTIVE STOCK OPTION OR NONSTATUTORY STOCK OPTION)

Pursuant to your Stock Option Grant Notice ("***Grant Notice***") and this Option Agreement, Trevena, Inc. (the "***Company***") has granted you an option under its 2023 Equity Incentive Plan (the "***Plan***") to purchase the number of shares of the Company's Common Stock indicated in your Grant Notice at the exercise price indicated in your Grant Notice. The option is granted to you effective as of the date of grant set forth in the Grant Notice (the "***Date of Grant***"). If there is any conflict between the terms in this Option Agreement and the Plan, the terms of the Plan will control. Capitalized terms not explicitly defined in this Option Agreement or in the Grant Notice but defined in the Plan will have the same definitions as in the Plan.

The details of your option, in addition to those set forth in the Grant Notice and the Plan, are as follows:

1. VESTING. Subject to the provisions contained herein, your option will vest as provided in your Grant Notice. Vesting will cease upon the termination of your Continuous Service.

2. NUMBER OF SHARES AND EXERCISE PRICE. The number of shares of Common Stock subject to your option and your exercise price per share in your Grant Notice will be adjusted for Capitalization Adjustments.

3. EXERCISE RESTRICTION FOR NON-EXEMPT EMPLOYEES. If you are an Employee eligible for overtime compensation under the Fair Labor Standards Act of 1938, as amended (that is, a "***Non-Exempt Employee***"), and except as otherwise provided in the Plan, you may not exercise your option until you have completed at least six (6) months of Continuous Service measured from the Date of Grant, even if you have already been an employee for more than six (6) months. Consistent with the provisions of the Worker Economic Opportunity Act, you may exercise your option as to any vested portion prior to such six (6) month anniversary in the case of (i) your death or disability, (ii) a Corporate Transaction in which your option is not assumed, continued or substituted, (iii) a Change in Control or (iv) your termination of Continuous Service on your "retirement" (as defined in the Company's benefit plans).

4. EXERCISE PRIOR TO VESTING ("EARLY EXERCISE"). You may not exercise your option prior to vesting.

5. METHOD OF PAYMENT. You must pay the full amount of the exercise price for the shares you wish to exercise. You may pay the exercise price in cash or by check, bank draft or

money order payable to the Company or in any other manner ***permitted by your Grant Notice,*** which may include one or more o`f the following:

(a) Provided that at the time of exercise the Common Stock is publicly traded, pursuant to a program developed under Regulation T as promulgated by the Federal Reserve Board that, prior to the issuance of Common Stock, results in either the receipt of cash (or check) by the Company or the receipt of irrevocable instructions to pay the aggregate exercise price to the Company from the sales proceeds. This manner of payment is also known as a "broker-assisted exercise", "same day sale", or "sell to cover".

(b) Provided that at the time of exercise the Common Stock is publicly traded, by delivery to the Company (either by actual delivery or attestation) of already-owned shares of Common Stock that are owned free and clear of any liens, claims, encumbrances or security interests, and that are valued at Fair Market Value on the date of exercise. "Delivery" for these purposes, in the sole discretion of the Company at the time you exercise your option, will include delivery to the Company of your attestation of ownership of such shares of Common Stock in a form approved by the Company. You may not exercise your option by delivery to the Company of Common Stock if doing so would violate the provisions of any law, regulation or agreement restricting the redemption of the Company's stock.

(c) If this option is a Nonstatutory Stock Option, subject to the consent of the Company at the time of exercise, by a "net exercise" arrangement pursuant to which the Company will reduce the number of shares of Common Stock issued upon exercise of your option by the largest whole number of shares with a Fair Market Value that does not exceed the aggregate exercise price. You must pay any remaining balance of the aggregate exercise price not satisfied by the "net exercise" in cash or other permitted form of payment. Shares of Common Stock will no longer be outstanding under your option and will not be exercisable thereafter if those shares (i) are used to pay the exercise price pursuant to the "net exercise," (ii) are delivered to you as a result of such exercise, and (iii) are withheld to satisfy your tax withholding obligations.

6. WHOLE SHARES. You may exercise your option only for whole shares of Common Stock.

7. SECURITIES LAW COMPLIANCE. In no event may you exercise your option unless the shares of Common Stock issuable upon exercise are then registered under the Securities Act or, if not registered, the Company has determined that your exercise and the issuance of the shares would be exempt from the registration requirements of the Securities Act. The exercise of your option also must comply with all other applicable laws and regulations governing your option, and you may not exercise your option if the Company determines that such exercise would not be in material compliance with such laws and regulations (including any restrictions on exercise required for compliance with Treas. Reg. 1.401(k)-1(d)(3), if applicable).

8. TERM. You may not exercise your option before the Date of Grant or after the expiration of the option's term. The term of your option expires, subject to the provisions of Section 5(h) of the Plan, upon the earliest of the following:

(a) immediately upon the termination of your Continuous Service for Cause;

(b) three (3) months after the termination of your Continuous Service for any reason other than Cause, your Disability or your death (except as otherwise provided in Section 8(d) below); *provided, however,* that if during any part of such three (3) month period your option is not exercisable solely because of the condition set forth in the section above relating to "Securities Law Compliance," your option will not expire until the earlier of the Expiration Date or until it has been exercisable for an aggregate period of three (3) months after the termination of your Continuous Service; *provided further,* if during any part of such three (3) month period, the sale of any Common Stock received upon exercise of your option would violate the Company's insider trading policy, then your option will not expire until the earlier of the Expiration Date or until it has been exercisable for an aggregate period of three (3) months after the termination of your Continuous Service during which the sale of the Common Stock received upon exercise of your option would not be in violation of the Company's insider trading policy. Notwithstanding the foregoing, if (i) you are a Non-Exempt Employee, (ii) your Continuous Service terminates within six (6) months after the Date of Grant, and (iii) you have vested in a portion of your option at the time of your termination of Continuous Service, your option will not expire until the earlier of (x) the later of (A) the date that is seven (7) months after the Date of Grant, and (B) the date that is three (3) months after the termination of your Continuous Service, and (y) the Expiration Date;

(c) twelve (12) months after the termination of your Continuous Service due to your Disability (except as otherwise provided in Section 8(d)) below;

(d) eighteen (18) months after your death if you die either during your Continuous Service or within three (3) months after your Continuous Service terminates for any reason other than Cause;

(e) the Expiration Date indicated in your Grant Notice; or

(f) the day before the tenth (10th) anniversary of the Date of Grant.

If your option is an Incentive Stock Option, note that to obtain the federal income tax advantages associated with an Incentive Stock Option, the Code requires that at all times beginning on the Date of Grant and ending on the day three (3) months before the date of your option's exercise, you must be an employee of the Company or an Affiliate, except in the event of your death or Disability. The Company has provided for extended exercisability of your option under certain circumstances for your benefit but cannot guarantee that your option will necessarily be treated as an Incentive Stock Option if you continue to provide services to the Company or an Affiliate as a Consultant or Director after your employment terminates or if you otherwise exercise your option more than three (3) months after the date your employment with the Company or an Affiliate terminates.

9. EXERCISE.

(a) You may exercise the vested portion of your option (and the unvested portion of your option if your Grant Notice so permits) during its term by (i) delivering a Notice of Exercise (in a form designated by the Company) or completing such other documents and/or procedures designated by the Company for exercise and (ii) paying the exercise price and any applicable withholding taxes to the Company's Secretary, stock plan administrator, or such other person as the Company may designate, together with such additional documents as the Company may then require.

(b) By exercising your option you agree that, as a condition to any exercise of your option, the Company may require you to enter into an arrangement providing for the payment by you to the Company of any tax withholding obligation of the Company arising by reason of (i) the exercise of your option, (ii) the lapse of any substantial risk of forfeiture to which the shares of Common Stock are subject at the time of exercise, or (iii) the disposition of shares of Common Stock acquired upon such exercise.

(c) If your option is an Incentive Stock Option, by exercising your option you agree that you will notify the Company in writing within fifteen (15) days after the date of any disposition of any of the shares of the Common Stock issued upon exercise of your option that occurs within two (2) years after the Date of Grant or within one (1) year after such shares of Common Stock are transferred upon exercise of your option.

(d) By accepting your option you agree that you will not sell, dispose of, transfer, make any short sale of, grant any option for the purchase of, or enter into any hedging or similar transaction with the same economic effect as a sale, any shares of Common Stock or other securities of the Company held by you, for a period of one hundred eighty (180) days following the effective date of a registration statement of the Company filed under the Securities Act or such longer period as the underwriters or the Company will request to facilitate compliance with FINRA Rule 2711 or NYSE Member Rule 472–or any successor or similar rules–or regulation–(the "Lock-Up Period"); provided, however, that nothing contained in this section will prevent the exercise of a repurchase option, if any, in favor of the Company during the Lock-Up Period. You further agree to execute and deliver such other agreements as may be reasonably requested by the Company or the underwriters that are consistent with the foregoing or that are necessary to give further effect thereto. In order to enforce the foregoing covenant, the Company may impose stop-transfer instructions with respect to your shares of Common Stock until the end of such period. You also agree that any transferee of any shares of Common Stock (or other securities) of the Company held by you will be bound by this Section 9(d). The underwriters of the Company's stock are intended third party beneficiaries of this Section 9(d) and will have the right, power and authority to enforce the provisions hereof as though they were a party hereto.

10. Transferability. Except as otherwise provided in this Section 10, your option is not transferable, except by will or by the laws of descent and distribution, and is exercisable during your life only by you.

(a) Certain Trusts. Upon receiving written permission from the Board or its duly authorized designee, you may transfer your option to a trust if you are considered to be the sole beneficial owner (determined under Section 671 of the Code and applicable state law) while the option is held in the trust. You and the trustee must enter into transfer and other agreements required by the Company.

(b) Domestic Relations Orders. Upon receiving written permission from the Board or its duly authorized designee, and provided that you and the designated transferee enter into transfer and other agreements required by the Company, you may transfer your option pursuant to the terms of a domestic relations order, official marital settlement agreement or other divorce or separation instrument as permitted by Treasury Regulation 1.421-1(b)(2) that contains the information required by the Company to effectuate the transfer. You are encouraged to discuss the proposed terms of any division of this option with the Company prior to finalizing the domestic relations order or marital settlement agreement to help ensure the required information is contained within the domestic relations order or marital settlement agreement. If this option is an Incentive Stock Option, this option may be deemed to be a Nonstatutory Stock Option as a result of such transfer.

(c) Beneficiary Designation. Upon receiving written permission from the Board or its duly authorized designee, you may, by delivering written notice to the Company, in a form approved by the Company and any broker designated by the Company to handle option exercises, designate a third party who, on your death, will thereafter be entitled to exercise this option and receive the Common Stock or other consideration resulting from such exercise. In the absence of such a designation, your executor or administrator of your estate will be entitled to exercise this option and receive, on behalf of your estate, the Common Stock or other consideration resulting from such exercise.

11. Option not a Service Contract. Your option is not an employment or service contract, and nothing in your option will be deemed to create in any way whatsoever any obligation on your part to continue in the employ of the Company or an Affiliate, or of the Company or an Affiliate to continue your employment. In addition, nothing in your option will obligate the Company or an Affiliate, their respective stockholders, boards of directors, officers or employees to continue any relationship that you might have as a Director or Consultant for the Company or an Affiliate.

12. Withholding Obligations.

(a) At the time you exercise your option, in whole or in part, and at any time thereafter as requested by the Company, you hereby authorize withholding from payroll and any other amounts payable to you, and otherwise agree to make adequate provision for (including by means of a “same day sale” pursuant to a program developed under Regulation T as promulgated by the Federal Reserve Board to the extent permitted by the Company), any sums required to satisfy the federal, state, local and foreign tax withholding obligations of the Company or an Affiliate, if any, which arise in connection with the exercise of your option.

(b) If this option is a Nonstatutory Stock Option, then upon your request and subject to approval by the Company, and compliance with any applicable legal conditions or restrictions, the Company may withhold from fully vested shares of Common Stock otherwise issuable to you upon the exercise of your option a number of whole shares of Common Stock having a Fair Market Value, determined by the Company as of the date of exercise, not in excess of the minimum amount of tax required to be withheld by law (or such lower amount as may be necessary to avoid classification of your option as a liability for financial accounting purposes). If the date of determination of any tax withholding obligation is deferred to a date later than the date of exercise of your option, share withholding pursuant to the preceding sentence shall not be permitted unless you make a proper and timely election under Section 83(b) of the Code, covering the aggregate number of shares of Common Stock acquired upon such exercise with respect to which such determination is otherwise deferred, to accelerate the determination of such tax withholding obligation to the date of exercise of your option. Notwithstanding the filing of such election, shares of Common Stock shall be withheld solely from fully vested shares of Common Stock determined as of the date of exercise of your option that are otherwise issuable to you upon such exercise. Any adverse consequences to you arising in connection with such share withholding procedure shall be your sole responsibility.

(c) You may not exercise your option unless the tax withholding obligations of the Company and/or any Affiliate are satisfied. Accordingly, you may not be able to exercise your option when desired even though your option is vested, and the Company will have no obligation to issue a certificate for such shares of Common Stock or release such shares of Common Stock from any escrow provided for herein, if applicable, unless such obligations are satisfied.

13. Tax Consequences. You hereby agree that the Company does not have a duty to design or administer the Plan or its other compensation programs in a manner that minimizes your tax liabilities. You will not make any claim against the Company, or any of its Officers, Directors, Employees or Affiliates related to tax liabilities arising from your option or your other compensation. In particular, you acknowledge that this option is exempt from Section 409A of the Code only if the exercise price per share specified in the Grant Notice is at least equal to the “fair market value” per share of the Common Stock on the Date of Grant and there is no other impermissible deferral of compensation associated with the option.

14. Notices. Any notices provided for in your option or the Plan will be given in writing (including electronically) and will be deemed effectively given upon receipt or, in the case of notices delivered by mail by the Company to you, five (5) days after deposit in the United States mail, postage prepaid, addressed to you at the last address you provided to the Company. The Company may, in its sole discretion, decide to deliver any documents related to participation in the Plan and this option by electronic means or to request your consent to participate in the Plan by electronic means. By accepting this option, you consent to receive such documents by electronic delivery and to participate in the Plan through an on-line or electronic system established and maintained by the Company or another third party designated by the Company.

15. Governing Plan Document. Your option is subject to all the provisions of the Plan, the provisions of which are hereby made a part of your option, and is further subject to all interpretations, amendments, rules and regulations, which may from time to time be promulgated and adopted pursuant to the Plan. If there is any conflict between the provisions of your option and those of the Plan, the provisions of the Plan will control. In addition, your option (and any compensation paid or shares issued under your option) is subject to recoupment in accordance with The Dodd–Frank Wall Street Reform and Consumer Protection Act and any implementing regulations thereunder, any clawback policy adopted by the Company and any compensation recovery policy otherwise required by applicable law.

16. Other Documents. You hereby acknowledge receipt of and the right to receive a document providing the information required by Rule 428(b)(1) promulgated under the Securities Act, which includes the Plan prospectus. In addition, you acknowledge receipt of the Company's policy permitting certain individuals to sell shares only during certain "window" periods and the Company's insider trading policy, in effect from time to time.

17. Effect on Other Employee Benefit Plans. The value of this option will not be included as compensation, earnings, salaries, or other similar terms used when calculating your benefits under any employee benefit plan sponsored by the Company or any Affiliate, except as such plan otherwise expressly provides. The Company expressly reserves its rights to amend, modify, or terminate any of the Company's or any Affiliate's employee benefit plans.

18. Voting Rights. You will not have voting or any other rights as a stockholder of the Company with respect to the shares to be issued pursuant to this option until such shares are issued to you. Upon such issuance, you will obtain full voting and other rights as a stockholder of the Company. Nothing contained in this option, and no action taken pursuant to its provisions, will create or be construed to create a trust of any kind or a fiduciary relationship between you and the Company or any other person.

19. Severability. If all or any part of this Option Agreement or the Plan is declared by any court or governmental authority to be unlawful or invalid, such unlawfulness or invalidity will not invalidate any portion of this Option Agreement or the Plan not declared to be unlawful or invalid. Any Section of this Option Agreement (or part of such a Section) so declared to be unlawful or invalid shall, if possible, be construed in a manner which will give effect to the terms of such Section or part of a Section to the fullest extent possible while remaining lawful and valid.

20. Miscellaneous.

(a) The rights and obligations of the Company under your option will be transferable to any one or more persons or entities, and all covenants and agreements hereunder will inure to the benefit of, and be enforceable by the Company's successors and assigns.

(b) You agree upon request to execute any further documents or instruments necessary or desirable in the sole determination of the Company to carry out the purposes or intent of your option.

(c) You acknowledge and agree that you have reviewed your option in its entirety, have had an opportunity to obtain the advice of counsel prior to executing and accepting your option, and fully understand all provisions of your option.

(d) This Option Agreement will be subject to all applicable laws, rules, and regulations, and to such approvals by any governmental agencies or national securities exchanges as may be required.

(e) All obligations of the Company under the Plan and this Option Agreement will be binding on any successor to the Company, whether the existence of such successor is the result of a direct or indirect purchase, merger, consolidation, or otherwise, of all or substantially all of the business and/or assets of the Company.

* * *

This Option Agreement will be deemed to be signed by you upon the signing by you of the Stock Option Grant Notice to which it is attached.

TREVENA INC. NOTICE OF EXERCISE

955 CHESTERBROOK BLVD

SUITE 110

CHESTERBROOK, PA 19487

Date of Exercise: _____

This constitutes notice to Trevena, Inc. (the "***Company***") under my stock option described below (the "***Option***") granted pursuant to the Company's 2023 Equity Incentive Plan (as it may be amended from time to time) as evidenced by the Stock Option Grant Notice and Option Agreement thereunder, that I elect to purchase the below number of shares of Common Stock of the Company (the "***Shares***") for the price set forth below.

Type of option (check one):	Incentive ☐	Nonstatutory ☐
Option Grant Date:	_____	_____
Number of Shares as to which the Option is exercised:	_____	_____
Certificates to be issued in name of:	_____	_____
Exercise price (per share):	$_____	$_____
Total exercise price:	$_____	$_____
Cash payment delivered herewith:	$_____	$_____

By this exercise, I agree (i) to provide such additional documents as you may require pursuant to the terms of the Company's 2023 Equity Incentive Plan (as it may be amended from time to time), (ii) to provide for the payment by me to the Company (in the manner designated by the Company) of the Company's withholding obligation, if any, relating to the exercise of the Option, and (iii) if this exercise relates to an Incentive Stock Option, to notify you in writing within 15 days after the date of any disposition of any of the Shares issued upon exercise of the Option that occurs within two years after the date of grant of the Option or within one year after such Shares are issued upon exercise of the Option.

Very truly yours,

_____

Office Use Only

Fair Value Price :

_____

Fair Value Date :

_____

Signature

_____

Print Name

Exhibit 10.21

TREVENA, INC.

2023 EQUITY INCENTIVE PLAN

RESTRICTED STOCK UNIT AWARD AGREEMENT

Pursuant to the Restricted Stock Unit Grant Notice (the "***Grant Notice***") and this Restricted Stock Unit Award Agreement (the "***Agreement***"), Trevena, Inc. (the "***Company***") has awarded you ("***Participant***") a Restricted Stock Unit Award (the "***Award***") pursuant to Section 6(b) of the Company's 2023 Equity Incentive Plan (the "***Plan***") for the number of Restricted Stock Units/shares indicated in the Grant Notice. Capitalized terms not explicitly defined in this Agreement or the Grant Notice shall have the same meanings given to them in the Plan. The terms of your Award, in addition to those set forth in the Grant Notice, are as follows.

1. GRANT OF THE AWARD. This Award represents the right to be issued on a future date one (1) share of Common Stock for each Restricted Stock Unit that vests on the applicable vesting date(s) (subject to any adjustment under Section 3 below) as indicated in the Grant Notice. As of the Date of Grant, the Company will credit to a bookkeeping account maintained by the Company for your benefit (the "***Account***") the number of Restricted Stock Units/shares of Common Stock subject to the Award. This Award was granted in consideration of your services to the Company.

2. VESTING. Subject to the limitations contained herein, your Award will vest, if at all, in accordance with the vesting schedule provided in the Grant Notice, provided that vesting will cease upon the termination of your Continuous Service. Upon such termination of your Continuous Service, the Restricted Stock Units/shares of Common Stock credited to the Account that were not vested on the date of such termination will be forfeited at no cost to the Company and you will have no further right, title or interest in or to such underlying shares of Common Stock.

3. NUMBER OF SHARES. The number of Restricted Stock Units/shares subject to your Award may be adjusted from time to time for Capitalization Adjustments, as provided in the Plan. Any additional Restricted Stock Units, shares, cash or other property that becomes subject to the Award pursuant to this Section 3, if any, shall be subject, in a manner determined by the Board, to the same forfeiture restrictions, restrictions on transferability, and time and manner of delivery as applicable to the other Restricted Stock Units and shares covered by your Award. Notwithstanding the provisions of this Section 3, no fractional shares or rights for fractional shares of Common Stock shall be created pursuant to this Section 3. Any fraction of a share will be rounded down to the nearest whole share.

4. SECURITIES LAW COMPLIANCE. You may not be issued any Common Stock under your Award unless the shares of Common Stock underlying the Restricted Stock Units are either (i) then registered under the Securities Act, or (ii) the Company has determined that such issuance would be exempt from the registration requirements of the Securities Act. Your Award must also comply with other applicable laws and regulations governing the Award, and you shall not receive

such Common Stock if the Company determines that such receipt would not be in material compliance with such laws and regulations.

5. Transfer Restrictions. Prior to the time that shares of Common Stock have been delivered to you, you may not transfer, pledge, sell or otherwise dispose of this Award or the shares issuable in respect of your Award, except as expressly provided in this Section 5. For example, you may not use shares that may be issued in respect of your Restricted Stock Units as security for a loan. The restrictions on transfer set forth herein will lapse upon delivery to you of shares in respect of your vested Restricted Stock Units.

(a) Death. Your Award is transferable by will and by the laws of descent and distribution. At your death, vesting of your Award will cease and your executor or administrator of your estate shall be entitled to receive, on behalf of your estate, any Common Stock or other consideration that vested but was not issued before your death.

(b) Domestic Relations Orders. Upon receiving written permission from the Board or its duly authorized designee, and provided that you and the designated transferee enter into transfer and other agreements required by the Company, you may transfer your right to receive the distribution of Common Stock or other consideration hereunder, pursuant to a domestic relations order or marital settlement agreement that contains the information required by the Company to effectuate the transfer. You are encouraged to discuss the proposed terms of any division of this Award with the Company General Counsel prior to finalizing the domestic relations order or marital settlement agreement to verify that you may make such transfer, and if so, to help ensure the required information is contained within the domestic relations order or marital settlement agreement.

6. Date of Issuance.

(a) The issuance of shares in respect of the Restricted Stock Units is intended to comply with Treasury Regulations Section 1.409A-1(b)(4) and will be construed and administered in such a manner. Subject to the satisfaction of the withholding obligations set forth in this Agreement, in the event one or more Restricted Stock Units vests, the Company shall issue to you one (1) share of Common Stock for each Restricted Stock Unit that vests on the applicable vesting date(s) (subject to any adjustment under Section 3 above). The issuance date determined by this paragraph is referred to as the "***Original Issuance Date***".

(b) If the Original Issuance Date falls on a date that is not a business day, delivery shall instead occur on the next following business day. In addition, if:

(i) the Original Issuance Date does not occur (1) during an "open window period" applicable to you, as determined by the Company in accordance with the Company's then-effective policy on trading in Company securities, or (2) on a date when you are otherwise permitted to sell shares of Common Stock on an established stock exchange or stock market, *and*

(ii) either (1) Withholding Taxes do not apply, or (2) the Company decides, prior to the Original Issuance Date, (A) not to satisfy the Withholding Taxes by

withholding shares of Common Stock from the shares otherwise due, on the Original Issuance Date, to you under this Award, and (B) not to permit you to pay your Withholding Taxes in cash,

then the shares that would otherwise be issued to you on the Original Issuance Date will not be delivered on such Original Issuance Date and will instead be delivered on the first business day when you are not prohibited from selling shares of the Company's Common Stock in the open public market, but in no event later than December 31 of the calendar year in which the Original Issuance Date occurs (that is, the last day of your taxable year in which the Original Issuance Date occurs), or, if and only if permitted in a manner that complies with Treasury Regulations Section 1.409A-1(b)(4), no later than the date that is the 15th day of the third calendar month of the applicable year following the year in which the shares of Common Stock under this Award are no longer subject to a "substantial risk of forfeiture" within the meaning of Treasury Regulations Section 1.409A-1(d).

(c) The form of delivery (*e.g.*, a stock certificate or electronic entry evidencing such shares) shall be determined by the Company.

7. Dividends. You shall receive no benefit or adjustment to your Award with respect to any cash dividend, stock dividend or other distribution that does not result from a Capitalization Adjustment.

8. Restrictive Legends. The shares of Common Stock issued under your Award shall be endorsed with appropriate legends as determined by the Company.

9. Execution of Documents. You hereby acknowledge and agree that the manner selected by the Company by which you indicate your consent to your Grant Notice is also deemed to be your execution of your Grant Notice and of this Agreement. You further agree that such manner of indicating consent may be relied upon as your signature for establishing your execution of any documents to be executed in the future in connection with your Award.

10. Award not a Service Contract.

(a) Nothing in this Agreement (including, but not limited to, the vesting of your Award or the issuance of the shares subject to your Award), the Plan or any covenant of good faith and fair dealing that may be found implicit in this Agreement or the Plan shall: (i) confer upon you any right to continue in the employ of, or affiliation with, the Company or an Affiliate; (ii) constitute any promise or commitment by the Company or an Affiliate regarding the fact or nature of future positions, future work assignments, future compensation or any other term or condition of employment or affiliation; (iii) confer any right or benefit under this Agreement or the Plan unless such right or benefit has specifically accrued under the terms of this Agreement or Plan; or (iv) deprive the Company of the right to terminate you at will and without regard to any future vesting opportunity that you may have.

(b) The Company has the right to reorganize, sell, spin-out or otherwise restructure one or more of its businesses or Affiliates at any time or from time to time, as it deems appropriate (a "***reorganization***"). Such a reorganization could result in the termination of your Continuous Service, or the termination of Affiliate status of your employer and the loss of benefits available to you under this Agreement, including but not limited to, the termination of the right to

continue vesting in the Award. This Agreement, the Plan, the transactions contemplated hereunder and the vesting schedule set forth herein or any covenant of good faith and fair dealing that may be found implicit in any of them do not constitute an express or implied promise of continued engagement as an employee or consultant for the term of this Agreement, for any period, or at all, and shall not interfere in any way with the Company's right to conduct a reorganization.

11. WITHHOLDING OBLIGATIONS.

(a) On each vesting date, and on or before the time you receive a distribution of the shares underlying your Restricted Stock Units, and at any other time as reasonably requested by the Company in accordance with applicable tax laws, you hereby authorize any required withholding from the Common Stock issuable to you and/or otherwise agree to make adequate provision in cash for any sums required to satisfy the federal, state, local and foreign tax withholding obligations of the Company or any Affiliate that arise in connection with your Award (the "***Withholding Taxes***"). Additionally, the Company or any Affiliate may, in its sole discretion, satisfy all or any portion of the Withholding Taxes obligation relating to your Award by any of the following means or by a combination of such means: (i) withholding from any compensation otherwise payable to you by the Company; (ii) causing you to tender a cash payment; (iii) permitting or requiring you to enter into a "same day sale" commitment, if applicable, with a broker-dealer that is a member of the Financial Industry Regulatory Authority (a "***FINRA Dealer***") whereby you irrevocably elect to sell a portion of the shares to be delivered in connection with your Restricted Stock Units to satisfy the Withholding Taxes and whereby the FINRA Dealer irrevocably commits to forward the proceeds necessary to satisfy the Withholding Taxes directly to the Company and/or its Affiliates; or (iv) withholding shares of Common Stock from the shares of Common Stock issued or otherwise issuable to you in connection with the Award with a Fair Market Value (measured as of the date shares of Common Stock are issued to pursuant to Section 6) equal to the amount of such Withholding Taxes; *provided*, *however*, that the number of such shares of Common Stock so withheld will not exceed the amount necessary to satisfy the Company's required tax withholding obligations using the minimum statutory withholding rates for federal, state, local and foreign tax purposes, including payroll taxes, that are applicable to supplemental taxable income; and *provided*, further, that to the extent necessary to qualify for an exemption from application of Section 16(b) of the Exchange Act, if applicable, such share withholding procedure will be subject to the express prior approval of the Company's Compensation Committee.

(b) Unless the tax withholding obligations of the Company and/or any Affiliate are satisfied, the Company shall have no obligation to deliver to you any Common Stock.

(c) In the event the Company's obligation to withhold arises prior to the delivery to you of Common Stock or it is determined after the delivery of Common Stock to you that the amount of the Company's withholding obligation was greater than the amount withheld by the Company, you agree to indemnify and hold the Company harmless from any failure by the Company to withhold the proper amount.

12. TAX CONSEQUENCES. The Company has no duty or obligation to minimize the tax consequences to you of this Award and shall not be liable to you for any adverse tax consequences to you arising in connection with this Award. You are hereby advised to consult with your own

personal tax, financial and/or legal advisors regarding the tax consequences of this Award and by signing the Grant Notice, you have agreed that you have done so or knowingly and voluntarily declined to do so. You understand that you (and not the Company) shall be responsible for your own tax liability that may arise as a result of this investment or the transactions contemplated by this Agreement.

13. Unsecured Obligation. Your Award is unfunded, and as a holder of a vested Award, you shall be considered an unsecured creditor of the Company with respect to the Company's obligation, if any, to issue shares or other property pursuant to this Agreement. You shall not have voting or any other rights as a stockholder of the Company with respect to the shares to be issued pursuant to this Agreement until such shares are issued to you pursuant to Section 6 of this Agreement. Upon such issuance, you will obtain full voting and other rights as a stockholder of the Company. Nothing contained in this Agreement, and no action taken pursuant to its provisions, shall create or be construed to create a trust of any kind or a fiduciary relationship between you and the Company or any other person.

14. Notices. Any notice or request required or permitted hereunder shall be given in writing to each of the other parties hereto and shall be deemed effectively given on the earlier of (i) the date of personal delivery, including delivery by express courier, or delivery via electronic means, or (ii) the date that is five (5) days after deposit in the United States Post Office (whether or not actually received by the addressee), by registered or certified mail with postage and fees prepaid, addressed at the following addresses, or at such other address(es) as a party may designate by ten (10) days' advance written notice to each of the other parties hereto:

Company: Trevena, Inc.
Attn: Stock Administrator
955 Chesterbrook Blvd., Suite 110
Chesterbrook, PA 19087

Participant: Your address as on file with the Company
at the time notice is given

15. Headings. The headings of the Sections in this Agreement are inserted for convenience only and shall not be deemed to constitute a part of this Agreement or to affect the meaning of this Agreement.

16. Miscellaneous.

(a) The rights and obligations of the Company under your Award shall be transferable by the Company to any one or more persons or entities, and all covenants and agreements hereunder shall inure to the benefit of, and be enforceable by, the Company's successors and assigns.

(b) You agree upon request to execute any further documents or instruments necessary or desirable in the sole determination of the Company to carry out the purposes or intent

of your Award.

(c) You acknowledge and agree that you have reviewed your Award in its entirety, have had an opportunity to obtain the advice of counsel prior to executing and accepting your Award and fully understand all provisions of your Award.

(d) This Agreement shall be subject to all applicable laws, rules, and regulations, and to such approvals by any governmental agencies or national securities exchanges as may be required.

(e) All obligations of the Company under the Plan and this Agreement shall be binding on any successor to the Company, whether the existence of such successor is the result of a direct or indirect purchase, merger, consolidation, or otherwise, of all or substantially all of the business and/or assets of the Company.

17. Governing Plan Document. Your Award is subject to all the provisions of the Plan, the provisions of which are hereby made a part of your Award, and is further subject to all interpretations, amendments, rules and regulations which may from time to time be promulgated and adopted pursuant to the Plan. Your Award (and any compensation paid or shares issued under your Award) is subject to recoupment in accordance with The Dodd–Frank Wall Street Reform and Consumer Protection Act and any implementing regulations thereunder, any clawback policy adopted by the Company and any compensation recovery policy otherwise required by applicable law. No recovery of compensation under such a clawback policy will be an event giving rise to a right to voluntarily terminate employment upon a resignation for "good reason," or for a "constructive termination" or any similar term under any plan of or agreement with the Company.

18. Effect on Other Employee Benefit Plans. The value of the Award subject to this Agreement shall not be included as compensation, earnings, salaries, or other similar terms used when calculating benefits under any employee benefit plan (other than the Plan) sponsored by the Company or any Affiliate except as such plan otherwise expressly provides. The Company expressly reserves its rights to amend, modify, or terminate any or all of the employee benefit plans of the Company or any Affiliate.

19. Choice of Law. The interpretation, performance and enforcement of this Agreement shall be governed by the law of the State of Delaware without regard to that state's conflicts of laws rules.

20. Severability. If all or any part of this Agreement or the Plan is declared by any court or governmental authority to be unlawful or invalid, such unlawfulness or invalidity shall not invalidate any portion of this Agreement or the Plan not declared to be unlawful or invalid. Any Section of this Agreement (or part of such a Section) so declared to be unlawful or invalid shall, if possible, be construed in a manner which will give effect to the terms of such Section or part of a Section to the fullest extent possible while remaining lawful and valid.

21. Other Documents. You hereby acknowledge receipt or the right to receive a document providing the information required by Rule 428(b)(1) promulgated under the Securities Act. In addition, you acknowledge receipt of the Company's *Insider Trading and Trading Window Policy*.

22. AMENDMENT. This Agreement may not be modified, amended or terminated except by an instrument in writing, signed by you and by a duly authorized representative of the Company. Notwithstanding the foregoing, this Agreement may be amended solely by the Board by a writing which specifically states that it is amending this Agreement, so long as a copy of such amendment is delivered to you, and provided that, except as otherwise expressly provided in the Plan, no such amendment materially adversely affecting your rights hereunder may be made without your written consent. Without limiting the foregoing, the Board reserves the right to change, by written notice to you, the provisions of this Agreement in any way it may deem necessary or advisable to carry out the purpose of the Award as a result of any change in applicable laws or regulations or any future law, regulation, ruling, or judicial decision, provided that any such change shall be applicable only to rights relating to that portion of the Award which is then subject to restrictions as provided herein.

23. COMPLIANCE WITH SECTION 409A OF THE CODE. This Award is intended to comply with the "short-term deferral" rule set forth in Treasury Regulation Section 1.409A-1(b)(4). Notwithstanding the foregoing, if it is determined that the Award fails to satisfy the requirements of the short-term deferral rule and is otherwise deferred compensation subject to Section 409A, and if you are a "Specified Employee" (within the meaning set forth in Section 409A(a)(2)(B)(i) of the Code) as of the date of your "separation from service" (within the meaning of Treasury Regulation Section 1.409A-1(h) and without regard to any alternative definition thereunder), then the issuance of any shares that would otherwise be made upon the date of the separation from service or within the first six (6) months thereafter will not be made on the originally scheduled date(s) and will instead be issued in a lump sum on the date that is six (6) months and one day after the date of the separation from service, with the balance of the shares issued thereafter in accordance with the original vesting and issuance schedule set forth above, but if and only if such delay in the issuance of the shares is necessary to avoid the imposition of adverse taxation on you in respect of the shares under Section 409A of the Code. Each installment of shares that vests is intended to constitute a "separate payment" for purposes of Treasury Regulation Section 1.409A-2(b)(2).

* * * * *

This Restricted Stock Unit Award Agreement shall be deemed to be signed by the Company and the Participant upon the signing by the Participant of the Restricted Stock Unit Grant Notice to which it is attached.

Exhibit 10.23

TREVENA, INC. AMENDED AND RESTATED EXECUTIVE EMPLOYMENT AGREEMENT

This Amended and Restated Employment Agreement (the "Agreement") is entered into as of May 1, 2020 (the "Effective Date") by and between Trevena, Inc. (the "Company"), a Delaware corporation, and Carrie L. Bourdow ("Executive").

WHEREAS, the Company desires to employ Executive to provide personal services to the Company, and Executive wishes to continue to be employed by the Company and provide personal services to the Company in return for certain compensation and benefits; and

WHEREAS, the Company and Executive executed that certain Executive Employment Agreement dated as of October 1, 2018 (the "Original Agreement"); and

WHEREAS, Company and executive wish to amend and restate the Original Agreement in its entirety as further provided herein.

Accordingly, in consideration of the mutual promises and covenants contained herein, the parties agree to the following:

1. Duties and Scope of Employment.

(a) Positions and Duties. Effective as of the Effective Date, Executive will serve as Chief Executive Officer and President of the Company. Executive will render such business and professional services in the performance of Executive's duties, consistent with Executive's position within the Company, as will reasonably be assigned to Executive by the Company's Board of Directors (the "Board"), to whom Executive will report. The period of Executive's employment under this Agreement is referred to herein as the "Employment Term."

(b) Obligations. During the Employment Term, Executive will perform Executive's duties faithfully and to the best of Executive's ability. For the duration of the Employment Term, Executive agrees not to actively engage in any other employment, occupation or consulting activity for any direct or indirect remuneration without the prior approval of the Board or the Compensation Committee of the Board (the "Compensation Committee"). Nothing in this Agreement or elsewhere shall prevent Executive from managing her personal investment and affairs, or from engaging in charitable and community affairs, so long as such activities do not either individually or in the aggregate interfere with the performance of her duties for the Company.

2. At-Will Employment. The parties agree that Executive's employment with the Company is "at-will" employment and may be terminated at any time with or without cause or notice. Executive's at-will employment status may not be changed except by way of written agreement signed by Executive and an authorized officer of the Company.

3. Compensation.

(a) Base Salary. During the Employment Term, the Company will pay Executive an initial annualized salary of $615,000 as compensation for services (the "Base Salary"). The Base Salary shall be paid in equal installments in accordance with the Company's normal payroll practices and subject to

required withholding and deductions. The Base Salary will be subject to review and adjustments will be made based upon the Company's normal performance review practices.

(b) Bonus. Subject to the terms and conditions set forth in the Trevena, Inc. Incentive Compensation Plan (the "ICP"), Executive may be eligible to receive an annual bonus in a target amount of 60% of the Base Salary, subject to, among other things, the achievement of corporate and individual performance objectives, which shall be established and assessed by the Company (the "Target Bonus"). In 2020, and for each subsequent calendar year, these objectives generally will be established within 90 days after the start of such calendar year. For 2020, Executive shall be eligible for the full year bonus target based on the company performance factor, subject to the terms and conditions of the ICP. The Company reserves the right to modify the terms of the ICP, the Target Bonus and other components of bonus compensation and criteria from year to year.

(c) Equity Awards. Following the Effective Date, Executive will be eligible to receive awards of stock options, restricted stock or other equity awards based upon Executive's performance, as determined by the Board from time to time. The Board or the Compensation Committee will determine in its discretion the timing and amount, if any, of any grant of such future equity awards to the Executive in accordance with the Trevena, Inc. 2013 Equity Incentive Plan, as amended (the "Plan").

4. Company Policies and Employee Benefits. During the Employment Term, Executive will be eligible to participate in the employee benefit plans currently and hereafter maintained by the Company of general applicability to other senior executives of the Company, including, without limitation, any such group medical, dental, vision, disability, life insurance, and flexible-spending account plans. All matters of eligibility for coverage and benefits under any benefit plan shall be determined in accordance with the provisions of such plan. The Company reserves the right to cancel or change the benefit plans and programs it offers to its employees at any time.

5. Vacation. While employed pursuant to this Agreement, Executive shall be eligible to take vacation subject to the Company's vacation policy.

6. Expenses. The Company will reimburse Executive for reasonable travel, entertainment or other expenses incurred by Executive in the furtherance of or in connection with the performance of Executive's duties hereunder, in accordance with the Company's expense reimbursement policy.

7. Termination of Employment. The provisions of this Section 7 govern the amount of compensation or benefit, if any, to be provided to Executive upon termination of employment and do not affect the right of either party to terminate the employment relationship at any time for any reason.

(a) Termination for other than Cause, Death or Disability. If at any time following the Effective Date (x) the Company terminates Executive's employment with the Company other than for Cause (as defined below), death or disability, or (y) Executive terminates her employment under this Agreement for Good Reason, then, subject to Section 8, Executive will be entitled to receive, less applicable withholdings and deductions:

(i) an amount equal to fifteen (15) months of Executive's annualized Base Salary in effect at the time of termination, payable in equal installments on the Company's regularly scheduled payroll dates beginning with the first payroll date following the effective date of the Release and Waiver;

(ii) (A) a pro-rata bonus for the calendar year of termination, determined by multiplying Executive's Target Bonus for such year (assuming employment for the entire year) by a fraction whose numerator is the number of days that Executive was employed during such year and whose denominator is the total number of days in such year, payable within 60 days following the date of Executive's termination of employment; and (B) to the extent not already paid, a cash incentive award under the Company's ICP or any similar incentive plan related to the fiscal year immediately preceding the year of termination in an amount as determined by the Company's Board or the Compensation Committee of the Board, as the case may be, in its sole judgment and discretion;

(iii) an amount equal to fifteen (15) months of Executive's Target Bonus in effect at the time of termination, payable in equal installments on the Company's regularly scheduled payroll dates beginning with the first payroll date following the effective date of the Release and Waiver;

(iv) if Executive timely elects continued coverage under COBRA for Executive and Executive's covered dependents under the Company's group health plans following such termination of employment, the Company will pay the COBRA premiums necessary to continue Executive's health insurance coverage in effect for Executive and Executive's eligible dependents on the termination date, as and when due to the insurance carrier or COBRA administrator (as applicable), until the earliest of (A) fifteen (15) months from the effective date of such termination, (B) the expiration of Executive's eligibility for the continuation coverage under COBRA, or (C) the date when Executive becomes eligible for substantially equivalent health insurance coverage in connection with new employment or self-employment (such period from the termination date through the earliest of (A) through (C), the "COBRA Payment Period"). Notwithstanding the foregoing, if at any time the Company determines, in its sole discretion, that the payment of the COBRA premiums would result in a violation of the nondiscrimination rules of Section 105(h)(2) of the Code or any statute or regulation of similar effect (including but not limited to the 2010 Patient Protection and Affordable Care Act, as amended by the 2010 Health Care and Education Reconciliation Act), then in lieu of providing the COBRA premiums, the Company will instead pay Executive on the last day of each remaining month of the COBRA Payment Period, a fully taxable cash payment equal to the COBRA premiums for that month, subject to applicable tax withholdings (such amount, the "Special Severance Payment"), for the remainder of the COBRA Payment Period.

And

(iv) accelerated vesting as to that number of unvested shares subject to any outstanding equity awards held by Executive at the time of termination that would have otherwise vested if Executive had remained a Company employee for twelve (12) months following the termination date.

(b) Termination in Connection With or Following a Change of Control. In the event that either (x) the Company terminates Executive's employment with the Company other than for Cause, death or disability (A) within the thirty (30) day period prior to a Change of Control, or (B) within the period between the Company's execution of a letter of intent for a proposed Change of Control which proposed Change of Control is later consummated (a "Designated Change of Control") and the consummation of such Designated Change of Control, or (C) within the twelve (12) month period after a Change of Control, or (y) Executive resigns for Good Reason within twelve (12) months after a Change of Control, then, in addition to the payments set forth in Section 7(a) above, and subject to Section 8 below, Executive shall also be entitled to, less applicable withholdings and deductions:

(i) an amount equal to twenty-one (21) months of Executive's annualized Base Salary in effect at the time of termination, payable in equal installments on the Company's regularly scheduled payroll dates beginning with the first payroll date following the effective date of the Release and Waiver;

(ii) (A) a pro-rata bonus for the calendar year of termination, determined by multiplying Executive's Target Bonus for such year (assuming employment for the entire year) by a fraction whose numerator is the number of days that Executive was employed during such year and whose denominator is the total number of days in such year, payable within 60 days following the date of Executive's termination of employment; and

(B) to the extent not already paid, a cash incentive award under the ICP related to the fiscal year immediately preceding the year of termination in an amount as determined by the Company's Board or the Compensation Committee of the Board, as the case may be, in its sole judgment and discretion;

(iii) an amount equal to twenty-one (21) months of Executive's annual Target Bonus in effect at the time of termination, payable in equal installments on the Company's regularly scheduled payroll dates beginning with the first payroll date following the effective date of the Release and Waiver;

(iv) if Executive timely elects continued coverage under COBRA for Executive and Executive's covered dependents under the Company's group health plans following such termination of employment, the Company will pay the COBRA premiums necessary to continue Executive's health insurance coverage in effect for Executive and Executive's eligible dependents on the termination date, as and when due to the insurance carrier or COBRA administrator (as applicable), until the earliest of (A) twenty-one (21) months from the effective date of such termination, (B) the expiration of Executive's eligibility for the continuation coverage under COBRA, or (C) the date when Executive becomes eligible for substantially equivalent health insurance coverage in connection with new employment or self-employment (such period from the termination date through the earliest of (A) through (C), the "COBRA Payment Period"). Notwithstanding the foregoing, if at any time the Company determines, in its sole discretion, that the payment of the COBRA premiums would result in a violation of the nondiscrimination rules of Section 105(h)(2) of the Code or any statute or regulation of similar effect (including but not limited to the 2010 Patient Protection and Affordable Care Act, as amended by the 2010 Health Care and Education Reconciliation Act), then in lieu of providing the COBRA premiums, the Company will instead pay Executive on the last day of each remaining month of the COBRA Payment Period, a fully taxable cash payment equal to the COBRA premiums for that month, subject to applicable tax withholdings (such amount, the "Special Severance Payment"), for the remainder of the COBRA Payment Period;

and

(v) immediate and full accelerated vesting of all unvested shares subject to any outstanding equity awards held by Executive at the time of termination; provided, however, that such acceleration shall not be interpreted to extend the post-termination exercise period of any stock option held by Executive at the time of termination, unless otherwise approved by the Board.

(c) Termination for Cause or Voluntary Termination. If Executive's employment with the Company terminates voluntarily by Executive (other than for Good Reason as set forth in the preceding

subsection (b)), for Cause by the Company or due to Executive's death or disability, then (i) all vesting will terminate immediately with respect to Executive's outstanding equity awards, (ii) all payments of compensation by the Company to Executive hereunder will terminate immediately (except as to amounts already earned).

(d) Termination due to Death or Disability. If Executive's employment with the Company terminates due to death or disability, then all outstanding equity awards will become immediately vested and remain exercisable for their full term.

(e) Termination by Mutual Consent. If at any time during the course of this Agreement the parties by mutual consent decide to terminate this Agreement, they shall do so by separate agreement setting forth the terms and condition of such termination.

8. Conditions to Receipt of Benefits under Section 7.

(a) Release of Claims. The receipt of any payment or benefit pursuant to Section 7 will be subject to Executive signing and not revoking a release and waiver of all claims in the form attached hereto as Exhibit A (or in such other form as may be specified by the Company in order to comply with then-existing legal requirements to effect a valid release of claims) (the "Release and Waiver") within the applicable time period set forth therein, but in no event later than forty-five days following termination of employment. No payment or benefit pursuant to Section 7 will be paid or provided until the Release and Waiver becomes effective.

(b) Other Conditions. The receipt of any payment or benefits pursuant to Section 7 will be subject to Executive not violating the Employee Proprietary Information, Inventions and NonSolicitation Agreement attached hereto as Exhibit B (the "PIIA"), returning all Company property, and complying with the Release and Waiver; provided, however, that Company must provide written notice to Executive of the condition under this Section 8(b) that could prevent the disbursement of any payment or benefits under Section 7 within thirty (30) days of the initial existence of such condition and such condition must not have been remedied by Executive within thirty (30) days of such written notice. Executive understands and agrees that payment or benefits received pursuant to Section 7 are in lieu of and not in addition to any severance or similar benefits that may be provided to other employees of the Company pursuant to a Company policy or plan.

(c) Section 409A. Notwithstanding anything to the contrary set forth herein, any payments and benefits provided under Section 7 above that constitute "deferred compensation" within the meaning of Section 409A of the Internal Revenue Code of 1986, as amended (the "Code") and the regulations and other guidance thereunder and any state law of similar effect (collectively "Section 409A") shall not commence in connection with Executive's termination of employment unless and until Executive has also incurred a "separation from service" (as such term is defined in Treasury Regulation Section 1.409A-1(h) ("Separation From Service"), unless the Company reasonably determines that such amounts may be provided to Executive without causing Executive to incur the additional 20% tax under Section 409A. Pay pursuant to Section 7 above, to the extent of payments made from the date of termination of Executive's employment through March 15 of the calendar year following such termination, are intended to constitute separate payments for purposes of Section 1.409A-2(b)(2) of the Treasury Regulations and thus payable pursuant to the "short-term deferral" rule set forth in Section 1.409A-1(b)(4) of the Treasury Regulations; to the extent such payments are made following said March 15, they

are intended to constitute separate payments for purposes of Section 1.409A-2(b)(2) of the Treasury Regulations made upon an involuntary termination of service and payable pursuant to Section 1.409A-1(b)(9)(iii) of the Treasury Regulations, to the maximum extent permitted by said provision, with any excess amount being regarded as subject to the distribution requirements of Section 409A(a)(2)(A) of the Internal Revenue Code, including, without limitation, the requirement of Section 409A(a)(2)(B)(i) of the Code that, if Executive is a "specified employee" within the meaning of the aforesaid Section of the Code at the time of such termination from employment, payments be delayed until the earlier of six months after termination of employment or Executive's death (such applicable date, the "Specified Employee Initial Payment Date"). Notwithstanding any other payment schedule set forth in herein, none of the payments under Section 7 will be paid or otherwise delivered prior to the effective date of the Release and Waiver. Except to the extent that payments may be delayed until the Specified Employee Initial Payment Date pursuant to the preceding sentence, on the first regular payroll pay day following the effective date of 7 the Release and Waiver, the Company will pay Executive the payments Executive would otherwise have received under Section 7 on or prior to such date but for the delay in payment related to the effectiveness of the Release and Waiver, with the balance of the payments being paid as originally scheduled. Notwithstanding anything to the contrary set forth herein, if any of the payments or benefits set forth in Section 7 constitute "deferred compensation" within the meaning of Section 409A of the Code and the period during which Executive may review, execute and revoke the Release and Waiver begins in one taxable year and ends in a second taxable year, such payments and benefits shall commence or be made in the second taxable year.

(d) Cooperation with the Company After Termination of Employment. Following termination of the Executive's employment for any reason, upon request by the Company, Executive will fully cooperate with the Company (at the Company's reasonable expense) in all matters reasonably relating to the winding up of pending work including, but not limited to, any litigation in which the Company is involved, and the orderly transfer of any such pending work to such other employees as may be designated by the Company.

9. Definitions.

(a) Cause. For purposes of this Agreement, "Cause" is defined as (i) an act of dishonesty by Executive in connection with Executive's responsibilities as an employee, (ii) Executive's conviction of, or plea of nolo contendere to, a felony or any crime involving fraud, embezzlement or any other act of moral turpitude, (iii) Executive's gross misconduct, (iv) Executive's unauthorized use or disclosure of any proprietary information or trade secrets of the Company or any other party to whom Executive owes an obligation of nondisclosure as a result of Executive's relationship with the Company, or (v) Executive's willful breach of any obligations under any written agreement or covenant with the Company.

(b) Change of Control. For purposes of this Agreement, "Change of Control" of the Company is defined as:

(i) any "person" (as such term is used in Sections 13(d) and 14(d) of the Securities Exchange Act of 1934, as amended) is or becomes the "beneficial owner" (as defined in Rule 13d-3 under said Act), directly or indirectly, of securities of the Company representing 50% or more of the total voting power represented by the Company's then outstanding voting securities; provided, however; that sales of equity or debt securities to investors primarily for capital raising purposes shall in no event be deemed a Change of Control; or

(ii) a change in the composition of the Board occurring within a two-year period, as a result of which less than a majority of the directors are Incumbent Directors. “Incumbent Directors” will mean directors who either (A) are directors of the Company as of the date hereof, or (B) are elected, or nominated for election, to the Board with the affirmative votes of at least a majority of the Incumbent Directors at the time of such election or nomination (but will not include an individual whose election or nomination is in connection with an actual or threatened proxy contest relating to the election of directors to the Company); provided, however; that no change in the composition of the Board in connection with the sale of equity or debt securities to investors primarily for capital raising purposes shall be deemed a Change of Control; or

(iii) the date of the consummation of a merger or consolidation of the Company that has been approved by the stockholders of the Company, other than a merger or consolidation which would result in the voting securities of the Company outstanding immediately prior thereto continuing to represent (either by remaining outstanding or by being converted into voting securities of the surviving entity) more than fifty percent (50%) of the total voting power represented by the voting securities of the Company or such surviving entity outstanding immediately after such merger or consolidation or the stockholders of the Company approve a plan of complete liquidation of the Company; or

(iv) the date of the consummation of the sale or disposition by the Company of all or substantially all the Company’s assets.

(c) Good Reason. For purposes of this Agreement, a resignation for “Good Reason” is defined as the resignation by Executive within thirty (30) days following the end of the Cure Period (defined below), if any of the following events occur without Executive’s express written consent: (i) the Company reduces the amount of the Base Salary, other than pursuant to a reduction that also is applied to substantially all other executives of the Company, (ii) the Company fails to pay the Base Salary or other benefits required to be provided by the Company hereunder, (iii) the Company materially reduces Executive’s core functions, duties or responsibilities in a manner that constitutes a demotion, or (iv) any change of Executive’s principal office location to a location more than thirty (30) miles from the Company’s office at 955 Chesterbrook Boulevard, Suite 110, Chesterbrook, PA; provided, however, that Executive must provide written notice to the Company of the condition that could constitute “Good Reason” within thirty (30) days of the initial existence of such condition and such condition must not have been remedied by the Company within thirty (30) days of such written notice (the “Cure Period”).

10. No Conflict with Existing Obligations. Executive represents that her performance of all the terms of this Agreement and, as an executive officer of the Company, do not and will not breach any agreement or obligation of any kind made prior to Executive’s employment by the Company, including agreements or obligations Executive may have with prior employers or entities for which Executive has provided services. Executive has not entered into, and Executive agrees that Executive will not enter into, any agreement or obligation, either written or oral, in conflict herewith.

11. Parachute Payments.

(a) If any payment or benefit Executive would receive pursuant to a Change of Control from the Company or otherwise (“Payment”) would (i) constitute a “parachute payment” within the meaning of Section 280G of the Internal Revenue Code of 1986, as amended (the “Code”), and (ii) but for this sentence, be subject to the excise tax imposed by Section 4999 of the Code (the “Excise Tax”), then such

Payment shall be reduced to the Reduced Amount. The “Reduced Amount” shall be either (x) the largest portion of the Payment that would result in no portion of the Payment being subject to the Excise Tax or (y) the largest portion, up to and including the total, of the Payment, whichever amount, after taking into account all applicable federal, state and local employment taxes, income taxes, and the Excise Tax (all computed at the highest applicable marginal rate), results in Executive’s receipt, on an after-tax basis, of the greater amount of the Payment notwithstanding that all or some portion of the Payment may be subject to the Excise Tax. If a reduction in payments or benefits constituting “parachute payments” is necessary so that the Payment equals the Reduced Amount, reduction shall occur in the following order unless Executive elects in writing a different order (provided, however, that such election shall be subject to Company approval if made on or after the date on which the event that triggers the Payment occurs): reduction of cash payments; cancellation of accelerated vesting of stock awards; reduction of employee benefits. In the event that acceleration of vesting of stock award compensation is to be reduced, such acceleration of vesting shall be cancelled in the reverse order of the date of grant of Executive’s stock awards unless Executive elects in writing a different order for cancellation.

(b) The accounting firm engaged by the Company for general audit purposes as of the day prior to the effective date of the Change of Control shall perform the foregoing calculations. If the accounting firm so engaged by the Company is serving as accountant or auditor for the individual, entity or group affecting the Change of Control, the Company shall appoint a nationally recognized accounting firm to make the determinations required hereunder. The Company shall bear all expenses with respect to the determinations by such accounting firm required to be made hereunder.

(c) The accounting firm engaged to make the determinations hereunder shall provide its calculations, together with detailed supporting documentation, to the Company and Executive within fifteen (15) calendar days after the date on which Executive’s right to a Payment is triggered (if requested at that time by the Company or Executive) or such other time as requested by the Company or Executive. If the accounting firm determines that no Excise Tax is payable with respect to a Payment, it shall furnish the Company and Executive with an opinion reasonably acceptable to Executive that no Excise Tax will be imposed with respect to such Payment. Any good faith determinations of the accounting firm made hereunder shall be final, binding and conclusive upon the Company and Executive.

12. Assignment. This Agreement will be binding upon and inure to the benefit of (a) the heirs, executors and legal representatives of Executive upon Executive’s death and (b) any successor of the Company. Any such successor of the Company will be deemed substituted for the Company under the terms of this Agreement for all purposes. For this purpose, “successor” means any person, firm, corporation or other business entity which at any time, whether by purchase, merger or otherwise, directly or indirectly acquires all or substantially all of the assets or business of the Company. None of the rights of Executive to receive any form of compensation payable pursuant to this Agreement may be assigned or transferred except by will or the laws of descent and distribution. Any other attempted assignment, transfer, conveyance or other disposition of Executive’s right to compensation or other benefits will be null and void.

13. Notices. All notices, requests, demands and other communications called for hereunder will be in writing and will be deemed given (i) on the date of delivery if delivered personally, (ii) one (1) day

after being sent by a nationally recognized commercial overnight service, specifying next day delivery, with written verification of receipt, or (iii) four (4) days after being mailed by registered or certified mail, return receipt requested, prepaid and addressed to the parties or their successors at the following addresses, or at such other addresses as the parties may later designate in writing:

If to the Company:

955 Chesterbrook Blvd, Suite 110, Chesterbrook, PA 19087

Attn: Vice President, Legal & Compliance

If to Executive:

at the last residential address known by the Company.

14. Severability. In the event that any provision of this Agreement becomes or is declared by a court of competent jurisdiction to be illegal, unenforceable or void, this Agreement will continue in full force and effect without said provision.

15. Arbitration.

(a) Arbitration. In consideration of Executive's employment with the Company, the Company and Executive agree that any and all controversies, claims, or disputes with anyone (including the Company and any employee, officer, director, shareholder or benefit plan of the Company in their capacity as such or otherwise) arising out of, relating to, or resulting from Executive's employment with the Company or the termination of Executive's employment with the Company, including any breach of this Agreement, but not including those arising out of, relating to, or resulting from the PIAA, will be subject to binding arbitration. Disputes which Executive agrees to arbitrate, and thereby agrees to waive any right to a trial by jury, include any statutory claims under state or federal law, including, but not limited to, claims under Title VII of the Civil Rights Act of 1964, the Americans with Disabilities Act of 1990, the Age Discrimination in Employment Act of 1967, the Older Workers Benefit Protection Act, the Worker Adjustment and Retraining Notification Act, the Family and Medical Leave Act, discrimination or wrongful termination and any statutory claims. Executive further understands that this Agreement to arbitrate also applies to any disputes that the Company may have with Executive. The parties shall each bear their own expenses, legal fees and other fee incurred in connection with this Agreement. Provided, however, in the event the Executive is required to incur attorney's fees in order to obtain any payments or benefits under this Agreement and provided that the Executive prevails on her claim(s), then the Company will reimburse the attorney's fees incurred by Executive.

(b) Procedure. Executive agrees that any arbitration will be administered by the American Arbitration Association ("AAA") and that the neutral arbitrator will be selected in a manner consistent with its National Rules for the Resolution of Employment Disputes (the "Rules"). Executive agrees that the arbitrator will administer and conduct any arbitration in a manner consistent with the Rules.

(c) Remedy. Except as provided by this Agreement and by the Rules, including any provisional relief offered therein, arbitration will be the sole, exclusive and final remedy for any dispute between Executive and the Company. Accordingly, except as provided for by the Rules and this Agreement, neither Executive nor the Company will be permitted to pursue court action regarding claims that are subject to arbitration.

(d) Administrative Relief. Executive understands that this Agreement does not prohibit Executive from pursuing an administrative claim with a local, state or federal administrative body such as the Equal Employment Opportunity Commission or the workers' compensation board. This Agreement does, however, preclude Executive from pursuing court action regarding any such claim.

(e) Voluntary Nature of Agreement. Executive acknowledges and agrees that Executive is executing this Agreement voluntarily and without any duress or undue influence by the Company or anyone else. Executive further acknowledges and agrees that Executive has carefully read this Agreement and that Executive has asked any questions needed for Executive to understand the terms, consequences and binding effect of this Agreement and fully understands it, including that Executive is waiving Executive's right to a jury trial. Finally, Executive agrees that Executive has been provided an opportunity to seek the advice of an attorney of Executive's choice before signing this Agreement. 16. Integration. This Agreement, together with the PIIA and the other documents referred to in this Agreement, represents the entire agreement and understanding between the parties as to the subject matter herein and supersedes all prior or contemporaneous agreements whether written or oral. This Agreement may be modified only by agreement of the parties by a written instrument executed by the parties that is designated as an amendment to this Agreement.

17. Waiver of Breach. The waiver of a breach of any term or provision of this Agreement, which must be in writing, will not operate as or be construed to be a waiver of any other previous or subsequent breach of this Agreement.

18. Headings. All captions and section headings used in this Agreement are for convenient reference only and do not form a part of this Agreement.

19. Governing Law. This Agreement will be governed by the laws of the Commonwealth of Pennsylvania.

20. Acknowledgment. Executive acknowledges that he has had the opportunity to discuss this matter with and obtain advice from Executive's private attorney, has had sufficient time to, and has carefully read and fully understands all the provisions of this Agreement, and is knowingly and voluntarily entering into this Agreement.

21. Counterparts. This Agreement may be executed in counterparts, and each counterpart will have the same force and effect as an original and will constitute an effective, binding agreement on the part of each of the undersigned.

22. Amendment and Restatement. The Parties acknowledge and agree that the Original Agreement hereby is amended in its entirety and restated herein. The terms of this Agreement shall supersede the Original Agreement except for those terms which expressly survive in the Original Agreement.

IN WITNESS WHEREOF, each of the parties has executed this Agreement, in the case of the Company by their duly authorized officers, as of the day and year first above written.

COMPANY: TREVENA, INC.

By: _____

Name: Robert Yoder

Title: SVP, Chief Business Officer

EXECUTIVE: _____

Carrie L. Bourdow

EXHIBIT A

Release and Waiver

TO BE SIGNED ON OR FOLLOWING THE SEPARATION DATE ONLY

In consideration of the payments and other benefits set forth in the Employment Agreement of (_____), to which this form is attached, I, (_____), hereby furnish TREVENA, INC. (the "Company"), with the following release and waiver of claims ("Release and Waiver").

In exchange for the consideration provided to me by the Employment Agreement that I am not otherwise entitled to receive, I hereby generally and completely release the Company and its current and former directors, officers, employees, stockholders, partners, agents, attorneys, predecessors, successors, parent and subsidiary entities, insurers, affiliates, and assigns (collectively, the "Released Parties") from any and all claims, liabilities and obligations, both known and unknown, that arise out of or are in any way related to events, acts, conduct, or omissions occurring prior to or on the date that I sign this Agreement (collectively, the "Released Claims"). The Released Claims include, but are not limited to: (a) all claims arising out of or in any way related to my employment with the Company, or the termination of that employment; (b) all claims related to my compensation or benefits from the Company including salary, bonuses, commissions, vacation pay, expense reimbursements, severance pay, fringe benefits, stock, stock options, or any other ownership interests in the Company; (c) all claims for breach of contract, wrongful termination, and breach of the implied covenant of good faith and fair dealing; (d) all tort claims, including claims for fraud, defamation, emotional distress, and discharge in violation of public policy; and (e) all federal, state, and local statutory claims, including claims for discrimination, harassment, retaliation, misclassification, attorneys' fees, or other claims arising under the federal Civil Rights Act of 1964 (as amended), the federal Americans with Disabilities Act of 1990, the federal Age Discrimination in Employment Act of 1967 (as amended) (the "ADEA"), any other federal, state or local civil or human rights law or any other local, state or federal law, regulation or ordinance, including, but not limited to, the State of Pennsylvania or any subdivision thereof; and any public policy, contract, tort, or common law. I hereby represent and warrant that, other than the Excluded Claims, I am not aware of any claims I have or might have against any of the Released Parties that are not included in the Released Claims.

In granting the release herein, which includes claims that may be unknown to me at present, I acknowledge that I expressly waive and relinquish any and all rights and benefits under any applicable law or statute providing, in substance, that a general release does not extend to claims which a party does not know or suspect to exist in his or her favor at the time of executing the release, which if known by him or her would have materially affected the terms of such release.

I acknowledge that, among other rights, I am waiving and releasing any rights I may have under ADEA, that this Release and Waiver is knowing and voluntary, and that the consideration given for this Release and Waiver is in addition to anything of value to which I was already entitled as an executive of the Company. If I am 40 years of age or older upon execution of this Release and Waiver, I further acknowledge that I have been advised, as required by the Older Workers Benefit Protection Act, that: (a) the release and waiver granted herein does not relate to claims under the ADEA which may arise after this Release and Waiver is executed; (b) I should consult with an attorney prior to executing this Release and Waiver; and (c) I have twenty-one (21) days from the date of termination of my employment with

the Company in which to consider this Release and Waiver (although I may choose voluntarily to execute this Release and Waiver earlier); (d) I have seven (7) days following the execution of this Release and Waiver to revoke my consent to this Release and Waiver; and (e) this Release and Waiver shall not be effective until the seven (7) day revocation period has expired without my having previously revoked this Release and Waiver.

I acknowledge my continuing obligations under my Employee Proprietary Information, Inventions and Non-Solicitation Agreement (the "PIIA"). Pursuant to the PIIA I understand that among other things, I must not use or disclose any confidential or proprietary information of the Company and I must immediately return all Company property and documents (including all embodiments of proprietary information) and all copies thereof in my possession or control. I understand and agree that my right to the severance benefits I am receiving in exchange for my agreement to the terms of this Release and Waiver is contingent upon my continued compliance with my PIIA.

This Release and Waiver constitutes the complete, final and exclusive embodiment of the entire agreement between the Company and me with regard to the subject matter hereof. I am not relying on any promise or representation by the Company that is not expressly stated herein. This Release and Waiver may only be modified by a writing signed by both me and a duly authorized officer of the Company.

Date: _____

Exhibit 10.27

AMENDMENT #1 TO THE AMENDED AND RESTATEMENT EMPLOYEMENT AGREEMENT DATED MAY 1, 2020

THIS AMENDMENT #1 TO AMEND AND RESTATED EMPLOYEMENT AGREEMENT (the "***Amendment***") is effective as of March 8, 2024, (the "***Amendment Effective Date***") and is made by and between Trevena, Inc., having offices at 955 Chesterbrook Blvd., Suite 100, Chesterbrook, PA 19087 ("***Company***") and Carrie L. Bourdow ("***Executive***").

WHEREAS, Company and Executive entered into that certain Amended and Restated Employment Agreement effective as of May 1, 2020 (the "Agreement"); and

WHEREAS, Company and Executive wish to amend the Agreement to fix a scrivener's error.

NOW, THEREFORE, Executive and Company agree as follows:

1. Terms not otherwise defined herein shall have the meanings ascribed to them in the Agreement.
2. Section 7(c) of the Agreement shall be deleted in its entirety and replaced with the following:

   (c) Termination for Cause or Voluntary Termination. If Executive's employment with the Company terminates voluntarily by Executive (other than for Good Reason as set for in the preceding subsection (b)) or for Cause by the Company, then (i) all vesting will terminate immediately with respect to the Executive's outstanding equity awards, (ii) all payments of compensation by the Company to Executive hereunder will terminate immediately (except as to amounts already earned).

3. Except as specifically amended herein, the terms and condition of the Agreement shall remain unchanged and in full force and effect.

IN WITNESS WHEREOF, and intending to be legally bound, the undersigned have caused this Amendment to be executed on the date first written above.

[SIGNATURES]

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

1) Registration Statement (Form S-8 No. 333-273294) pertaining to the Trevena, Inc. 2023 Equity Incentive Plan,
2) Registration Statement (Form S-8 No. 333-215420) pertaining to the Trevena, Inc. Inducement Plan,
3) Registration Statement (Form S-3 No. 333-275866) of Trevena, Inc., and
4) Registration Statement (Form S-3 No. 333-276458) of Trevena, Inc.

of our report dated April 1, 2024, with respect to the financial statements of Trevena, Inc. included in this Annual Report (Form 10-K) of Trevena, Inc. for the year ended December 31, 2023.

/s/ Ernst & Young LLP

Philadelphia, Pennsylvania
April 1, 2024

Exhibit 31.1

Certification of Principal Executive Officer of Trevena, Inc.
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Carrie L. Bourdow, certify that:

1. I have reviewed this Annual Report on Form 10-K of Trevena, Inc.;

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

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

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

    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant is made known to us by others within those entities, particularly during the period in which this report is being prepared;

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

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

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

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

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

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

Date: April 1, 2024

/s/ CARRIE L. BOURDOW
Carrie L. Bourdow
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

Certification of Principal Financial Officer of Trevena, Inc.
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Barry Shin, certify that:

1. I have reviewed this Annual Report on Form 10-K of Trevena, Inc.;

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

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

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

    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant is made known to us by others within those entities, particularly during the period in which this report is being prepared;

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

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

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

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

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

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

Date: April 1, 2024

/s/ BARRY SHIN
Barry Shin
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

Certification Of
Principal Executive Officer
Pursuant To 18 U.S.C. Section 1350,
As Adopted Pursuant To
Section 906 Of The Sarbanes-Oxley Act Of 2002

In connection with the Annual Report of Trevena, Inc. (the "Company") on Form 10-K for the year ended December 31, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Carrie L. Bourdow, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

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

2) The information contained in the Report fairly presents, in all material respects, the financial condition of the Company at the end of the period covered by the Report and results of operations of the Company for the period covered by the Report.

Date: April 1, 2024

/s/ CARRIE L. BOURDOW
Carrie L. Bourdow
President and Chief Executive Officer
(Principal Executive Officer)

This certification accompanies the Report and shall not be deemed "filed" by the Company with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Report), irrespective of any general incorporation language contained in such filing.

Exhibit 32.2

Certification Of
Principal Financial Officer
Pursuant To 18 U.S.C. Section 1350,
As Adopted Pursuant To
Section 906 Of The Sarbanes-Oxley Act Of 2002

In connection with the Annual Report of Trevena, Inc. (the "Company") on Form 10-K for the year ended December 31, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Barry Shin, Chief Financial Officer, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

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

2) The information contained in the Report fairly presents, in all material respects, the financial condition of the Company at the end of the period covered by the Report and results of operations of the Company for the period covered by the Report.

Date: April 1, 2024

/s/ BARRY SHIN
Barry Shin
Chief Financial Officer
(Principal Financial Officer)

This certification accompanies the Report and shall not be deemed "filed" by the Company with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Report), irrespective of any general incorporation language contained in such filing.

Exhibit 97

TREVENA, INC.

CLAWBACK POLICY

The Compensation Committee (the "Compensation Committee") of the Board of Directors (the "Board") of Trevena, Inc., a Delaware corporation (the "Company") has adopted the following Clawback Policy (this "Policy") on September 13, 2023, effective as of October 2, 2023 (the "Effective Date").

1. Purpose. The purpose of this Policy is to provide for the recoupment of certain incentive compensation pursuant to Section 954 of the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, in the manner required by Section 10D of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), Rule 10D-1 promulgated thereunder, and the Applicable Listing Standards (as defined below) (collectively, the "Dodd-Frank Rules").

2. Administration. This Policy shall be administered by the Compensation Committee. Any determinations made by the Compensation Committee shall be final and binding on all affected individuals.

3. Definitions. For purposes of this Policy, the following capitalized terms shall have the meanings set forth below.

(a) "***Accounting Restatement***" shall mean an accounting restatement of the Company's financial statements due to the material noncompliance of the Company with any financial reporting requirement under the securities laws, including any required accounting restatement (i) to correct an error in previously issued financial statements that is material to the previously issued financial statements (*i.e.,* a "Big R" restatement), or (ii) that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period (*i.e.,* a "little r" restatement).

(b) "***Affiliate***" shall mean each entity that directly or indirectly controls, is controlled by, or is under common control with the Company.

(c) "***Applicable Exchange"*** shall mean The Nasdaq Stock Market.

(d) "***Applicable Listing Standards***" shall mean Nasdaq Listing Rule 5608.

(e) "***Clawback Eligible Incentive Compensation***" shall mean Incentive-Based Compensation Received by a Covered Executive (i) on or after the Effective Date, (ii) after beginning service as a Covered Executive, (iii) if such individual served as a Covered Executive at any time during the performance period for such Incentive-Based Compensation (irrespective of whether such individual continued to serve as a Covered Executive upon or following the Restatement Trigger Date), (iv) while the Company has a class of securities listed on a national securities exchange or a national securities association, and (v) during the applicable Clawback Period. For the avoidance of doubt, Incentive-Based Compensation Received by a Covered Executive on or after the Effective Date could, by the terms of this Policy, include amounts approved, awarded, or granted prior to such date.

(f) "***Clawback Period***" shall mean, with respect to any Accounting Restatement, the three completed fiscal years of the Company immediately preceding the Restatement Trigger Date and any transition period (that results from a change in the Company's fiscal year) within or immediately following

those three completed fiscal years (except that a transition period between the last day of the Company's previous fiscal year end and the first day of its new fiscal year that comprises a period of at least nine months shall count as a completed fiscal year).

(g) "***Company Group***" shall mean the Company and its Affiliates.

(h) "***Covered Executive***" shall mean any "executive officer" of the Company as defined under the Dodd-Frank Rules, and, for the avoidance of doubt, includes each individual identified as an executive officer of the Company in accordance with Item 401(b) of Regulation S-K under the Exchange Act.

(i) "***Erroneously Awarded Compensation***" shall mean the amount of Clawback Eligible Incentive Compensation that exceeds the amount of Incentive-Based Compensation that otherwise would have been Received had it been determined based on the restated amounts, computed without regard to any taxes paid. With respect to any compensation plan or program that takes into account Incentive-Based Compensation, the amount contributed to a notional account that exceeds the amount that otherwise would have been contributed had it been determined based on the restated amount, computed without regard to any taxes paid, shall be considered Erroneously Awarded Compensation, along with earnings accrued on that notional amount.

(j) "***Financial Reporting Measures***" shall mean measures that are determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, and all other measures that are derived wholly or in part from such measures. Stock price and total shareholder return (and any measures that are derived wholly or in part from stock price or total shareholder return) shall for purposes of this Policy be considered Financial Reporting Measures. For the avoidance of doubt, a measure need not be presented in the Company's financial statements or included in a filing with the U.S. Securities and Exchange Commission (the "SEC") in order to be considered a Financial Reporting Measure.

(k) "***Incentive-Based Compensation***" shall mean any compensation that is granted, earned or vested based wholly or in part upon the attainment of a Financial Reporting Measure.

(l) "***Received***" shall mean the deemed receipt of Incentive-Based Compensation. Incentive-Based Compensation shall be deemed received for this purpose in the Company's fiscal period during which the Financial Reporting Measure specified in the applicable Incentive-Based Compensation award is attained, even if payment or grant of the Incentive-Based Compensation occurs after the end of that period.

(m) "***Restatement Trigger Date***" shall mean the earlier to occur of (i) the date the Board, a committee of the Board, or the officer(s) of the Company authorized to take such action if Board action is not required, concludes, or reasonably should have concluded, that the Company is required to prepare an Accounting Restatement, or (ii) the date a court, regulator or other legally authorized body directs the Company to prepare an Accounting Restatement.

4. **Recoupment of Erroneously Awarded Compensation**. Upon the occurrence of a Restatement Trigger Date, the Company shall recoup Erroneously Awarded Compensation reasonably promptly, in the manner described below. For the avoidance of doubt, the Company's obligation to recover Erroneously Awarded Compensation under this Policy is not dependent on if or when restated financial statements are filed following the Restatement Trigger Date.

(a) ***Process.*** The Compensation Committee shall use the following process for recoupment:

(i) First, the Compensation Committee will determine the amount of any Erroneously Awarded Compensation for each Covered Executive in connection with such Accounting Restatement. For

Incentive-Based Compensation based on (or derived from) stock price or total shareholder return where the amount of Erroneously Awarded Compensation is not subject to mathematical recalculation directly from the information in the applicable Accounting Restatement, the amount shall be determined by the Compensation Committee based on a reasonable estimate of the effect of the Accounting Restatement on the stock price or total shareholder return upon which the Incentive-Based Compensation was Received (in which case, the Company shall maintain documentation of such determination of that reasonable estimate and provide such documentation to the Applicable Exchange).

(ii) Second, the Compensation Committee will provide each affected Covered Executive with a written notice stating the amount of the Erroneously Awarded Compensation, a demand for recoupment, and the means of recoupment that the Company will accept.

(b) ***Means of Recoupment.*** The Compensation Committee shall have discretion to determine the appropriate means of recoupment of Erroneously Awarded Compensation, which may include without limitation: (i) recoupment of cash or shares of Company stock, (ii) forfeiture of unvested cash or equity awards (including those subject to service-based and/or performance-based vesting conditions), (iii) cancellation of outstanding vested cash or equity awards (including those for which service-based and/or performance-based vesting conditions have been satisfied), (iv) to the extent consistent with Section 409A of the Internal Revenue Code of 1986, as amended ("Section 409A"), offset of other amounts owed to the Covered Executive or forfeiture of deferred compensation, (v) reduction of future compensation, and (vi) any other remedial or recovery action permitted by law. Notwithstanding the foregoing, the Company Group makes no guarantee as to the treatment of such amounts under Section 409A, and shall have no liability with respect thereto. For the avoidance of doubt, appropriate means of recoupment may include amounts approved, awarded, or granted prior to the Effective Date. Except as set forth in Section 4(d) below, in no event may the Company Group accept an amount that is less than the amount of Erroneously Awarded Compensation in satisfaction of a Covered Executive's obligations hereunder.

(c) ***Failure to Repay.*** To the extent that a Covered Executive fails to repay all Erroneously Awarded Compensation to the Company Group when due (as determined in accordance with Section 4(a) above), the Company shall, or shall cause one or more other members of the Company Group to, take all actions reasonable and appropriate to recoup such Erroneously Awarded Compensation from the applicable Covered Executive. In such instance, the applicable Covered Executive shall be required to reimburse the Company Group for any and all expenses reasonably incurred (including legal fees) by the Company Group in recouping such Erroneously Awarded Compensation.

(d) ***Exceptions.*** Notwithstanding anything herein to the contrary, the Company shall not be required to recoup Erroneously Awarded Compensation if one of the following conditions is met and the Compensation Committee determines that recoupment would be impracticable:

(i) The direct expense paid to a third party to assist in enforcing this Policy against a Covered Executive would exceed the amount to be recouped, after the Company has made a reasonable attempt to recoup the applicable Erroneously Awarded Compensation, documented such attempts, and provided such documentation to the Applicable Exchange;

(ii) Recoupment would violate home country law where that law was adopted prior to November 28, 2022, provided that, before determining that it would be impracticable to recoup any amount of Erroneously Awarded Compensation based on violation of home country law, the Company has obtained an opinion of home country counsel, acceptable to the Applicable Exchange, that recoupment would result in such a violation and a copy of the opinion is provided to the Applicable Exchange; or

(iii) Recoupment would likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to employees, to fail to meet the requirements of 26 U.S.C. 401(a)(13) or 26 U.S.C. 411(a) and regulations thereunder.

5. Reporting and Disclosure. The Company shall file all disclosures with respect to this Policy in accordance with the requirements of the Dodd-Frank Rules.

6. Indemnification Prohibition. No member of the Company Group shall be permitted to indemnify any current or former Covered Executive against (i) the loss of any Erroneously Awarded Compensation that is recouped pursuant to the terms of this Policy, or (ii) any claims relating to the Company Group's enforcement of its rights under this Policy. The Company may not pay or reimburse any Covered Executive for the cost of third-party insurance purchased by a Covered Executive to fund potential recoupment obligations under this Policy.

7. Acknowledgment. To the extent required by the Compensation Committee, each Covered Executive shall be required to sign and return to the Company the acknowledgement form attached hereto as Exhibit A pursuant to which such Covered Executive will agree to be bound by the terms of, and comply with, this Policy. For the avoidance of doubt, each Covered Executive will be fully bound by, and must comply with, the Policy, whether or not such Covered Executive has executed and returned such acknowledgment form to the Company.

8. Interpretation. The Compensation Committee is authorized to interpret and construe this Policy and to make all determinations necessary, appropriate, or advisable for the administration of this Policy. The Compensation Committee intends that this Policy be interpreted consistent with the Dodd-Frank Rules.

9. Amendment; **Termination**. The Compensation Committee may amend or terminate this Policy from time to time in its discretion, including as and when it determines that it is legally required to do so by any federal securities laws, SEC rule or the rules of any national securities exchange or national securities association on which the Company's securities are listed.

10. Other Recoupment Rights. The Compensation Committee intends that this Policy be applied to the fullest extent of the law. The Compensation Committee may require that any employment agreement, equity award, cash incentive award, or any other agreement entered into be conditioned upon the Covered Executive's agreement to abide by the terms of this Policy. Any right of recoupment under this Policy is in addition to, and not in lieu of, any other remedies or rights of recoupment that may be available to the Company Group, whether arising under applicable law, regulation or rule, pursuant to the terms of any other policy of the Company Group, pursuant to any employment agreement, equity award, cash incentive award, or other agreement applicable to a Covered Executive, or otherwise (the "Separate Clawback Rights"). Notwithstanding the foregoing, there shall be no duplication of recovery of the same Erroneously Awarded Compensation under this Policy and the Separate Clawback Rights, unless required by applicable law.

11. **Successors**. This Policy shall be binding and enforceable against all Covered Executives and their beneficiaries, heirs, executors, administrators or other legal representatives.

Exhibit A

TREVENA, INC.

CLAWBACK POLICY

ACKNOWLEDGEMENT FORM

By signing below, the undersigned acknowledges and confirms that the undersigned has received and reviewed a copy of the Trevena, Inc. Clawback Policy (the "***Policy***"). Capitalized terms used but not otherwise defined in this Acknowledgement Form (this "***Acknowledgement Form***") shall have the meanings ascribed to such terms in the Policy.

By signing this Acknowledgement Form, the undersigned acknowledges and agrees that the undersigned is and will continue to be subject to the Policy and that the Policy will apply both during and after the undersigned's employment with the Company Group. Further, by signing below, the undersigned agrees to abide by the terms of the Policy, including, without limitation, by returning any Erroneously Awarded Compensation to the Company Group reasonably promptly to the extent required by, and in a manner permitted by, the Policy, as determined by the Compensation Committee of the Company's Board of Directors in its sole discretion.

Sign: _____
Name:

Date: _____