
**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, 2022

Or

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

For the transition period from _____ to _____
Commission File Number 001-36193

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 <input type="checkbox"/>	Accelerated filer <input type="checkbox"/>
Non-accelerated filer <input checked="" type="checkbox"/>	Smaller reporting company <input checked="" type="checkbox"/>
Emerging growth company <input type="checkbox"/>	

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 7, 2022: 173,686,168
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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.” In particular, we caution you that our forward-looking statements are subject to the ongoing and developing circumstances related to the COVID-19 pandemic, which may have a material adverse effect on our business, operations and future financial results. 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, including the ongoing COVID-19 pandemic and the effects to mitigate it, could disrupt our operations and/or materially and adversely affect our business and financial conditions;
- our intellectual property position and our ability to obtain and maintain patent protection and defend our intellectual property rights against third parties; and
- our ability to satisfy all applicable Nasdaq continued listing requirements.

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You should refer to the “Risk Factors” section of this Quarterly Report and our Annual Report for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this 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, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	\$ 22,431	\$ 66,923
Marketable securities	17,961	—
Inventories	785	2,352
Prepaid expenses and other current assets	1,363	1,448
Total current assets	42,540	70,723
Restricted cash	2,557	1,311
Property and equipment, net	1,570	1,841
Right-of-use lease asset	4,352	4,706
Other assets	—	1,543
Total assets	\$ 51,019	\$ 80,124
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable, net	\$ 1,416	\$ 4,547
Accrued expenses and other current liabilities	6,794	3,847
Current portion of loans payable, net	174	—
Lease liability	873	792
Total current liabilities	9,257	9,186
Loan payable, net	13,359	—
Leases, net of current portion	5,672	6,309
Warrant liability	868	—
Total liabilities	29,156	15,495
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Preferred stock—\$0.001 par value; 5,000,000 shares authorized, none issued or outstanding at September 30, 2022 and December 31, 2021	—	—
Common stock—\$0.001 par value; 200,000,000 shares authorized at September 30, 2022 and December 31, 2021; 173,686,168 and 165,520,007 shares issued and outstanding at September 30, 2022 and December 31, 2021, respectively	173	165
Additional paid-in capital	562,485	558,566
Accumulated deficit	(540,767)	(494,102)
Accumulated other comprehensive loss	(28)	—
Total stockholders' equity	21,863	64,629
Total liabilities and stockholders' equity	\$ 51,019	\$ 80,124

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,	
	2022	2021	2022	2021
Revenue:				
Product revenue	\$ (438)	\$ 112	\$ (438)	\$ 499
License revenue	—	69	20	69
Total revenue	<u>(438)</u>	<u>181</u>	<u>(418)</u>	<u>568</u>
Operating expenses:				
Cost of goods sold	2,368	199	2,791	620
Selling, general and administrative	7,683	10,438	29,003	28,351
Research and development	5,266	3,404	14,816	9,489
Total operating expenses	<u>15,317</u>	<u>14,041</u>	<u>46,610</u>	<u>38,460</u>
Loss from operations	<u>(15,755)</u>	<u>(13,860)</u>	<u>(47,028)</u>	<u>(37,892)</u>
Other income (expense):				
Change in fair value of warrant liability	651	1	651	6
Other income, net	65	51	174	127
Interest income	127	39	246	130
Interest expense	(401)	—	(726)	—
Loss on foreign currency exchange	18	(2)	18	(6)
Total other income (expense), net	<u>460</u>	<u>89</u>	<u>363</u>	<u>257</u>
Net Loss	<u>(15,295)</u>	<u>(13,771)</u>	<u>(46,665)</u>	<u>(37,635)</u>
Unrealized gain (loss) on marketable securities	32	—	(28)	—
Comprehensive loss	<u>\$ (15,263)</u>	<u>\$ (13,771)</u>	<u>\$ (46,693)</u>	<u>\$ (37,635)</u>
Per share information:				
Net loss per share of common stock, basic and diluted	<u>\$ (0.09)</u>	<u>\$ (0.08)</u>	<u>\$ (0.28)</u>	<u>\$ (0.23)</u>
Weighted average common shares outstanding, basic and diluted	<u>170,725,392</u>	<u>164,510,570</u>	<u>167,276,563</u>	<u>162,811,136</u>

See accompanying notes to consolidated financial statements.

TREVENA, INC.

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

	Stockholders' Equity								
	Common Stock		Preferred Stock		Additional Paid-in Capital	Subscription Receivable	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
	Number of Shares	\$0.001 Par Value	Number of Shares	Value					
Balance, January 1, 2022	165,520,007	\$ 165	—	—	\$ 558,566	\$ —	\$ (494,102)	\$ —	\$ 64,629
Stock-based compensation expense	—	—	—	—	1,155	—	—	—	1,155
Net loss	—	—	—	—	—	—	(16,389)	—	(16,389)
Balance, March 31, 2022	165,520,007	\$ 165	—	—	\$ 559,721	\$ —	\$ (510,491)	\$ —	\$ 49,395
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	161,078	—	—	—	—	(23)	—	—	(23)
Unrealized loss on marketable securities	—	—	—	—	—	—	—	(60)	(60)
Net loss	—	—	—	—	—	—	(14,981)	—	(14,981)
Balance, June 30, 2022	165,681,085	\$ 165	—	—	\$ 561,332	\$ (23)	\$ (525,472)	\$ (60)	\$ 35,942
Stock-based compensation expense	—	—	—	—	764	—	—	—	764
Issuance of Preferred Stock	—	—	2,000	397	—	—	—	—	397
Conversion of Preferred Stock to Common Stock	8,000,000	8	(2,000)	(397)	389	—	—	—	—
Issuance of common stock upon vesting of RSUs, net of shares withheld for employee taxes	5,083	—	—	—	—	23	—	—	23
Unrealized loss on marketable securities	—	—	—	—	—	—	—	32	32
Net loss	—	—	—	—	—	—	(15,295)	—	(15,295)
Balance, September 30, 2022	173,686,168	\$ 173	—	—	\$ 562,485	\$ —	\$ (540,767)	\$ (28)	\$ 21,863

Stockholders' Equity									
	Common Stock		Preferred Stock		Additional Paid-in Capital	Subscription Receivable	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
	Number of Shares	\$0.001 Par Value	Number of Shares	Value					
Balance, January 1, 2021	159,999,917	\$ 160	—	—	\$ 546,422	\$ —	\$ (442,514)	—	\$ 104,068
Stock-based compensation expense	—	—	—	—	1,111	—	—	—	1,111
Exercise of stock options	5,000	—	—	—	9	—	—	—	9
Issuance of common stock upon vesting of RSUs, net of shares withheld for employee taxes	49,720	—	—	—	(69)	—	—	—	(69)
Issuance of common stock, net of issuance costs	1,219,023	1	—	—	2,791	—	—	—	2,792
Unrealized gain on marketable securities	—	—	—	—	—	—	—	—	—
Net loss	—	—	—	—	—	—	(9,842)	—	(9,842)
Balance, March 31, 2021	<u>161,273,660</u>	<u>\$ 161</u>	<u>—</u>	<u>\$ —</u>	<u>\$ 550,264</u>	<u>\$ —</u>	<u>\$ (452,356)</u>	<u>\$ —</u>	<u>\$ 98,069</u>
Stock-based compensation expense	—	—	—	—	1,182	—	—	—	1,182
Exercise of stock options	132,184	1	—	—	170	—	—	—	171
Issuance of common stock, net of issuance costs	3,058,879	3	—	—	5,153	—	—	—	5,156
Issuance of common stock upon vesting of RSUs, net of shares withheld for employee taxes	44,115	—	—	—	(48)	—	—	—	(48)
Unrealized gain on marketable securities	—	—	—	—	—	—	—	—	—
Net loss	—	—	—	—	—	—	(14,022)	—	(14,022)
Balance, June 30, 2021	<u>164,508,838</u>	<u>\$ 165</u>	<u>—</u>	<u>\$ —</u>	<u>\$ 556,721</u>	<u>\$ —</u>	<u>\$ (466,378)</u>	<u>\$ —</u>	<u>\$ 90,508</u>
Stock-based compensation expense	—	—	—	—	978	—	—	—	978
Subscription receivable	9,375	—	—	—	—	—	—	—	—
Issuance of common stock upon vesting of RSUs, net of shares withheld for employee taxes	—	—	—	—	8	(8)	—	—	—
Issuance of common stock, net of issuance costs	—	—	—	—	—	—	—	—	—
Net exercise of common stock warrant	—	—	—	—	—	—	—	—	—
Net loss	—	—	—	—	—	—	(13,771)	—	(13,771)
Balance, September 30, 2021	<u>164,518,213</u>	<u>\$ 165</u>	<u>—</u>	<u>\$ —</u>	<u>\$ 557,707</u>	<u>(8)\$</u>	<u>(480,149)</u>	<u>\$ —</u>	<u>\$ 77,715</u>

See accompanying notes to consolidated financial statements.

TREVENA, INC.

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

	Nine Months Ended September 30,	
	2022	2021
Operating activities:		
Net loss	\$ (46,665)	\$ (37,635)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	300	322
Stock-based compensation	2,927	3,271
Noncash interest expense on loan	230	—
Inventory valuation adjustment	2,070	—
Revaluation of warrant liability	(651)	(6)
Returns reserve adjustment	383	—
Accretion of bond discount on marketable securities	(36)	—
Change in right-of-use asset	354	304
Changes in operating assets and liabilities:		
Accounts receivable, prepaid expenses and other assets	1,628	(1,801)
Inventories	(503)	(1,310)
Insurance recovery	—	9,000
Settlement liability	—	(9,000)
Operating lease liabilities	(552)	(512)
Accounts payable, accrued expenses and other liabilities	(298)	(214)
Net cash used in operating activities	<u>(40,813)</u>	<u>(37,581)</u>
Investing activities:		
Purchases of property and equipment	(28)	(16)
Maturities of marketable securities	15,000	—
Long term deposits	—	(1,164)
Purchases of marketable securities	(32,954)	—
Net cash used in investing activities	<u>(17,982)</u>	<u>(1,180)</u>
Financing activities:		
Proceeds from exercise of common stock options	—	180
Proceeds from issuance of common stock, net	—	7,948
Payment of employee withholding taxes on vested restricted stock units	—	(117)
Finance lease payments	(4)	(6)
Proceeds from debt	13,906	—
Proceeds from issuance of convertible Series A and Series B preferred stock and warrants, net of issuance costs	1,647	—
Net cash provided by financing activities	<u>15,549</u>	<u>8,005</u>
Net decrease in cash, cash equivalents and restricted cash	(43,246)	(30,756)
Cash, cash equivalents and restricted cash—beginning of period	68,234	110,713
Cash, cash equivalents and restricted cash—end of period	<u>\$ 24,988</u>	<u>\$ 79,957</u>
Supplemental disclosure of cash flow information:		
Cash paid for interest	\$ 268	\$ —
Subscription receivable on exercise of options	\$ —	\$ 8
Allocation of loan payable proceeds to common stock warrants	\$ 603	\$ —
Preferred stock proceeds allocated to warrant liability	\$ (603)	\$ —
Conversion of Series A and Series B preferred stock to common stock	<u>\$ (396)</u>	<u>\$ —</u>

See accompanying notes to consolidated financial statements.

TREVENA, INC.

**Notes to Unaudited Consolidated Financial Statements
September 30, 2022**

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, 2022, the Company had an accumulated deficit of \$540.8 million. The Company's net loss was \$46.7 million and \$37.6 million for the nine months ended September 30, 2022 and 2021, 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, 2022 is sufficient to fund operations into the third quarter of 2023, but not 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, or that the COVID-19 pandemic will not have an impact on the Company's ability to raise capital or fund its operations as planned. 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, 2022, its results of operations and its comprehensive loss for the three and nine months ended September 30, 2022 and 2021, its consolidated statements of stockholders' equity for the period from January 1, 2022 to September 30, 2022 and for the period January 1, 2021 to September 30, 2021, and its consolidated statements of cash flows for the nine months ended September 30, 2022 and 2021. 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, 2021. 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, 2022 and 2021 are not necessarily indicative of the results to be expected for the year ending December 31, 2022, any other interim periods, or any future year or period.

We have been actively monitoring the novel coronavirus, or COVID-19, situation and its impact globally. Remote working arrangements and travel restrictions imposed by various jurisdictions have had a limited impact on our ability to maintain operations. The full extent to which the COVID-19 pandemic will directly or indirectly impact our business, results of operations and financial condition will depend on future developments that are highly uncertain, including vaccine adoption and effectiveness, the impact of emerging variants of the novel coronavirus, and the actions taken to contain or treat COVID-19.

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, 2022. All 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 reported amounts of assets and liabilities at the date of the consolidated financial statements and the reported amounts of expenses during the reporting period. These estimates and assumptions are based on current facts, historical experience as well as other pertinent industry and regulatory authority information, including the potential future effects of COVID-19, the results of which form the basis for making judgements about the carrying values of assets and liabilities and the recording expenses that are not readily apparent from other sources. 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, marketable securities, restricted cash, accounts payable, and accrued expenses approximate their fair values, given their short-term nature. Additionally, at September 30, 2022, the Company believes the carrying value of the loan payable approximated its fair value as the interest rate is reflective of the rate the Company could obtain on debt with similar terms and conditions.

Recently Adopted Accounting Standards

In August 2020, the FASB issued ASU 2020-06, *Debt — Debt with Conversion and Other Options (Subtopic 470-20)*, to address the complexity associated with applying GAAP to certain financial instruments with characteristics of liabilities and equity, which the Company adopted on January 1, 2022. ASU 2020-06 eliminated the beneficial conversion (and cash conversion) accounting models in ASC 470-20 that require separate accounting for embedded conversion features, and simplified the settlement assessment to determine whether it qualifies for equity classification. In addition, the new guidance requires entities to use the if-converted method to calculate earnings per share for all convertible instruments and to include the effect of share settlement for instruments that may be settled in cash or shares. The Company adopted ASU 2020-06 using the modified retrospective approach and applied the guidance to all financial instruments that were outstanding as of the beginning of 2022. As the Company had not previously separated any financial instruments under the beneficial conversion or cash conversion accounting models, there was no cumulative effect adjustment to the opening balance of retained earnings as a result of adopting ASU 2020-06.

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.

Cash, Cash Equivalents, Marketable Securities, and Restricted Cash

The following table presents fair value of the Company's cash, cash equivalents, marketable securities, and restricted cash as of September 30, 2022 and December 31, 2021 (in thousands):

	September 30, 2022						
	Adjusted Cost	Unrealized Gains	Unrealized Losses	Fair Value	Cash and Cash Equivalents	Restricted Cash	Marketable Securities
Cash	\$ 17,584	\$ —	\$ —	\$ 17,584	\$ 15,027	\$ 2,557	\$ —
Level 1 (1):							
Money market funds	3,424	—	—	3,424	3,424	—	—
U.S. treasury securities	21,970	—	(28)	21,942	3,980	—	17,961
Subtotal	25,394	—	(28)	25,366	7,404	—	17,961
Total	\$ 42,978	\$ —	\$ (28)	\$ 42,950	\$ 22,431	\$ 2,557	\$ 17,961
	December 31, 2021						
	Adjusted Cost	Unrealized Gains	Unrealized Losses	Fair Value	Cash and Cash Equivalents	Restricted Cash	Marketable Securities
Cash	\$ 9,459	\$ —	\$ —	\$ 9,459	\$ 8,148	\$ 1,311	\$ —
Level 1 (1):							
Money market funds	58,775	—	—	58,775	58,775	—	—
Subtotal	58,775	—	—	58,775	58,775	—	—
Total	\$ 68,234	\$ —	\$ —	\$ 68,234	\$ 66,923	\$ 1,311	\$ —

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

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

In April 2022, the Company placed \$2.0 million into an interest reserve account in connection with the royalty-based loan agreement (the "Loan Agreement") with R-Bridge Investment Four Pte. Ltd. ("R-Bridge"). Payments of interest under the Loan Agreement are made quarterly from certain royalties on the Company's net sales of OLINVYK in the United States and proceeds from royalties from the Company's license agreement with Jiangsu Nwha Pharmaceuticals Co. Ltd., or Nwha. On each interest payment date, if the royalty payments received do not equal the total interest due for the respective quarter, the interest payment due will be paid from the interest reserve account. This

interest reserve account is classified as restricted cash in the Company's consolidated balance sheet at September 30, 2022.

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, 2022, or the year ended December 31, 2021.

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):

	<u>September 30, 2022</u>	<u>December 31, 2021</u>
Finished goods	\$ 2,990	\$ 2,488
Inventory Valuation Adjustment	(2,205)	(136)
Total Inventories	<u>\$ 785</u>	<u>\$ 2,352</u>

The Company recorded an inventory valuation adjustment of \$2.2 million during the quarter ended September 30, 2022 and an inventory valuation adjustment of \$0.1 million during the year ended December 31, 2021. The valuation adjustments were recorded to account for slow moving or obsolete inventory due to uncertainty of commercial activities and future expected OLINVYK sales.

5. Loan Payable

In April 2022, the Company, through its wholly-owned subsidiary Trevena SPV2 LLC, entered into 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, or the R-Bridge Financing. Term loan borrowings will be advanced in three tranches. The first tranche of \$15.0 million was advanced in April 2022. The second tranche of \$10.0 million will become available upon achievement of either a commercial or financing milestone as set forth in the Loan Agreement. The third tranche of \$15.0 million will become available upon the first commercial sale of OLINVYK in China.

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

	September 30, 2022
Gross proceeds	\$ 14,826
Unamortized debt discount	(1,467)
Loans payable, net	13,359
Current portion of loans payable, net	174
Carrying Value	\$ 13,533

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. In the event Nhwa obtains Chinese approval of OLINVYK by December 31, 2023, royalties from net sales of OLINVYK in the United States will be capped at \$10.0 million. In the event Chinese approval does not occur by December 31, 2023, the royalties from net sales in the United States will increase to 7.0% and will continue until certain combined totals from license agreement with Nhwa and royalties from net sales of OLINVYK are paid. 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 ranging from 125% to 150% of the outstanding principal and interest at the time of repayment and in the event the Company has not obtained approval for OLINVYK in China. In the event the Company obtains approval for OLINVYK in China, the premium, if triggered, would be 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.

In April 2022, the Company placed \$2.0 million into an interest reserve account in connection with the Loan Agreement. Payments of interest under the Loan Agreement are made quarterly from the royalty on the Company's net sales of OLINVYK in the United States and proceeds from royalties from the Company's license agreement with Nhwa. On each interest payment date, if the royalty payments received do not equal the total interest due for the respective quarter, the interest payment due will be paid from the interest reserve account. This interest reserve account is classified as restricted cash in the Company's consolidated balance sheet at September 30, 2022.

Repayments of all borrowings, interest and other related payments, under the Loan Agreement are guaranteed by the Company and secured by substantially all of the assets associated with the license agreement with Nhwa, the Chinese intellectual property related to OLINVYK, and deposit accounts established to hold amounts received on account for repayment of the borrowings and related interest under the Loan Agreement. The Loan Agreement contains certain customary affirmative and negative covenants and contains customary defined events of default, upon which any outstanding principal and unpaid interest shall be due on demand. At September 30, 2022, 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 5,000,000 shares of the Company's common stock at an initial exercise price of \$0.82 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 three and nine months ended September 30, 2022, the Company recognized interest expense of \$0.4 million and \$0.7 million, respectively, of which \$0.2 million pertained to the amortization of the debt discount.

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

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

6. Stockholders' Equity

Equity Offerings

Under its certificate of incorporation, the Company was authorized to issue up to 200,000,000 shares of common stock as of September 30, 2022. The Company also was authorized to issue up to 5,000,000 shares of preferred stock as of September 30, 2022. The Company is required, at all times, to reserve and keep available out of its authorized but unissued shares of common stock sufficient shares to effect the conversion of the shares of the preferred stock and all outstanding stock options and warrants.

Registered Direct Stock Offering and Concurrent Warrant Issuance

In July 2022, the Company announced a targeted registered direct financing of 1,800 shares of the Company's Series A convertible preferred stock, or the Series A Preferred, and 200 shares of the Company's Series B convertible preferred stock, or Series B Preferred. The shares of preferred stock issued in this offering are convertible into an aggregate of 8,000,000 shares of common stock. The Series A Preferred has voting rights equal to the number of shares of common stock into which the Series A Preferred is convertible. The Series B Preferred has voting rights, only with respect to a proposal to effect a reverse split of the Company's common stock, equal to 25,000,000 votes per share of Series B Preferred, provided that any votes cast by the Series B Preferred with respect to the reverse split proposal must be counted by the Company in the same proportion as the shares of common stock and Series A Preferred voted on such proposal. The shares of preferred stock were convertible at the option of the holder at any time following the date of issuance, and in August 2022 these shares of preferred stock were converted into shares of common stock.

In connection with this registered direct offering, the Company also issued warrants to purchase 8,000,000 shares of common stock ("Common Stock Warrant") (together with the Series A Preferred and Series B Preferred, the "Preferred Stock Transaction"). These warrants have an exercise price of \$0.263 per share, will be exercisable beginning on the later of six months following the date of issuance and the effective date of a reverse stock split of our common stock in an amount sufficient to permit the exercise in full of the warrants and will expire five and one-half years following the date of issuance. The Common Stock Warrants are classified as a liability. The Company evaluates its warrants to determine if the contracts qualify as liabilities in accordance with ASC 480-10, Distinguishing Liabilities from Equity and ASC 815, Derivatives and Hedging. The Common Stock Warrant, valued using the Black Scholes valuation model, were initially recorded at their issuance date fair value and are remeasured on each subsequent balance sheet date with changes in fair value recorded as a component of other income (expense), net.

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

Common Stock Warrant liability	\$	1,519
Series A and Series B Preferred Stock		481
Gross Proceeds	\$	<u>2,000</u>

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

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

	July 29, 2022	September 30, 2022
Expected term of warrants (in years)	5.0	4.8
Risk-free interest rate	2.7 %	4.1 %
Expected volatility	104.3 %	105.5 %
Dividend yield	— %	— %

On August 2, 2022, the Series A Preferred and Series B Preferred were converted into 8,000,000 share of common stock.

The following is a roll forward of the Common Stock Warrant liability from the date of issuance to September 30, 2022:

Date of issuance, July 29, 2022	\$	1,519
Change in fair value		(651)
Balance, September 30, 2022	\$	<u>868</u>

R-Bridge Financing

In connection with the R-Bridge Financing, the Company issued a warrant to purchase 5,000,000 shares of common stock. This warrant has a term of 3 years, is immediately exercisable and has an exercise price of \$0.82 per share. It was issued in April 2022 upon receipt of the first \$15.0 million tranche.

ATM Programs

In April 2019, the Company entered into a Common Stock Sales Agreement with H.C. Wainwright & Co., LLC, or Wainwright, pursuant to which the Company may offer and sell through Wainwright, from time to time at the Company's sole discretion, shares of its common stock, having an aggregate offering price of up to \$50.0 million, or the HCW ATM Program. Sales of the shares of common stock are deemed to be "at-the-market offerings," as defined in Rule 415 under the Securities Act. In December 2020, the Company and Wainwright entered into Amendment No. 1 to Common Stock Sales Agreement, or the Amendment, to amend the Common Stock Sales Agreement to, among other things, update the reference to the registration statement pursuant to which the shares of common stock may be sold and to include an additional \$50.0 million of shares of common stock in the HCW ATM Program. There were no sales under the HCW ATM Program during the nine months ended September 30, 2022. As of September 30, 2022, there was approximately \$41.9 million remaining available for future issuances under the HCW ATM Program.

Registered Direct Offering and Concurrent Warrant Issuance

In connection with the Company's January 2019 securities purchase agreements, the Company issued warrants to purchase 500,000 shares of common stock to certain designees of H.C. Wainwright & Co., LLC. These warrants have a term of five years, are immediately exercisable and have an exercise price of \$1.25 per share. As of September 30, 2022, 172,500 of these warrants remain outstanding.

Equity Incentive Plans

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

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

On December 15, 2016, the Company adopted the Trevena, Inc. Inducement Plan, or the Inducement Plan, effective January 1, 2017, pursuant to which the Company reserved 500,000 shares of the Company's common stock for issuance under the Inducement Plan. The Inducement Plan provides for nonqualified stock options and restricted stock unit awards. The only persons eligible to receive grants of awards under the Inducement Plan are individuals who satisfy the standards for inducement grants under Nasdaq Marketplace Rule 5635(c)(4) and the related guidance under Nasdaq IM 5635-1, including individuals who were not previously an employee or director of the Company or are following a bona fide period of non-employment, in each case as an inducement material to such individual's agreement to enter into employment with the Company.

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

The estimated grant date fair value of the Company's 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):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Research and development	\$ 178	\$ 279	\$ 672	\$ 787
Selling, general and administrative	601	690	2,257	2,455
Cost of goods sold	(15)	9	(2)	29
Total stock-based compensation	<u>\$ 764</u>	<u>\$ 978</u>	<u>\$ 2,927</u>	<u>\$ 3,271</u>

Stock Options

A summary of stock option activity and related information through September 30, 2022 follows:

	Options Outstanding		
	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)
Balance, December 31, 2021	12,449,870	\$ 2.67	7.11
Granted	999,950	0.46	
Exercised	—	—	
Forfeited/Cancelled	(4,080,550)	3.72	
Balance, September 30, 2022	<u>9,369,270</u>	\$ 1.97	7.05
Vested or expected to vest at September 30, 2022	<u>9,369,270</u>	\$ 1.97	7.05
Exercisable at September 30, 2022	<u>5,875,106</u>	\$ 2.32	6.03

The aggregate intrinsic value of options exercisable as of September 30, 2022 was zero, based on the difference between the Company's closing stock price of \$0.1532 and the exercise price of each stock option. At September

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30, 2022, there was \$3.6 million of total unrecognized compensation expense related to unvested options that will be recognized over the weighted average remaining vesting period of 2.30 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, 2022 and 2021 was estimated at \$0.36 and \$1.45 per share, respectively, on the date of grant using the Black-Scholes option pricing model with the following weighted-average assumptions:

	September 30,	
	2022	2021
Expected term of options (in years)	5.7	6.1
Risk-free interest rate	2.7 %	0.9 %
Expected volatility	98.0 %	97.8 %
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, 2022:

	Number of Awards	Weighted Average Grant Date Fair Value
Non-vested at December 31, 2021	5,918,496	\$ 1.08
Granted	—	
Vested	(167,953)	0.82
Forfeited	(994,399)	1.22
Non-vested at September 30, 2022	4,756,144	\$ 1.06

For the three and nine months ended September 30, 2022, the Company recorded \$0.3 million and \$1.2 million, respectively, in stock-based compensation expense related to RSUs, which is reflected in the consolidated statements of operations and comprehensive loss.

As of September 30, 2022, there was \$3.86 million of total unrecognized compensation expense related to unvested RSUs that will be recognized over the weighted average remaining period of 2.68 years.

Shares Available for Future Grant

At September 30, 2022, the Company has the following shares available to be granted under its equity incentive plans:

	2013 Plan	Inducement Plan
Available at December 31, 2021	4,178,805	252,500
Authorized	6,620,800	—
Granted	(999,950)	—
Forfeited/Cancelled	4,883,886	47,500
Available at September 30, 2022	<u>14,683,541</u>	<u>300,000</u>

Shares Reserved for Future Issuance

At September 30, 2022, the Company has reserved the following shares of common stock for issuance:

Stock options outstanding under 2013 Plan	9,169,270
Restricted stock units outstanding under 2013 Plan	4,756,144
Stock options outstanding under Inducement Plan	200,000
Shares reserved for future issuance under Inducement Plan	300,000
Shares reserved for future issuance under 2013 Employee Stock Purchase Plan	225,806
Warrants outstanding	5,275,430
Total shares of common stock reserved for future issuance	<u>19,926,650</u>

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., or Vanguard, whereby Vanguard agreed to sublease the 40,565 square feet of space on the second floor for an initial term of 37 months. On October 2, 2020, Vanguard notified the Company that they exercised the first option to extend the sublease term for three years through November 30, 2024. Vanguard has a second option to extend the sublease term for an additional three years through November 30, 2027. 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).

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

	September 30, 2022	December 31, 2021
Operating leases:		
Operating lease right-of-use assets	\$ 4,352	\$ 4,706
Other current lease liabilities	864	788
Operating lease liabilities	5,653	6,309
Total operating lease liabilities	<u>\$ 6,517</u>	<u>\$ 7,097</u>
Finance leases:		
Property and equipment, at cost	\$ 29	\$ 45
Accumulated depreciation	(1)	(41)
Property and equipment, net	28	4
Other current lease liabilities	9	4
Other long-term liabilities	19	—
Total finance lease liabilities	<u>\$ 28</u>	<u>\$ 4</u>

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

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2022	2021	2022	2021
Operating lease costs:				
Operating lease rental expense	\$ 330	\$ 309	\$ 993	\$ 1,362
Other income	(340)	(305)	(999)	(881)
Total operating lease costs	<u>\$ (10)</u>	<u>\$ 4</u>	<u>\$ (6)</u>	<u>\$ 481</u>
Finance lease costs:				
Amortization of right-of-use assets	1	2	5	6
Interest on lease liabilities	—	—	—	—
Total finance lease costs	<u>\$ 1</u>	<u>\$ 2</u>	<u>\$ 5</u>	<u>\$ 6</u>

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

	Nine Months Ended	
	September 30,	
	2022	2021
Cash paid for amounts included in the measurement of lease liabilities		
Operating cash flows from operating leases	\$ (230)	\$ (647)
Financing cash flows from finance leases	(4)	(6)

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

	Operating Leases	Financing Leases
2022 (October 1 - December 31)	\$ 355	\$ 2
2023	1,425	11
2024	1,450	11
2025	1,474	7
2026	1,498	—
2027 and beyond	2,163	—
Total minimum lease payments	\$ 8,365	\$ 31
Interest Expense	(1,848)	(3)
Lease liability	\$ 6,517	\$ 28

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

	Sublease
2022 (October 1 - December 31)	\$ 282
2023	1,139
2024	996
Total minimum lease payments	\$ 2,417

Lease term and discount rates are as follows:

	Nine Months Ended September 30,	
	2022	2021
Weighted average remaining lease term (years)		
Operating leases	6	7
Finance leases	3	1
Weighted average discount rate		
Operating leases	9.2%	9.2%
Finance leases	6.5%	6.5%

Legal Proceedings

In October and November 2018, the Company and certain current and former officers and directors were sued in three purported class actions filed in the U.S. District Court for the Eastern District of Pennsylvania, or the EDPA, alleging violations of the federal securities laws. In January 2019, the three lawsuits were consolidated into one action. On February 11, 2021, the parties agreed in principle to a settlement of \$8.5 million, all of which was to be paid by the Company's insurance carriers, subject to approval by the Court. The Court approved the settlement on August 2, 2021. The Company and the individual defendants did not acknowledge any wrongdoing as part of the settlement. The Company recorded the \$8.5 million estimated settlement liability and the \$8.5 million estimated insurance recovery in its 2020 financial statements. As expected, the \$8.5 million was paid by the Company's insurance carriers, and the litigation is now resolved. The Company continues to believe that the claims were without merit.

In December 2018, a shareholder derivative action was filed on behalf of the Company and against certain current and former officers and directors in the EDPA, and in February 2019, two additional, similar shareholder derivative actions were filed in the U.S. District Court for the District of Delaware. A fourth similar shareholder derivative action was filed in the EDPA in September 2019, and a fifth, similar derivative action was filed in the EDPA in November 2019. A similar sixth derivative action was filed in the EDPA in September 2020. These cases involved facts similar to the consolidated securities lawsuits. The parties agreed to a settlement, which was approved by the Court on August 2, 2021. The individual defendants did not acknowledge any wrongdoing as part of the settlement. The Company agreed to make certain corporate governance changes, and a monetary payment of \$500,000 was made to plaintiffs' counsel, all of which was funded by the Company's insurance carriers. The Company recorded in the fourth

quarter of 2020 an estimated liability of \$0.5 million and a corresponding insurance recovery of the same amount. The litigation is now resolved.

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, 2022 (in thousands):

	Sales Discounts	Chargebacks	Fee for Service
Balance, January 1, 2022	\$ 1	\$ 41	\$ 45
Provision related to current period sales	—	—	—
Adjustment related to prior period sales	—	—	—
Credit or payments made during the period	—	—	—
Balance, September 30, 2022	<u>\$ 1</u>	<u>\$ 41</u>	<u>\$ 45</u>

As of September 30, 2022, the Company has \$18,000 of outstanding accounts receivable and, as a result, the portion of the trade receivable allowance in excess of accounts receivable of \$68,000 has been included with accrued expenses and other current liabilities on the Company's consolidated balance sheets

The company also recorded a \$0.4 million returns reserve adjustment for OLINVYK during the quarter ended September 30, 2022. The adjustment was recorded to account for expected returns from our wholesalers.

9. License Revenue

License and Commercialization Agreement with Pharmbio Korea Inc.

In April 2018, the Company entered into an exclusive license agreement with Pharmbio Korea Inc., or Pharmbio, for the development and commercialization of OLINVYK for the management of moderate to severe acute pain in South Korea. Under the terms of the agreement, the Company received an upfront, non-refundable cash payment of \$3.0 million (less applicable withholding taxes of \$0.5 million) in June 2018, and will receive a cash commercial milestone of up to \$0.5 million if OLINVYK is approved in South Korea and tiered royalties on product sales in South

Korea ranging from high single digits to 20%, less applicable withholding taxes. As part of the agreement, the Company also granted Pharmbio an option to manufacture OLINVYK, on a non-exclusive basis, for the development and commercialization of the product in South Korea, subject to a separate arrangement to be entered into if Pharmbio exercises the option. The license agreement is terminable by Pharmbio for any reason upon 180 days written notice.

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

License Agreement with Jiangsu Nhwa Pharmaceutical Co. Ltd.

In April 2018, the Company also entered into an exclusive license agreement with Jiangsu Nhwa Pharmaceutical Co. Ltd., or Nhwa, for the development and commercialization of OLINVYK for the management of moderate to severe acute pain in China. Under the terms of this agreement, the Company received an upfront, non-refundable cash payment of \$2.5 million (less applicable withholding taxes of \$0.3 million) in July 2018. In August 2020, the Company received a milestone payment of \$3.0 million (less applicable withholding taxes of \$0.3 million), that became payable by Nhwa upon FDA approval of OLINVYK. The Company is also eligible to receive a cash milestone payment of \$3.0 million, subject to Chinese withholding taxes, upon regulatory approval of OLINVYK in China, 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. 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 agreed to form a Joint Manufacturing and Commercialization Committee at least six months prior to the anticipated date of regulatory approval of OLINVYK in China to provide overall coordination and oversight of the manufacture and commercialization of OLINVYK in China.

For the three and nine months ended September 30, 2022 and 2021, license revenue in the accompanying consolidated statements of operations and comprehensive loss is comprised of the following:

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2022	2021	2022	2021
Pharmbio Korea Inc.	\$ —	\$ —	\$ 20	\$ —
Jiangsu Nhwa Pharmaceutical Co. Ltd.	—	—	—	—
Total license revenues	\$ —	\$ —	\$ 20	\$ —

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):

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2022</u>	<u>2021</u>	<u>2022</u>	<u>2021</u>
Basic and diluted net loss per common share calculation:				
Net loss	\$ (15,295)	\$ (13,771)	\$ (46,665)	\$ (37,635)
Weighted average common shares outstanding	<u>170,725,392</u>	<u>164,510,570</u>	<u>167,276,563</u>	<u>162,811,136</u>
Net loss per share of common stock - basic and diluted	<u>\$ (0.09)</u>	<u>\$ (0.08)</u>	<u>\$ (0.28)</u>	<u>\$ (0.23)</u>

The following outstanding securities at September 30, 2022 and 2021 have been excluded from the computation of diluted weighted shares outstanding, as they would have been anti-dilutive:

	<u>September 30,</u>	
	<u>2022</u>	<u>2021</u>
Options outstanding	9,369,270	11,553,876
RSUs outstanding	4,756,144	3,031,017
Warrants outstanding	5,275,430	295,591
Total	<u>19,400,844</u>	<u>14,880,484</u>

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, 2021, which are included in our [Annual Report on Form 10-K filed with the Securities and Exchange Commission, or SEC, on March 31, 2022](#). 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, or the FDA, in August 2020. In October 2020, we announced that OLINVYK had received scheduling from the U.S. Drug Enforcement Administration, or DEA, and was classified as a Schedule II controlled substance. 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 patient, such as those patients with certain co-morbidities, elderly, obese or renal impairment. We intend to evolve and expand 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, 2022, we had an accumulated deficit of \$540.8 million. Our net loss was \$46.7 million and \$37.6 million for the nine months ended September 30, 2022 and 2021, 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

TRV045 Phase I Data

On November 9, 2022 we announced positive topline results from the Phase I study of TRV045, our novel S1P receptor modulator for diabetic neuropathic pain and epilepsy. The study included single-ascending dose, food effect and multiple dose phases. TRV045 was well tolerated, with no serious adverse events reported. The PK profile of TRV045 showed a half-life consistent with anticipated once-daily dosing. Based on the PK exposure, the calculated free plasma concentrations of TRV045 exceeded the targeted efficacy range based on nonclinical measures of in vitro and in vivo pharmacodynamics. A targeted set of laboratory measures were studied to characterize the tolerability of TRV045, including total lymphocyte counts, ECGs, and ophthalmologic examinations, as these adverse events have been associated with existing S1P-targeted compounds. No lymphopenia, cardiac, pulmonary or ophthalmologic adverse events were reported in the Phase I study for TRV045.

Approval of Reverse Stock Split

In September at a Special Meeting, shareholders voted to approve an amendment to the Company's Amended and Restated Articles of Incorporation, as amended, to effect a reverse stock split of our outstanding shares of common stock by a ratio of any whole number between 1-for-2 and 1-for-25, at any time prior to December 19, 2022, with the exact ratio to be set within that range at the discretion of the Board of Directors.

COVID-19

The impact of the COVID-19 pandemic on the global economy and on our business continues to be a fluid situation. We responded quickly across our organization to guard the health and safety of our team and participants in our clinical trials, support our partners and vendors and mitigate risk. Thus far, our employees have rapidly adapted to working remotely and we are monitoring the COVID-19 pandemic on a daily basis to ensure we have all necessary plans in place for mitigating disruptions in our operations. Our commercial launch was impacted by the pandemic via a lack of traditional access to our customers and delayed formulary review processes. Many of our customers experienced capacity constraints as a result of COVID-19 and this frequently limited their ability to fully assess the clinical profile of OLINVYK. Like other companies, our clinical trials have experienced some degree of disruption due to access limitations to institutions currently impacted, and we may need to make further adjustments to clinical trials in the future to comply with evolving FDA guidance or otherwise. The extent to which the COVID-19 pandemic will impact our efforts to commercialize OLINVYK and to achieve market acceptance is uncertain and will depend upon future developments.

We continue to proactively assess, monitor and respond to domestic and international developments related to the COVID-19 pandemic, and we will implement risk-mitigation plans as needed to minimize the impact on our clinical trials and business operations, including our commercialization efforts of OLINVYK.

Senior Secured Tranched Term Loan Credit Facility

In September 2014, we entered into a loan and security agreement with Oxford Finance LLC and Pacific Western Bank (formerly Square 1 Bank), pursuant to which the lenders agreed to lend us up to \$35.0 million in a three-tranche series of term loans, or the Term Loans. On March 2, 2020, we made our final payment under the loan and security agreement with the lenders.

In connection with entering into the agreement, we issued to the lenders and the placement agent certain warrants to purchase an aggregate of 7,678 shares of our common stock. As of September 30, 2022, warrants exercisable for 5,728 shares of common stock remain outstanding. These warrants were exercisable upon issuance and have an exercise price of \$5.8610 per share. The warrants may be exercised on a cashless basis and will terminate on the earlier of September 19, 2024 or the closing of a merger or consolidation transaction in which we are not the surviving entity. In connection with our draw of the second term loan tranche, we issued to the lenders and the placement agent additional warrants to purchase an aggregate of 34,961 shares of our common stock. These warrants have substantially the same terms as those noted above and have an exercise price of \$10.6190 per share and an expiration date of December 23, 2025. In connection with our draw of the third term loan tranche, we issued to the lenders and placement agent

additional warrants to purchase an aggregate of 62,241 shares of our common stock. These warrants have substantially the same terms as those noted above and have an exercise price of \$3.6150 per share and an expiration date of March 31, 2027. These detachable warrant instruments qualified for equity classification and were allocated based upon the relative fair value of the base instrument and the warrants, according to the guidance of ASC 470-20-25-2.

Critical Accounting Policies and Significant Judgments and Estimates

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.

A summary of our significant accounting policies appears in the notes to our audited consolidated financial statements for the year ended December 31, 2021 included in our Annual Report. 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, and restricted stock unit awards, may be granted to employees, non-employee directors, and non-employee consultants. We also have an inducement plan under which various types of equity-based awards, including non-qualified stock options and restricted stock unit awards, may be granted to new employees.

We recognize compensation expense for all stock-based awards based on the estimated grant-date fair values. For restricted stock unit awards to employees, the fair value is based on the closing price of our common stock on the date of grant. The value of the portion of the award that is ultimately expected to vest is recognized as expense on a straight-line basis over the requisite service period. The fair value of stock options is determined using the Black-Scholes option pricing model. 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. In connection with the early adoption of ASU 2016-09 in the quarter ended December 31, 2016, 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.

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, 2022 and 2021 (in thousands)

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2022	2021	Change	2022	2021	Change
Revenue:						
Product revenue	\$ (438)	\$ 112	\$ (550)	\$ (438)	\$ 499	\$ (937)
License revenue	—	69	(69)	20	69	(49)
Total revenue	(438)	181	(619)	(418)	568	(986)
Operating expenses:						
Cost of goods sold	2,368	199	2,169	2,791	620	2,171
Selling, general and administrative	7,683	10,438	(2,755)	29,003	28,351	652
Research and development	5,266	3,404	1,862	14,816	9,489	5,327
Total operating expenses	15,317	14,041	1,276	46,610	38,460	8,150
Loss from operations	(15,755)	(13,860)	(1,895)	(47,028)	(37,892)	(9,136)
Other income (expense):						
Change in fair value of warrant liability	651	1	650	651	6	645
Other income, net	65	51	14	174	127	47
Interest income	127	39	88	246	130	116
Interest expense	(401)	—	(401)	(726)	—	(726)
Loss on foreign currency exchange	18	(2)	20	18	(6)	24
Total other income (expense), net	460	89	371	363	257	106
Net Loss	<u>\$ (15,295)</u>	<u>\$ (13,771)</u>	<u>\$ (1,524)</u>	<u>\$ (46,665)</u>	<u>\$ (37,635)</u>	<u>\$ (9,030)</u>

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. In the third quarter of 2022, we recorded a returns reserve adjustment of \$0.4 million for expected returns from our wholesalers.

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. We expect cost of sales to increase as we deplete these inventories.

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,		
	2022	2021	% Increase (Decrease)	2022	2021	% Increase (Decrease)
Cost of goods sold	\$ 2,368	\$ 199	1090%	\$ 2,791	\$ 620	350%

Cost of goods sold increased by \$2.2 million for the three and nine months ended September 30, 2022, respectively, compared to the same periods in 2021, due to a \$2.2 million non-cash valuation adjustment for slow-moving or obsolete inventory due to the uncertainty of commercial activities and future expected OLINVYK sales. 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 months ended September 30, 2022 decreased by \$2.8 million, or 26%, as compared to the same period in 2021 primarily related to a reduction in full time employees and termination of our contract sales force agreement. Selling, general and administrative expenses for the nine months ended September 30, 2022 increased by \$0.7 million, or 2% as compared to the same period in 2021 primarily related to increases in outsourced IT activities and legal costs.

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 increased by \$1.9 million, or 55%, for the three months ended September 31, 2022, as compared to the same period in 2021, and increased by \$5.3 million, or 56%, for the nine months ended September 30, 2022 as compared to the same period in 2021. The following table summarizes our research and development expenses (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Personnel-related costs	\$ 1,279	\$ 1,481	\$ 4,600	\$ 4,125
OLINVYK	635	420	2,960	1,026
TRV027	38	383	338	606
TRV045	2,621	431	4,537	2,384
TRV250	—	476	579	673
Other research and development	693	213	1,802	675
	<u>\$ 5,266</u>	<u>\$ 3,404</u>	<u>\$ 14,816</u>	<u>\$ 9,489</u>

The higher research and development expenses incurred during the three months ended September 30, 2022 compared to the same period in 2021 were the result of increased spend to advance TRV045. The higher research and development expenses incurred during the nine months ended September 30, 2022 compared to the same period in 2021 were the result of increased spend on OLINVYK post-approval clinical studies in respiratory physiology and cognitive function.

Total other income (expense), net

Total other income (expense), net for the three and nine months ended September 30, 2022 was higher than the same periods in prior year primarily because of change in fair value of warrant liability.

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 \$8.8 million pursuant to licensing agreements for the development and commercialization of OLINVYK in China and South Korea.

At September 30, 2022, we had an accumulated deficit of \$540.8 million, working capital of \$33.3 million, cash and cash equivalents of \$22.4 million, restricted cash of \$2.6 million, and marketable securities of \$18.0 million. In November 2020, we filed a \$250.0 million shelf registration statement, which includes the HCW ATM Program, of which there was approximately \$41.9 million of available capacity as of September 30, 2022.

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 increased in the three and nine months ended September 30, 2022 as compared to the same periods in 2021 as a result of the commercial launch of OLINVYK. 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 \$40.8 million and \$37.6 million for the nine months ended September 30, 2022 and 2021, respectively. We incurred net losses of \$46.7 million and \$37.6 million for those same periods.

Cash Flows

The following table summarizes our cash flows for the nine months ended September 30, 2022 and 2021 (in thousands):

	<u>September 30,</u>	
	<u>2022</u>	<u>2021</u>
Net cash (used in) provided by:		
Operating activities	\$ (40,813)	\$ (37,581)
Investing activities	(17,982)	(1,180)
Financing activities	15,549	8,005
Net decrease in cash, cash equivalents and restricted cash	<u>\$ (43,246)</u>	<u>\$ (30,756)</u>

Net cash used in operating activities

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 and changes in operating assets and liabilities of \$0.3 million, partially offset by stock-based compensation of \$2.9 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 operating activities was \$37.6 million for the nine months ended September 30, 2021 and consisted primarily of a net loss of \$37.6 million and changes in operating assets and liabilities of \$3.8 million, partially offset by stock-based compensation of \$3.3 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 \$18.0 million for the nine months ended September 30, 2022 due to maturities and purchases of marketable securities. Net cash used in investing activities was \$1.1 million for the nine months ended September 30, 2021 due to long term deposits on commercial contracts.

Net cash provided by financing activities

Net cash provided by financing activities was \$15.6 million for the nine months ended September 30, 2022, which was due to proceeds from the Loan Agreement. Net cash provided by financing activities was \$8.0 million for the nine months ended September 30, 2021, which was primarily due to net proceeds of \$7.9 million from the HCW ATM Program.

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 decrease compared to the previous twelve months.

We believe that our cash and cash equivalents as of September 30, 2022, together with interest thereon, will be sufficient to fund our operating expenses and capital expenditure requirements into the third quarter of 2023, 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 other product candidates;
- our ability to generate sales and other revenues from OLINVYK or any of our other product candidates, once approved, including setting an acceptable price for and obtaining adequate coverage and hospital formulary acceptance of such products;
- the size and growth potential of the markets for OLINVYK and our ability to serve those markets;
- the scope, progress, results and costs of researching and developing our product candidates or any future product candidates, both in the United States and in territories outside the United States;
- the number and development requirements of any other product candidates that we may pursue;
- our ability to enter into collaborative agreements for the development and/or commercialization of our product candidates, including for OLINVYK;
- the costs, timing, and outcome of any regulatory review of OLINVYK and any future product candidates, both in the United States and in territories outside the United States;
- the costs, timing, and extent of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval;
- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;

- any product liability or other lawsuits, including the recently filed class action complaints, related to our products or us;
- the expenses needed to attract and retain skilled personnel; and
- the costs involved in preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending our intellectual property-related claims, both in the United States and in territories outside the United States.

Please see “Risk Factors” 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, 2022, 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, 2021](#), with the exception of the following risk factors. The risk factors disclosed in our Annual Report are incorporated herein by reference.

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

Through an indirect subsidiary, we entered into a royalty-based loan agreement, or the Loan Agreement, with R-Bridge Healthcare Investment Advisory, Ltd., or R-Bridge, pursuant to which we may incur up to \$40.0 million of indebtedness. Our ability to make scheduled payments of the principal of, to pay interest on or to refinance our indebtedness under the Loan Agreement depends on our future performance, which is subject to regulatory, economic, financial, competitive and other factors beyond our control. We are a biopharmaceutical company that has not yet generated profit from product sales. We expect to continue to incur losses as we add infrastructure and personnel to support our commercialization and product development efforts and operations. Accordingly, our business may not generate cash flow from operations in the future sufficient to service our indebtedness under the Loan Agreement and make necessary capital expenditures. If we are unable to generate such cash flow, we may be required to adopt one or more alternatives, such as selling assets, restructuring debt or obtaining additional equity capital on terms that may be onerous or highly dilutive. Our ability to refinance our indebtedness will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms. Any of this could result in a failure of our ability to satisfy our debt obligations under the Loan Agreement. In turn, such failure could result in an event of default and, as a result, R-Bridge could accelerate all of the amounts due under the Loan Agreement. In the event of any such acceleration of amounts due as a result of an event of default, we may not have sufficient funds or may be unable to arrange for additional financing to repay our indebtedness. In addition, R-Bridge could seek to enforce its respective security interests in certain assets.

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

The Loan Agreement contains certain customary affirmative covenants, including those relating to: use of proceeds; maintenance of books and records; financial reporting and notification; compliance with laws; and protection of our intellectual property. The Loan Agreement also contains certain customary negative covenants, barring our subsidiary that is party to the Loan Agreement from: certain fundamental transactions; issuing dividends and distributions (other than certain exceptions, including distributing the loan proceeds to us); incurring additional indebtedness outside of the ordinary course of business; engaging in any business activity other than related to our license agreement relating to OLINVYK with our partner in China, Jiangsu Nwha Pharmaceutical Co. Ltd.; and permitting any additional liens on the collateral provided to R-Bridge under the Loan Agreement. Our failure to observe or breach of these covenants could result in an event of default and, as a result, R-Bridge could accelerate all of the amounts then due under the Loan Agreement or otherwise give R-Bridge certain rights over us which would have an adverse effect on our business.

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

We maintain significant inventories of OLINVYK and evaluate these inventories on a periodic basis for potential slow-moving or obsolete amounts on hand. During the third quarter of 2022, we recognized an inventory valuation adjustment of \$2.2 million for OLINVYK inventories of hand, due to uncertainty of commercial activities and future expected OLINVYK sales. During the third quarter of 2022, we also recorded a \$0.4 million returns reserve adjustment for OLINVYK to account for expected returns from our wholesalers. The inventory valuation adjustment and returns reserve adjustment were based upon our analysis of current OLINVYK inventory on hand and at our wholesalers, and the remaining shelf-life, in relation to our projected demand for the product.

Our adjustments for slow-moving or obsolete inventory is subjective and requires forecasting of the future market demand for our products. Forecasting demand for OLINVYK following its launch in 2021, with no sales history, coupled with the unpredictable commercial environment as a result of the COVID pandemic, particularly with respect to hospitals, has been difficult. We will continue to evaluate our inventories and amounts held at wholesalers on a periodic basis. The value of our inventories could be impacted if actual sales differ significantly from our estimates of future demand and if any significant, unanticipated changes in future product demand or market conditions occur. Any of these events, or a combination thereof, could result in additional inventory write-downs in future periods, or further adjustments to returns or other reserves, which could be material.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

None.

ITEM 5. OTHER INFORMATION

None.

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, 2022, formatted in Inline XBRL (eXtensible Business Reporting Language): (i) Consolidated Balance Sheets as of September 30, 2022 and December 31, 2021, (ii) Consolidated Statements of Operations and Comprehensive Income (Loss) for the three and nine months ended September 30, 2022 and 2021, (iii) Consolidated Statements of Stockholders' Equity for the period from January 1, 2022 to September 30, 2022, (iv) Consolidated Statements of Cash Flows for the nine months ended September 30, 2022 and 2021 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.

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 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 9, 2022

/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 9, 2022

/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, 2022, 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 9, 2022

/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, 2022, 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 9, 2022

/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.
