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

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES
EXCHANGE ACT OF 1934**

For the quarterly period ended September 30, 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

(State or Other Jurisdiction of Incorporation or Organization)

26-1469215

(I.R.S. Employer Identification No.)

955 Chesterbrook Boulevard, Suite 110

Chesterbrook, PA

(Address of Principal Executive Offices)

19087

(Zip Code)

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

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

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
Common Stock, \$0.001 par value	TRVN	The Nasdaq Stock Market LLC

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, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.:

Large accelerated filer ☐

Accelerated filer ☐

Non-accelerated filer ☒

Smaller reporting company ☒

Emerging growth company ☐

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

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

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practical date.

Common Stock, \$0.001 par value

Shares outstanding as of November 13, 2023: 15,172,929

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Cautionary Note Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q, or this “Quarterly Report,” contains forward-looking statements that involve substantial risks and uncertainties. The forward-looking statements are contained principally in the section entitled “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” but also are contained elsewhere in this Quarterly Report, as well as in sections such as “Risk Factors” that are incorporated by reference into this Quarterly Report from our most recent [Annual Report on Form 10-K](#), or the “Annual Report” and our most recent Quarterly Reports on Form 10-Q for the periods ended March 31, 2023 and June 30, 2023. 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 Quarterly 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 statements about:

- our ability to successfully commercialize OLINVYK and any 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;
- 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 and maintain all applicable Nasdaq continued listing requirements.

You should refer to the “Risk Factors” section of this Quarterly Report, our Quarterly Reports for the periods ended March 31, 2023 and June 30, 2023, and our Annual Report for a discussion of important factors that may cause

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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 Quarterly 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. CONSOLIDATED FINANCIAL STATEMENTS****TREVENA, INC.****Consolidated Balance Sheets (Unaudited)**
(in thousands, except share and per share data)

	September 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	\$ 34,952	\$ 38,320
Accounts Receivable, net	179	—
Inventories	900	906
Prepaid expenses and other current assets	3,447	1,782
Total current assets	39,478	41,008
Restricted cash	540	1,960
Property and equipment, net	1,259	1,488
Right-of-use lease assets	3,813	4,224
Other assets	43	—
Total assets	\$ 45,133	\$ 48,680
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable, net	\$ 1,545	\$ 2,372
Accrued expenses and other current liabilities	3,629	5,461
Lease liabilities	982	899
Total current liabilities	6,156	8,732
Loan payable, net	29,642	13,430
Leases, net of current portion	4,689	5,436
Warrant liability	1,097	5,483
Total liabilities	41,584	33,081
Stockholders' equity:		
Preferred stock—\$0.001 par value; 5,000,000 shares authorized, none issued or outstanding at September 30, 2023 and December 31, 2022	—	—
Common stock—\$0.001 par value; 200,000,000 shares authorized at September 30, 2023 and December 31, 2022; 14,721,342 and 7,744,692 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively	15	8
Additional paid-in capital	575,067	563,362
Accumulated deficit	(571,533)	(547,772)
Accumulated other comprehensive income	—	1
Total stockholders' equity	3,549	15,599
Total liabilities and stockholders' equity	\$ 45,133	\$ 48,680

See accompanying notes to consolidated financial statements.

TREVENA, INC.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Revenue:				
Product revenue	\$ 1	\$ (438)	\$ 28	\$ (438)
License and royalty revenue	179	—	3,179	20
Total revenue	180	(438)	3,207	(418)
Operating expenses:				
Cost of goods sold	175	2,368	389	2,791
Selling, general and administrative	4,572	7,683	15,799	29,003
Research and development	4,260	5,266	12,160	14,816
Total operating expenses	9,007	15,317	28,348	46,610
Loss from operations	(8,827)	(15,755)	(25,141)	(47,028)
Other income (expense):				
Change in fair value of warrant liability	682	651	2,385	651
Other income, net	61	65	118	174
Interest income	377	127	989	246
Interest expense	(210)	(401)	(1,778)	(726)
(Loss) gain on foreign currency exchange	(13)	18	(34)	18
Foreign income tax expense	—	—	(300)	—
Total other income, net	897	460	1,380	363
Net Loss	(7,930)	(15,295)	(23,761)	(46,665)
Unrealized gain (loss) on marketable securities	—	32	—	(28)
Comprehensive loss	<u>\$ (7,930)</u>	<u>\$ (15,263)</u>	<u>\$ (23,761)</u>	<u>\$ (46,693)</u>
Per share information:				
Net loss per share of common stock, basic and diluted	<u>\$ (0.57)</u>	<u>\$ (2.24)</u>	<u>\$ (2.03)</u>	<u>\$ (6.97)</u>
Weighted average common shares outstanding, basic and diluted	<u>13,964,301</u>	<u>6,829,013</u>	<u>11,728,842</u>	<u>6,691,061</u>

See accompanying notes to consolidated financial statements.

TREVENA, INC.

Consolidated Statements of Stockholders' Equity (Unaudited)
(in thousands, except share data)

	Stockholders' Equity						Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
	Common Stock		Preferred Stock		Additional Paid-in Capital	Accumulated Deficit		
	Number of Shares	\$0.001 Par Value	Number of Shares	\$0.001 Par Value				
Balance, January 1, 2023	7,744,692	\$ 8	—	\$ —	\$ 563,362	\$ (547,772)	\$ 1	\$ 15,599
Stock-based compensation expense	—	—	—	—	806	—	—	806
Unrealized loss on marketable securities	—	—	—	—	—	—	(1)	(1)
Exercise of pre-funded warrants and related reclassification of warrant liability	1,230,380	1	—	—	1,568	—	—	1,569
Net loss	—	—	—	—	—	(7,819)	—	(7,819)
Balance, March 31, 2023	8,975,072	\$ 9	—	\$ —	\$ 565,736	\$ (555,591)	\$ —	\$ 10,154
Stock-based compensation expense	—	—	—	—	702	—	—	702
Issuance of common stock, net of issuance costs	4,116,039	4	—	—	6,500	—	—	6,504
Issuance of common stock upon vesting of RSUs, net of shares withheld for employee taxes	2,028	—	—	—	—	—	—	—
Exercise of pre-funded warrants and related reclassification of warrant liability	619,000	1	—	—	433	—	—	434
Net loss	—	—	—	—	—	(8,012)	—	(8,012)
Balance, June 30, 2023	13,712,139	\$ 14	—	\$ —	\$ 573,371	\$ (563,603)	\$ —	\$ 9,782
Stock-based compensation expense	—	—	—	—	689	—	—	689
Issuance of common stock, net of issuance costs	1,009,000	1	—	—	1,007	—	—	1,008
Issuance of common stock upon vesting of RSUs, net of shares withheld for employee taxes	203	—	—	—	—	—	—	—
Net loss	—	—	—	—	—	(7,930)	—	(7,930)
Balance, September 30, 2023	14,721,342	\$ 15	—	\$ —	\$ 575,067	\$ (571,533)	\$ —	\$ 3,549

	Stockholders' Equity							Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
	Common Stock Number of Shares	\$0.001 Par Value	Preferred Stock Number of Shares	\$0.001 Par Value	Additional Paid-in Capital	Subscription Receivable	Accumulated Deficit		
Balance, January 1, 2022	6,618,096	\$ 7	—	\$ —	\$ 558,724	\$ —	\$ (494,102)	\$ —	\$ 64,629
Stock-based compensation expense	—	—	—	—	1,155	—	—	—	1,155
Net loss	—	—	—	—	—	—	(16,389)	—	(16,389)
Balance, March 31, 2022	<u>6,618,096</u>	<u>\$ 7</u>	<u>—</u>	<u>\$ —</u>	<u>\$ 559,879</u>	<u>\$ —</u>	<u>\$ (510,491)</u>	<u>\$ —</u>	<u>\$ 49,395</u>
Stock-based compensation expense	—	—	—	—	1,008	—	—	—	1,008
Issuance of common stock warrants in connection with loan payable	—	—	—	—	603	—	—	—	603
Issuance of common stock upon vesting of RSUs, net of shares withheld for employee taxes	6,441	—	—	—	—	(23)	—	—	(23)
Unrealized loss on marketable securities	—	—	—	—	—	—	—	(60)	(60)
Net loss	—	—	—	—	—	—	(14,981)	—	(14,981)
Balance, June 30, 2022	<u>6,624,537</u>	<u>\$ 7</u>	<u>—</u>	<u>\$ —</u>	<u>\$ 561,490</u>	<u>\$ (23)</u>	<u>\$ (525,472)</u>	<u>\$ (60)</u>	<u>\$ 35,942</u>
Stock-based compensation expense	—	—	—	—	764	—	—	—	764
Issuance of Preferred Stock	—	—	2,000	397	—	—	—	—	397
Conversion of Preferred Stock to Common Stock	320,000	—	(2,000)	(397)	389	—	—	—	(8)
Issuance of common stock upon vesting of RSUs, net of shares withheld for employee taxes	203	—	—	—	—	23	—	—	23
Unrealized loss on marketable securities	—	—	—	—	—	—	—	32	32
Net loss	—	—	—	—	—	—	(15,295)	—	(15,295)
Balance, September 30, 2022	<u>6,944,740</u>	<u>\$ 7</u>	<u>—</u>	<u>\$ —</u>	<u>\$ 562,643</u>	<u>\$ —</u>	<u>\$ (540,767)</u>	<u>\$ (28)</u>	<u>\$ 21,855</u>

See accompanying notes to consolidated financial statements.

TREVENA, INC.

Consolidated Statements of Cash Flows (Unaudited)
(in thousands)

	Nine Months Ended September 30,	
	2023	2022
Operating activities:		
Net loss	\$ (23,761)	\$ (46,665)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	249	300
Stock-based compensation	2,197	2,927
Noncash interest expense on loan	1,004	230
Inventory valuation adjustment	—	2,070
Change in fair value of warrant liability	(2,385)	(651)
Returns reserve adjustment	—	383
Accretion of bond discount on marketable securities	—	(36)
Change in right-of-use asset	411	354
Changes in operating assets and liabilities:		
Accounts receivable, prepaid expenses and other assets	(1,454)	1,628
Inventories	6	(503)
Operating lease liabilities	(656)	(552)
Accounts payable, accrued expenses and other liabilities	(2,661)	(298)
Net cash used in operating activities	(27,050)	(40,813)
Investing activities:		
Purchases of property and equipment	(20)	(28)
Maturities of marketable securities	—	15,000
Purchases of marketable securities	—	(32,954)
Net cash used in investing activities	(20)	(17,982)
Financing activities:		
Proceeds from issuance of common stock, net of issuance costs	7,513	—
Proceeds from exercise of pre-funded warrants	2	—
Finance lease payments	(8)	(4)
Proceeds from debt	14,775	13,906
Proceeds from issuance of convertible Series A and Series B preferred stock warrants, net of issuance costs	—	1,647
Net cash provided by financing activities	22,282	15,549
Net decrease in cash, cash equivalents and restricted cash	(4,788)	(43,246)
Cash, cash equivalents and restricted cash—beginning of period	40,280	68,234
Cash, cash equivalents and restricted cash—end of period	\$ 35,492	\$ 24,988
Supplemental disclosure of cash flow information:		
Cash paid for interest	\$ 801	\$ 268
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	\$ —	\$ 396

See accompanying notes to consolidated financial statements.

TREVENA, INC.

**Notes to Unaudited Consolidated Financial Statements
September 30, 2023**

1. Organization and Description of the Business

Trevena, Inc., or the Company, was incorporated in Delaware as Parallax Therapeutics, Inc. on November 9, 2007. The Company began operations in December 2007, and its name was changed to Trevena, Inc. on January 3, 2008. 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 commercializing its lead asset, OLINVYK® (oliceridine) injection, or OLINVYK, and to research and development, including nonclinical studies and clinical trials. The Company has never been profitable. 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 its inception, the Company has incurred losses and negative cash flows from operations. At September 30, 2023, the Company had an accumulated deficit of \$571.5 million. The Company's net loss was \$23.8 million and \$46.7 million for the nine months ended September 30, 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 September 30, 2023 is not sufficient to fund operations for more than 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 may 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. 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.

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.

The consolidated financial statements include all normal and recurring adjustments that are considered necessary for the fair presentation of the Company's consolidated balance sheets as of September 30, 2023, its results of operations and its comprehensive loss for the three and nine months ended September 30, 2023 and 2022, its consolidated statements of stockholders' equity for the period from January 1, 2023 to September 30, 2023 and for the period January 1, 2022 to September 30, 2022, and its consolidated statements of cash flows for the nine months ended September 30, 2023 and 2022. The information included in this Quarterly Report on Form 10-Q should be read in conjunction with the financial statements and accompanying notes included in the Company's most recent Annual Report on Form 10-K for the year ended December 31, 2022. Since the date of those financial statements, there have been no changes to the Company's significant accounting policies. The financial data and other information disclosed in these notes related to the nine months ended September 30, 2023 are not necessarily indicative of the results to be expected for the year ending December 31, 2023, any other interim periods, or any future year or period.

Principles of Consolidation

In connection with the royalty-based financing agreement disclosed in Note 5, 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 September 30, 2023. All significant intercompany accounts and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of consolidated 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. These estimates and assumptions are based on current facts, historical experience as well as other pertinent industry and regulatory authority information. Actual results may differ materially and adversely from these estimates. To the extent there are material differences between the estimates and actual results, the Company's future results of operations will be affected.

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, at September 30, 2023, 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.

Product Revenue

The Company accounts for product revenue in accordance with ASC Topic 606, Revenue from Contracts with Customers (ASC 606). The Company performs 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. The Company only recognizes revenue when it believes that it is probable that it will collect the consideration to which it is entitled in exchange for the goods or services that will be transferred to the customer.

The Company sells OLINVYK to wholesalers in the US (collectively, "customers"). These customers subsequently resell the Company's products generally to hospitals, ambulatory surgical centers and other purchasers of OLINVYK. The Company recognizes 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

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 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 the Company's estimates. If actual results in the future vary from the Company's estimates, the Company will adjust these estimates, which would affect product sales and earnings in the period such variances become known.

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. The Company reduces the chargeback allowance when a chargeback request from a wholesaler is processed.

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.

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.

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. Since the Company did not have a history of OLINVYK returns when the product was launched, the Company estimated returns based on industry data for comparable products in the market. 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, the Company placed more reliance on historical purchasing, demand from hospitals and ambulatory surgical centers, return patterns of its customers and the amount of OLINVYK held by wholesalers, when evaluating 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.

3. Fair Value of Financial Instruments

ASC 820, *Fair Value Measurement*, 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 fair value of the Company's cash, cash equivalents, restricted cash and warrant liability as of September 30, 2023 and December 31, 2022 (in thousands):

Description:	September 30, 2023	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Unobservable Inputs (Level 3)
Assets:				
Cash	\$ 3,138	\$ 3,138	\$ —	\$ —
Money Market Funds	31,814	31,814	—	—
Restricted Cash	540	540	—	—
Total assets measured and recorded at fair value	\$ 35,492	\$ 35,492	\$ —	\$ —
Liabilities:				
Warrant Liability	1,097	—	—	1,097
Total liabilities measured and recorded at fair value	\$ 1,097	\$ —	\$ —	\$ 1,097

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 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 nine months ended September 30, 2023.

The common stock warrants issued in connection with the Company's equity raises in July 2022 and November 2022 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.

Registered Direct Stock Offering and Concurrent Warrant Issuance

The fair value of the July 2022 Offering 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:

	September 30, 2023	December 31, 2022
Expected term of warrants (in years)	3.7	4.6
Risk-free interest rate	4.7 %	4.0 %
Expected volatility	124.8 %	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		(172)
Balance, September 30, 2023	\$	<u>87</u>

November 2022 Equity Offering and Warrant Issuance

The fair value of the November 2022 Offering 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:

	September 30, 2023	December 31, 2022
Expected term of warrants (in years)	4.1	4.9
Risk-free interest rate	4.7 %	4.0 %
Expected volatility	127.4 %	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	(2,213)
Exercise of pre-funded common stock warrants	(2,001)
Balance, September 30, 2023	\$ <u>1,010</u>

Warrants

As of September 30, 2023, the Company had the following common stock warrants outstanding:

	Classification	Warrants	Exercise Price	Expiration Date
July 2022 Offering	Liability	320,000	\$6.58	12/28/2027
November 2022 Offering	Liability	2,614,380	2.95	11/18/2027
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
		<u>3,145,394</u>		

The Company classifies investments available to fund current operations as current assets on its balance sheet. As of September 30, 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.

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. OLINVYK was approved by the FDA in August 2020. Prior to FDA approval, all manufacturing costs for OLINVYK were expensed to research and development. Upon FDA approval, manufacturing costs for OLINVYK manufactured for commercial sale have been capitalized as inventory cost. 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.

Inventory consists of the following (in thousands):

	September 30, 2023	December 31, 2022
Finished goods	\$ 900	\$ 3,111
Inventory Valuation Adjustment	—	(2,205)
Total Inventories	<u>\$ 900</u>	<u>\$ 906</u>

5. Loan Payable

In April 2022, the Company, through its wholly owned subsidiary Trevena SPV2 LLC, 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):

	September 30, 2023
Principal and accreted interest	\$ 31,107
Unamortized debt discount	(1,465)
Loans payable, net	<u>\$ 29,642</u>

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, 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 OLINVIK 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 September 30, 2023, there was \$0.6 million of prepaid interest on the Company's consolidated balance sheet that will be applied to future payments under the Loan Agreement.

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 OLINVIK, 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 September 30, 2023, there were no events of default pursuant to the Loan Agreement and the Company was 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 nine months ended September 30, 2023, the Company recognized interest expense of \$1.8 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 OLINVIK 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.

6. Stock Compensation

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

	Nine Months Ended September 30,	
	2023	2022
Research and development	\$ 444	\$ 672
Selling, general and administrative	1,753	2,257
Cost of goods sold	—	(2)
Total stock-based compensation	<u>\$ 2,197</u>	<u>\$ 2,927</u>

Stock Options

A summary of stock option activity and related information through September 30, 2023 follows:

	Options Outstanding		
	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)
Balance, December 31, 2022	351,709	\$ 49.15	6.94
Granted	130,150	1.01	
Forfeited/Cancelled	(51,060)	47.51	
Balance, September 30, 2023	<u>430,799</u>	\$ 34.80	7.12
Vested or expected to vest at September 30, 2023	<u>430,799</u>	\$ 34.80	7.12
Exercisable at September 30, 2023	263,962	\$ 48.18	5.87

The aggregate intrinsic value of options exercisable as of September 30, 2023 was zero, based on the difference between the Company's closing stock price of \$0.60 and the exercise price of each stock option. At September 30, 2023, there was \$1.7 million of total unrecognized compensation expense related to unvested options that will be recognized over the weighted average remaining vesting period of 1.43 years.

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 common 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 common stock.

The per-share weighted-average grant date fair value of the options granted to employees and directors during the nine months ended September 30, 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:

	September 30,	
	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	— %	— %

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.

The following is a summary of changes in the status of non-vested RSUs during the nine months ended September 30, 2023:

	Number of Awards	Weighted Average Grant Date Fair Value
Non-vested at December 31, 2022	366,777	\$ 10.43
Granted	500,000	1.78
Vested	(3,025)	24.55
Forfeited/Cancelled	(82,792)	5.73
Non-vested at September 30, 2023	780,960	\$ 7.90

For the nine months ended September 30, 2023, the Company recorded \$1.1 million, in stock-based compensation expense related to RSUs, which is reflected in the consolidated statements of operations and comprehensive loss.

As of September 30, 2023, there was \$2.6 million of total unrecognized compensation expense related to unvested RSUs that will be recognized over the weighted average remaining period of 2.10 years.

Shares Available for Future Grant

At September 30, 2023, the Company has the following shares available to be granted under its equity incentive plans:

	2023 Plan	Inducement Plan
Available at December 31, 2022	404,807	12,000
Authorized	1,287,958	—
Granted	(630,150)	—
Shares withheld for taxes not issued	794	—
Forfeited/Cancelled	133,852	—
Available at September 30, 2023	1,197,261	12,000

Shares Reserved for Future Issuance

At September 30, 2023, the Company has reserved the following shares of common stock for issuance:

Stock options outstanding under 2013 Plan	306,349
Stock options outstanding under 2023 Plan	116,450
Restricted stock units outstanding under 2013 Plan	780,960
Stock options outstanding under Inducement Plan	8,000
Warrants outstanding	3,145,394
Total shares of common stock reserved for future issuance	4,357,153

7. 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. ("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 to the Company by Vanguard under the sublease is (i) \$0.50 less during months 2 through 13 of the sublease and (ii) in month 14 and thereafter of the sublease, \$1.00 less than the base rent payable by the Company under its 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 consolidated statements of operations and comprehensive loss as other income (expense).

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

	September 30, 2023	December 31, 2022
Operating leases:		
Operating lease right-of-use assets	\$ 3,813	\$ 4,224
Other current lease liabilities	973	890
Operating lease liabilities	4,679	5,419
Total operating lease liabilities	<u>\$ 5,652</u>	<u>\$ 6,309</u>
Finance leases:		
Property and equipment, at cost	\$ 29	\$ 29
Accumulated depreciation	(11)	(4)
Property and equipment, net	18	25
Other current lease liabilities	9	9
Other long-term liabilities	10	17
Total finance lease liabilities	<u>\$ 19</u>	<u>\$ 26</u>

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Operating lease costs:				
Operating lease expense	\$ 351	\$ 330	\$ 1,097	\$ 993
Other income	(357)	(340)	(1,054)	(999)
Total operating lease costs	<u>\$ (6)</u>	<u>\$ (10)</u>	<u>\$ 43</u>	<u>\$ (6)</u>
Finance lease costs:				
Amortization of right-of-use assets	2	1	7	5
Total finance lease costs	<u>\$ 2</u>	<u>\$ 1</u>	<u>\$ 7</u>	<u>\$ 5</u>

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

	Nine Months Ended September 30,	
	2023	2022
Cash paid for amounts included in the measurement of lease liabilities		
Operating cash flows from operating leases	\$ (288)	\$ (230)
Financing cash flows from finance leases	(8)	(4)

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

	Operating Leases	Financing Leases
2023 (October 1 - December 31)	360	3
2024	1,450	11
2025	1,474	7
2026	1,498	—
2027	1,523	—
2028 and beyond	640	—
Total minimum lease payments	\$ 6,945	\$ 21
Less: imputed interest	(1,293)	(2)
Lease liability	\$ 5,652	\$ 19

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

	Sublease
2023 (October 1 - December 31)	287
2024	1,158
2025	1,178
2026	1,198
2027	1,166
2028	254
Total minimum lease payments	\$ 5,241

Lease term and discount rates are as follows:

	Nine Months Ended September 30,	
	2023	2022
Weighted average remaining lease term (years)		
Operating leases	5	6
Finance leases	2	3
Weighted average discount rate		
Operating leases	9.2%	9.2%
Finance leases	6.5%	6.5%

8. 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.

Sales-Related Deductions

The following table presents a roll forward of the major categories of sales-related deductions included in trade receivable allowances for the nine months ended September 30, 2023 (in thousands):

	Sales Discounts	Chargebacks	Fee for Service
Balance, January 1, 2023	\$ 1	30	36
Adjustment related to prior period sales	—	4	(28)
Balance, September 30, 2023	<u>\$ 1</u>	<u>\$ 34</u>	<u>\$ 8</u>

As of September 30, 2023, the Company has \$27,000 outstanding accounts receivable and, as a result, the portion of the trade receivable allowance in excess of accounts receivable of \$16,000 has been included with accrued expenses and other current liabilities on the Company's consolidated balance sheets.

9. License and Royalty 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

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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 three and nine months ended September 30, 2023 and 2022, license and royalty revenue in the accompanying consolidated statements of operations and comprehensive loss is comprised of the following:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	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	—	179	—
Total royalty revenues	\$ 179	\$ —	\$ 179	\$ —
Total license and royalty revenues	\$ 179	\$ —	\$ 3,179	\$ 20

License revenue recorded for the nine months ended September 30, 2023 related to the milestone payment that became payable by Nhwa upon regulatory approval of OLINVYK in China. License revenue for the nine months ended September 30, 2022 related to materials shipped to Pharmbio to support the development of oliceridine efforts in South Korea.

Royalty revenue recorded for the three and nine months ended September 30, 2023, relates to royalties earned on OLINVYK sales by Nhwa in China and payable to R-Bridge.

10. 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):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Basic and diluted net loss per common share calculation:				
Net loss	\$ (7,930)	\$ (15,295)	\$ (23,761)	\$ (46,665)
Weighted average common shares outstanding	13,964,301	6,829,013	11,728,842	6,691,061
Net loss per share of common stock - basic and diluted	\$ (0.57)	\$ (2.24)	\$ (2.03)	\$ (6.97)

The following outstanding securities at September 30, 2023 and 2022 have been excluded from the computation of diluted weighted shares outstanding, as they would have been anti-dilutive:

	September 30,	
	2023	2022
Options outstanding	430,799	380,494
RSUs outstanding	780,960	190,244
Warrants outstanding	3,145,394	211,014
Total	4,357,153	781,752

ITEM 2. MANAGEMENT’S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited consolidated financial statements and related notes that appear in Item 1 of this Quarterly Report on Form 10-Q and with our audited financial statements and related notes for the year ended December 31, 2022, which are included in our [Annual Report on Form 10-K filed with the Securities and Exchange Commission, or SEC, on March 31, 2023](#). Unless the context otherwise requires, we use the terms “Trevena,” “Company,” “we,” “us” and “our” to refer to Trevena, Inc.

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 (the “FDA”), in August 2020. In October 2020, we announced that OLINVYK had received scheduling from the U.S. Drug Enforcement Administration (the “DEA”), and was classified as a Schedule II controlled substance. 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 initiated commercial launch of OLINVYK in the first quarter of 2021. Our commercial launch strategy is to focus on a subset of core specialties and clinically challenging patients, such as those patients with certain co-morbidities, obese or renal impairment. We intend to evolve this focus as customers gain experience with OLINVYK. We are also developing a pipeline of product candidates based on our proprietary product platform, including TRV045 for diabetic neuropathic pain and epilepsy; TRV250 for acute migraines; and TRV734 for 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, establishing our intellectual property portfolio, and commercializing our lead product. We have financed our operations primarily through private placements and public offerings of our equity securities, debt borrowings and royalty-based financing. As of September 30, 2023, we had an accumulated deficit of \$571.5 million. Our net loss was \$23.8 million and \$46.7 million for the nine months ended September 30, 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 commercialize TRV045, TRV250, or TRV734.

We expect to incur significant expenses and operating losses for the foreseeable future as we continue to commercialize OLINVYK 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

Carrie Bourdow, President and Chief Executive Officer, appointed as the new Chair of the Board, and Scott Braunstein, M.D. appointed as the Lead Independent Director of the Board

As disclosed by Form 8-K on November 9, 2023, Leon O. Moulder, Jr. informed us of his planned retirement from the Board effective as of December 31, 2023. In connection with his retirement, Mr. Moulder also resigned as Chairman of the Board, effective November 9, 2023. Mr. Moulder has confirmed to us that his departure is not the result of any disagreement with us on any matter relating to our operations, policies or practices.

In conjunction with Mr. Moulder's resignation as Chairman of the Board, the Board appointed and approved Carrie Bourdow, our President and Chief Executive Officer, as the new Chair of the Board, and Scott Braunstein, M.D. as the Lead Independent Director of the Board effective as of November 9, 2023.

Receipt of \$15.0 million Tranche from ex-US royalty based financing, triggered by first commercial sale of OLINVYK by Jiangsu Nhwa, our partner in China

On September 6, 2023, we announced receipt of a \$15.0 million tranche under our non-dilutive ex-US royalty-based financing (the R-Bridge Financing). This tranche of funding was triggered by the first commercial sale of OLINVYK in China by Jiangsu Nhwa, our licensee in China. As part of the R-Bridge Financing, we may receive an additional \$10.0 million upon achievement of either a commercial or financing milestone.

Favorable TRV045 Topline Safety and Tolerability Data from Proof-of-Concept Studies

On October 16, 2023, we announced favorable topline safety and tolerability data for the two Phase 1 proof-of-concept (POC) studies of TRV045, a novel sphingosine-1 phosphate receptor modulator selective for the S1P receptor subtype 1.

The Target Engagement POC study was a randomized, double-blind, placebo-controlled, single dose four-way cross-over study (n=25 subjects). Each subject received three different single doses of TRV045 (50mg, 150mg and 300mg) and placebo on four separate visits across the study duration.

The TMS POC study was a randomized, double-blind, placebo-controlled, multiple dose, two-way cross-over study (n=25 subjects). 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.

There were no drug-related adverse events reported in either POC study, and no serious adverse events were reported in either POC study. Of the adverse events, 98% (102 of 104) were reported as mild in the Target Engagement POC study, and 99% (79 of 80) were reported as mild in the TMS POC 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 new 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 our 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.

As previously announced, TRV045 demonstrated a statistically significant, dose-dependent analgesic effect in capsaicin-induced model of neuropathic pain in the Target Engagement POC study. In the TMS POC study, TRV045 provided statistically significant evidence of CNS activity on day 4 as measured by EEG power spectral analysis. Data

from both studies demonstrated CNS penetration and target engagement, as well as plasma exposures in the anticipated active dose range, supporting the therapeutic potential of TRV045.

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 consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of our consolidated 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 consolidated financial statements for the year ended December 31, 2022 included in our 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.

Stock-Based Compensation

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 costs related to stock options granted to employees based on the estimated fair value of the awards on the date of grant.

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, restricted stock unit awards and performance 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.

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 6, included in Part 1, Item 1 of this Quarterly Report, 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, we entered into a Loan Agreement with R-Bridge, pursuant to which we 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 will become available 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 over the earlier of the (i) the life of the arrangement or (ii) the point in time in which the arrangement is eligible to be recognized as a sale of the license and satisfaction of all outstanding related debt obligations. As of December 31, 2022, the \$15.0 million in borrowings would be capped at \$30.0 million in repayments if we were unsuccessful in obtaining approval in

China. As of September 30, 2023 and as a result of receiving approval in China, the estimated repayments are no longer capped. The aggregate future estimated royalty and milestone payments, less the \$30.0 million of net proceeds we received, are recorded as interest expense over the life of the liability. 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

See Note 2, included in Part 1, Item 1 of this Quarterly Report for information on recent accounting pronouncements.

Results of Operations

Comparison of the three and nine months ended September 30, 2023 and 2022 (in thousands)

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2023	2022	Change	2023	2022	Change
Revenue:						
Product revenue	\$ 1	\$ (438)	\$ 439	\$ 28	\$ (438)	\$ 466
License and royalty revenue	179	—	179	3,179	20	3,159
Total revenue	180	(438)	618	3,207	(418)	3,625
Operating expenses:						
Cost of goods sold	175	2,368	(2,193)	389	2,791	(2,402)
Selling, general and administrative	4,572	7,683	(3,111)	15,799	29,003	(13,204)
Research and development	4,260	5,266	(1,006)	12,160	14,816	(2,656)
Total operating expenses	9,007	15,317	(6,310)	28,348	46,610	(18,262)
Loss from operations	(8,827)	(15,755)	6,928	(25,141)	(47,028)	21,887
Other income (expense):						
Change in fair value of warrant liability	682	651	31	2,385	651	1,734
Other income, net	61	65	(4)	118	174	(56)
Interest income	377	127	250	989	246	743
Interest expense	(210)	(401)	191	(1,778)	(726)	(1,052)
Gain (loss) on foreign currency transactions	(13)	18	(31)	(34)	18	(52)
Foreign income tax expense	—	—	—	(300)	—	(300)
Total other income, net	897	460	437	1,380	363	1,017
Net Loss	\$ (7,930)	\$ (15,295)	\$ 7,365	\$ (23,761)	\$ (46,665)	\$ 22,904
Unrealized loss on marketable securities	—	32	(32)	—	(28)	28
Comprehensive loss	\$ (7,930)	\$ (15,263)	\$ 7,333	\$ (23,761)	\$ (46,693)	\$ 22,932

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 three and nine months ended September 30, 2023, we recorded \$1,000 and \$28,000, respectively, in product revenue from the shipment of drug product to wholesalers. For the three and nine months ended September 30, 2022, product revenue includes a returns reserve adjustment of \$0.4 million for expected returns from our wholesalers.

License and royalty revenue for the three months ended September 30, 2023 relates to royalties earned on OLINVYK sales by Nhwa in China. License and royalty revenue for the nine months ended September 30, 2023 relates to the milestone payment that became payable by Nhwa upon regulatory approval of OLINVYK in China. License and royalty revenue recorded for the nine months ended September 30, 2022 related to materials shipped to Pharmbio to support the development of oliceridine efforts in South Korea.

In November 2022, we filed our report on Form 10-Q for the third quarter of 2022, in which 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.

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 three and nine months ended September 30, 2023 were approximately \$20,300 and \$58,700 respectively. Commercial sell through from our wholesalers to hospitals and ASCs for the three months and nine months ended September 30, 2022 were approximately \$7,600 and \$24,700 respectively. While there is a general upward trend compared to the prior period, the overall level of these sales remains low and we cannot be certain that this trend will continue.

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. 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.

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

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2023	2022	2023	2022
Product revenue, gross	\$ 10	\$ (51)	\$ 44	\$ (51)
GTN Accruals				
Chargebacks and cash discounts	(1)	—	(3)	—
Returns	(7)	—	(8)	—
Other rebates, discounts and adjustments	(1)	—	(5)	—
Total GTN Accruals	(9)	—	(16)	—
Product revenue	1	(51)	28	(51)
Adjustments to prior period accruals				
Returns reserve	—	(383)	—	(383)
Other GTN accrual adjustments	—	(3)	—	(3)
Product revenue, net	<u>\$ 1</u>	<u>\$ (438)</u>	<u>\$ 28</u>	<u>\$ (438)</u>

Cost of goods sold

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

We expensed the cost of producing validation batches of OLINVYK that we are using in the commercial launch as research and development expense prior to the regulatory approval and DEA scheduling of OLINVYK. As of September 30, 2023, we are no longer using the validation batches for shipment of drug product to wholesalers. We expect cost of sales to increase as we continue to sell from our finished goods inventory.

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

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2023	2022	% Increase (Decrease)	2023	2022	% Increase (Decrease)
Cost of goods sold	\$ 175	\$ 2,368	-93%	\$ 389	\$ 2,791	-86%

Cost of goods sold decreased by \$2.2 million and \$2.4 million for the three and nine months ended September 30, 2023, respectively, compared to the same periods in 2022, due to a \$2.2 million non-cash valuation adjustment for slow moving or obsolete inventory in 2022 and a reduction in indirect overhead costs. If future sales of OLINVYK do not materialize as anticipated, we may be required to further adjust the valuation of additional inventory.

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 for the three and nine months ended September 30, 2023 decreased by \$3.1 million or 40%, as compared to the same period in 2022, and decreased by \$13.2 million, or 46% for the nine months ended September 30, 2023 as compared to the same period in 2022. The decrease was primarily related to a reduction in full time employees, and termination of our contract sales force agreement in 2022 and a reduction in marketing expenses.

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 \$1.0 million, or 19%, for the three months ended September 30, 2023, as compared to the same period in 2022, and decreased by \$2.7 million or 18%, for the nine months ended September 30, 2023 as compared to the same period in 2022. The following table summarizes our research and development expenses (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
TRV045	\$ 2,596	\$ 2,621	\$ 6,824	\$ 4,537
OLINVYK	132	635	479	2,960
TRV250	26	—	2	579
TRV027	31	38	116	338
Personnel-related costs	758	1,279	2,631	4,600
Other research and development	717	693	2,108	1,802
	<u>\$ 4,260</u>	<u>\$ 5,266</u>	<u>\$ 12,160</u>	<u>\$ 14,816</u>

The lower research and development expenses incurred during the three and nine months ended September 30, 2023 compared to the same period in 2022 were the result of decreased spending on OLINVYK post-approval clinical studies, TRV250 and TRV027, offset by increased spend to advance TRV045.

Total other income (expense), net

Total other income (expense), net for the three months ended September 30, 2023 was higher than the same periods in the prior year primarily due to the \$0.4 million increase in interest income, net of interest expense. Total other income (expense), net for the nine months ended September 30, 2023 was higher than the same periods in the prior year primarily attributable to the gain on the change in fair value of our liability classified warrants. The change in fair value was primarily driven by the change in our stock price during the nine months ended September 30, 2023. The change in fair value of our warrants were offset by the \$0.3 million increase in interest expense, net of interest income, and is attributable to the interest associated with our royalty financing obligation with R-Bridge.

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 \$11.9 million pursuant to licensing agreements for the development and commercialization of OLINVYK in China and South Korea.

At September 30, 2023, we had an accumulated deficit of \$571.5 million, working capital of \$33.3 million, cash and cash equivalents of \$35.0 million, and restricted cash of \$0.5 million. In November 2020, we filed a \$250.0 million shelf registration statement, which includes the HCW ATM Program, of which there was approximately \$34.3 million of available capacity as of September 30, 2023, subject to the restrictions set forth in General Instruction I.B.6 of Form S-3.

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. These expenses have decreased in the three and nine months ended September 30, 2023 as compared to the same period in 2022 as a result of a reduction in full time employees and termination of our contract sales force agreement in 2022 and a decrease in spending on OLINVYK post-approval clinical studies. 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 \$27.1 million and \$40.8 million for the nine months ended September 30, 2023 and 2022, respectively. We incurred net losses of \$23.8 million and \$46.7 million for those same periods.

Our success is dependent on the successful commercialization of OLINVYK, advancement of our other product candidates, 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 September 30, 2023 is sufficient to fund operations into the third quarter of 2024, but not for more than 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 for the nine months ended September 30, 2023 (in thousands):

	September 30,	
	2023	2022
Net cash (used in) provided by:		
Operating activities	\$ (27,050)	\$ (40,813)
Investing activities	(20)	(17,982)
Financing activities	22,282	15,549
Net decrease in cash, cash equivalents and restricted cash	<u>\$ (4,788)</u>	<u>\$ (43,246)</u>

Net cash used in operating activities

Net cash used in operating activities was \$27.1 million for the nine months ended September 30, 2023 and consisted primarily of a net loss of \$23.8 million net of the \$2.4 million non-cash gain related to the change in fair value of our liability classified warrants, and changes in operating assets and liabilities of \$4.8 million, partially offset by stock-based compensation of \$2.2 million, noncash interest expense on our loan of \$1.0 million and depreciation expense of \$0.2 million. Changes in prepaid expenses and other assets, accounts payable and accrued expenses result from timing differences between the receipt and payment of cash and when the transactions are recognized in our results of operations.

Net cash used in operating activities was \$40.8 million for the nine months ended September 30, 2022 and consisted primarily of a net loss of \$46.7 million net of the \$0.7 million non-cash gain related to the change in fair value of our liability classified warrants, partially offset by stock-based compensation of \$2.9 million, a non-cash inventory reserve of \$2.1 million, a non-cash returns reserve of \$0.4 million, and depreciation expense of \$0.3 million. Changes in prepaid expenses and other assets, accounts payable and accrued expenses result from timing differences between the receipt and payment of cash and when the transactions are recognized in our results of operations.

Net cash used in investing activities

Net cash used in investing activities was \$20,000 for the nine months ended September 30, 2023 due to capital expenditures related to cybersecurity and technology updates.

Net cash used in investing activities was \$18.0 million for the nine months ended September 30, 2022 due to purchases of marketable securities.

Net cash provided by financing activities

Net cash provided by financing activities was \$22.3 million for the nine months ended September 30, 2023, which was due to \$14.8 million of net proceeds from the Loan Agreement and \$7.5 million from the HCW ATM Program.

Net cash provided by financing activities was \$15.5 million for the nine months ended September 30, 2022, which was due to proceeds from the Loan Agreement.

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 commercialize OLINVYK and continue to advance TRV045 and TRV250. Over the next twelve months, we anticipate that our total operating expenses will be comparable to the previous twelve months.

We believe that our cash and cash equivalents as of September 30, 2023, together with interest thereon, will be sufficient to fund our operating expenses and capital expenditure requirements into the third quarter of 2024, but not for more than 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 commercialize OLINVYK 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 commercialize OLINVYK and our product candidates, if approved;
- our ability to generate sales and other revenues from OLINVYK or any of our product candidates, for which we receive approval, 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 OLINVYK or our product candidates, if approved;
- the costs, timing, and outcome of any regulatory review of our product candidates, any future product candidates, and OLINVYK, in the United States and/or in territories outside the United States;
- the costs and timing of commercializing OLINVYK, and 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;
- any product liability or other lawsuits related to our product 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” section of this Quarterly Report and our Annual Report 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.

Off-Balance Sheet Arrangements

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

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not required.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer, or CEO, and our Chief Financial Officer, or CFO, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2023, the end of the period covered by this Quarterly Report.

Based on our evaluation, our CEO and CFO concluded that our “disclosure controls and procedures” (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act) as of the date of our Quarterly Report have been designed and are functioning effectively to provide reasonable assurance that the information required to be disclosed by us in reports filed under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms. We believe that a controls system, no matter how well designed and operated, cannot provide absolute assurance that the objectives of the controls system are met, and no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within a company have been detected.

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.

PART II

ITEM 1. LEGAL PROCEEDINGS

None

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 Quarterly Report, 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.

There have been no material changes to our risk factors disclosed in our [Annual Report for the year ended December 31, 2022](#), as updated by the risk factors in our Quarterly Reports for the periods ended March 31, 2023 and June 30, 2023, with the exception of the following risk factors. The risk factors disclosed in our Annual Report for the year ended December 31, 2023 and Quarterly Reports for the periods ended March 31, 2023 and June 30, 2023 are incorporated herein by reference.

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.

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 delisting 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 delisting, 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.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES, USE OF PROCEEDS, AND ISSUER PURCHASES OF EQUITY SECURITIES

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

None.

ITEM 5. OTHER INFORMATION

During the three months ended September 30, 2023, none of our directors or officers (as defined in Rule 16a-1(f) of the Securities Exchange Act of 1934, as amended) adopted, modified or terminated a Rule 10b5-1 trading arrangement or non-Rule 10b5-1 trading arrangement (as such terms are defined in Item 408 of Regulation S-K of the Securities Act of 1933).

ITEM 6. EXHIBITS

The following is a list of exhibits filed as part of this Quarterly Report on Form 10-Q.

Exhibit Number	Description
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.
101#	The following financial information from this Quarterly Report on Form 10-Q for the three and nine months ended September 30, 2023, formatted in Inline XBRL (eXtensible Business Reporting Language): (i) Consolidated Balance Sheets as of September 30, 2023 and December 31, 2022, (ii) Consolidated Statements of Operations and Comprehensive Income (Loss) for the three and nine months ended September 30, 2023 and 2022, (iii) Consolidated Statements of Stockholders' Equity for the period from January 1, 2023 to September 30, 2023, (iv) Consolidated Statements of Cash Flows for the nine months ended September 30, 2023 and 2022, and (v) Notes to Unaudited Consolidated 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.

* These certifications are being furnished solely to accompany this quarterly report pursuant to 18 U.S.C. Section 1350, and are not being filed for purposes of Section 18 of the Exchange Act and are not to be incorporated by reference into any filing of the registrant, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Filed herewith.

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: November 14, 2023

TREVENA, INC.

By: /s/ BARRY SHIN
Barry Shin
Chief Financial Officer

**Certification of Principal Executive Officer of Trevena, Inc.
Pursuant to Rules 13a-14(a) and 15d-15(a) under the Securities Exchange Act of 1934
As Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**

I, Carrie L. Bourdow, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q 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, including its consolidated subsidiaries, is 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: November 14, 2023

/s/ CARRIE L. BOURDOW
Carrie L. Bourdow
President and Chief Executive Officer
(Principal Executive Officer)

**Certification of Principal Financial Officer of Trevena, Inc.
Pursuant to Rules 13a-14(a) and 15d-15(a) under the Securities Exchange Act of 1934
As Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**

I, Barry Shin, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q 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, including its consolidated subsidiaries, 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: November 14, 2023

/s/ BARRY SHIN
Barry Shin
Chief Financial Officer

**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 Quarterly Report of Trevena, Inc. (the "Company") on Form 10-Q for the period ended September 30, 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: November 14, 2023

/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.

**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 Quarterly Report of Trevena, Inc. (the "Company") on Form 10-Q for the period ended September 30, 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.

Dated: November 14, 2023

/s/ BARRY SHIN
Barry Shin
Chief 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.
