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, 2021

Or

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

For the transition period from to

Commission File Number 001-36193

Trevena, Inc.
(Exact Name of Registrant as Specified in Its Charter)

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

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

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

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.:

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

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

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

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

Common Stock, $0.001 par value — Shares outstanding as of November 12, 2021: 164,518,213

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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 preclinical studies for our product candidates;
- our ability to have the FDA clinical hold lifted on the TRV045 Phase 1 study;
- 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 logistic 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, 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;

- ongoing litigation; and
- our ability to satisfy all applicable Nasdaq continued listing requirements.

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. FINANCIAL STATEMENTS

TREVENA, INC.

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

	September 30, 2021 (unaudited)	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 78,646	$ 109,403
Accounts receivable, net	103	71
Inventories	1,310	—
Insurance recovery	—	9,000
Prepaid expenses and other current assets	2,345	570
Total current assets	82,404	119,044
Restricted cash	1,311	1,310
Property and equipment, net	1,947	2,253
Right-of-use lease asset	4,815	5,119
Other assets	1,171	13
Total assets	$ 91,648	$ 127,739
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable, net	$ 2,969	$ 1,693
Accrued expenses and other current liabilities	3,678	5,168
Estimated settlement liability	—	9,000
Lease liability	770	703
Total current liabilities	7,417	16,564
Leases, net of current portion	6,516	7,101
Warrant liability	—	6
Total liabilities	13,933	23,671
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Common stock—$0.001 par value; 200,000,000 shares authorized at September 30, 2021 and December 31, 2020; 164,518,213 and 159,999,917 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively	165	160
Preferred stock—$0.001 par value; 5,000,000 shares authorized, none issued or outstanding at September 30, 2021 and December 31, 2020	—	—
Additional paid-in capital	557,707	546,422
Subscription receivable	(8)	—
Accumulated deficit	(480,149)	(442,514)
Total stockholders' equity	77,715	104,068
Total liabilities and stockholders' equity	$ 91,648	$ 127,739

See accompanying notes to financial statements.

TREVENA, INC.

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,	
	2021	**2020**	**2021**	**2020**
Revenue:				
Product revenue	$ 112	$ —	$ 499	$ —
License revenue	69	3,000	69	3,000
Total revenue	181	3,000	568	3,000
Operating expenses:				
Cost of goods sold	199	—	620	—
Selling, general and administrative	10,438	4,089	28,351	11,021
Research and development	3,404	4,301	9,489	9,450
Total operating expenses	14,041	8,390	38,460	20,471
Loss from operations	(13,860)	(5,390)	(37,892)	(17,471)
Other income (expense):				
Change in fair value of warrant liability	1	(14)	6	(17)
Other income, net	51	75	127	170
Interest income	39	78	130	146
Interest expense	—	—	—	(29)
(Loss) gain on foreign currency exchange	(2)	—	(6)	3
Total other income	89	139	257	273
Loss before income tax expense	(13,771)	(5,251)	(37,635)	(17,198)
Foreign income tax expense	—	(300)	—	(300)
Net loss and comprehensive loss	$ (13,771)	$ (5,551)	$ (37,635)	$ (17,498)
Per share information:				
Net loss per share of common stock, basic and diluted	$ (0.08)	$ (0.04)	$ (0.23)	$ (0.15)
Weighted average common shares outstanding, basic and diluted	164,510,570	144,335,143	162,811,136	117,420,221

See accompanying notes to financial statements.

TREVENA, INC.

Statement of Stockholders' Equity (Unaudited)
(*in thousands, except share data*)

	Stockholders' Equity					
	Common Stock					
	Number of Shares	$0.001 Par Value	Additional Paid-in Capital	Subscription Receivable	Accumulated Deficit	Total Stockholders' Equity
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
Net loss	—	—	—	—	(9,842)	(9,842)
Balance, March 31, 2021	161,273,660	$ 161	$ 550,264	$ —	$ (452,356)	$ 98,069
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)
Net loss	—	—	—	—	(14,022)	(14,022)
Balance, June 30, 2021	164,508,838	$ 165	$ 556,721	$ —	$ (466,378)	$ 90,508
Stock-based compensation expense	—	—	978	—	—	978
Subscription receivable	9,375	—	8	(8)	—	—
Net loss	—	—	—	—	(13,771)	(13,771)
Balance, September 30, 2021	164,518,213	$ 165	$ 557,707	$ (8)	$ (480,149)	$ 77,715
Balance, January 1, 2020	94,213,760	$ 94	$ 443,129	$ —	$ (413,145)	$ 30,078
Stock-based compensation expense	—	—	891	—	—	891
Issuance of common stock, net of issuance costs	4,816,244	5	3,546	—	—	3,551
Net loss	—	—	—	—	(5,725)	(5,725)
Balance, March 31, 2020	99,030,004	$ 99	$ 447,566	$ —	$ (418,870)	$ 28,795
Stock-based compensation expense	—	—	766	—	—	766
Issuance of common stock, net of issuance costs	28,135,057	28	32,001	—	—	32,029
Issuance of common stock upon vesting of RSUs, net of shares withheld for employee taxes	45,211	—	(40)	—	—	(40)
Net loss	—	—	—	—	(6,222)	(6,222)
Balance, June 30, 2020	127,210,272	$ 127	$ 480,293	$ —	$ (425,092)	$ 55,328
Stock-based compensation expense	—	—	787	—	—	787
Subscription receivable	197,640	—	135	(135)	—	—
Issuance of common stock, net of issuance costs	29,420,175	30	60,614	—	—	60,644
Net exercise of common stock warrant	201,925	—	—	—	—	—
Net loss	—	—	—	—	(5,551)	(5,551)
Balance, September 30, 2020	157,030,012	$ 157	$ 541,829	$ (135)	$ (430,643)	$ 111,208

See accompanying notes to financial statements.

TREVENA, INC.

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

	Nine Months Ended September 30, 2021	Nine Months Ended September 30, 2020
Operating activities:		
Net loss	$ (37,635)	$ (17,498)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	322	368
Stock-based compensation	3,271	2,444
Noncash interest expense on loans	—	8
Revaluation of warrant liability	(6)	17
Change in right-of-use asset	304	259
Changes in operating assets and liabilities:		
Accounts receivable, prepaid expenses and other assets	(1,801)	680
Inventories	(1,310)	—
Insurance recovery	9,000	—
Settlement liability	(9,000)	—
Operating lease liabilities	(512)	(448)
Accounts payable, accrued expenses and other liabilities	(214)	(92)
Net cash used in operating activities	(37,581)	(14,262)
Investing activities:		
Purchases of property and equipment	(16)	—
Long term deposits	(1,164)	—
Maturities of marketable securities	—	3,500
Net cash (used in) provided by investing activities	(1,180)	3,500
Financing activities:		
Proceeds from exercise of common stock options	180	—
Proceeds from issuance of common stock, net	7,948	96,233
Payment of employee withholding taxes on vested restricted stock units	(117)	(40)
Finance lease payments	(6)	(8)
Repayments of loans payable, net	—	(5,045)
Net cash provided by financing activities	8,005	91,140
Net decrease in cash, cash equivalents and restricted cash	(30,756)	80,378
Cash, cash equivalents and restricted cash—beginning of period	110,713	33,614
Cash, cash equivalents and restricted cash—end of period	$ 79,957	$ 113,992
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ —	$ 19
Subscription receivable on exercise of options	$ 8	$ 135

See accompanying notes to financial statements.

TREVENA, INC.

Notes to Unaudited Financial Statements
September 30, 2021

1. Organization and Description of the Business

Trevena, Inc., or the Company, was incorporated in Delaware as Parallax Therapeutics, Inc. in November 2007. The Company began operations in December 2007, and its name was changed to Trevena, Inc. in January 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 United States Food and Drug Administration, or FDA, approved the new drug application, or NDA, for OLINVYK. 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, 2021, the Company had an accumulated deficit of $480.1 million. The Company's net loss was $37.6 million and $17.5 million for the nine months ended September 30, 2021 and 2020, 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*, 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, 2021 is sufficient to fund operations for more than one year after the date of this filing. 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 financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America, or 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 Update, or ASU, of FASB. The Company's functional currency is the U.S. dollar.

The financial statements include all normal and recurring adjustments that are considered necessary for the fair presentation of the Company's balance sheets as of September 30, 2021, its results of operations and its comprehensive loss for the three and nine months ended September 30, 2021 and 2020, its statement of stockholders' equity for the period from January 1, 2021 to September 30, 2021 and for the period January 1, 2020 to September 30, 2020, and its statements of cash flows for the nine months ended September 30, 2021 and 2020. 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, 2020. 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, 2021 and 2020 are not necessarily indicative of the results to be expected for the year ending December 31, 2021, 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.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the 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.

Recently Adopted Accounting Standards

In December 2019, the FASB issued ASU 2019-12, *Simplifying the Accounting for Income Taxes*, which removed certain exceptions to the general principles of the accounting for income taxes and also improves consistent application of and simplification of other areas when accounting for income taxes. The effective date for this standard was January 1, 2021. The Company adopted this standard on January 1, 2021. There was no impact to the Company's financial statements or related disclosures upon the adoption.

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 and Marketable Securities

The following table presents fair value of the Company's cash, cash equivalents, and marketable securities as of September 30, 2021 and December 31, 2020 (in thousands):

	September 30, 2021						
	Adjusted Cost	Unrealized Gains	Unrealized Losses	Fair Value	Cash and Cash Equivalents	Restricted Cash	Marketable Securities
Cash	$ 7,214	$ —	$ —	$ 7,214	$ 5,903	$ 1,311	$ —
Level 1 (1):							
Money market funds	72,743	—	—	72,743	72,743	—	—
Subtotal	72,743	—	—	72,743	72,743	—	—
Total	$ 79,957	$ —	$ —	$ 79,957	$ 78,646	$ 1,311	$ —

	December 31, 2020						
	Adjusted Cost	Unrealized Gains	Unrealized Losses	Fair Value	Cash and Cash Equivalents	Restricted Cash	Marketable Securities
Cash	$ 6,100	$ —	$ —	$ 6,100	$ 4,790	$ 1,310	$ —
Level 1 (1):							
Money market funds	104,613	—	—	104,613	104,613	—	—
Subtotal	104,613	—	—	104,613	104,613	—	—
Total	$ 110,713	$ —	$ —	$ 110,713	$ 109,403	$ 1,310	$ —

(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 $1.3 million as collateral under a letter of credit for the Company's facility lease obligations in Chesterbrook, Pennsylvania. The Company has recorded this deposit and accumulated interest thereon as restricted cash on its balance sheet.

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, 2021, or the year ended December 31, 2020.

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.

5. Stockholders' Equity

Equity Offerings

Under its certificate of incorporation, the Company was authorized to issue up to200,000,000 shares of common stock as of September 30, 2021. The Company also was authorized to issue up to 5,000,000 shares of preferred stock as of September 30, 2021. 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 Underwritten Public Offering

In August 2020, the Company closed a registered underwritten public offering of 25,000,000 shares of its common stock at a public offering price of $2.30 per share for net proceeds to the Company of approximately $53.7 million, after deducting underwriting discounts and commissions and offering expenses.

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 in the third quarter of 2021. As of September 30, 2021, there was approximately $41.9 million remaining available for future issuances under the HCW ATM Program.

Registered Direct Offering and Concurrent Warrant Issuance

In January 2019, the Company entered into securities purchase agreements with two institutional investors wherein the Company agreed to sell to the investors an aggregate of 10,000,000 shares of its common stock, at an offering price of $1.00 per share, in a registered direct offering made pursuant to the Company's existing registration statement on Form S-3. The net proceeds to the Company from the offering were $9.2 million, after deducting fees and the expenses of the placement agent. Pursuant to a letter agreement dated January 28, 2019, the Company engaged H.C. Wainwright & Co., LLC, or Wainwright, to act as its exclusive placement agent in connection with the issuance and sale of the shares. The Company paid Wainwright 7.0% of the aggregate gross proceeds in the offering and $50,000 for certain expenses, and it issued warrants to purchase 500,000 shares of common stock to certain designees of Wainwright. These warrants have a term of five years, are immediately exercisable and have an exercise price of $1.25 per share. During the year ended December 31, 2020, 327,500 of these warrants were exercised in a cashless exercise for 201,925 common shares. The warrants are classified as equity and were recorded at fair value as of the date of issuance on the Company's Consolidated Balance Sheets and no further adjustments to their valuation are made. The letter agreement also includes indemnification obligations of the Company and other provisions customary for transactions of this nature.

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Research and development	$ 279	$ 203	$ 787	$ 616
Selling, general and administrative	690	584	2,455	1,828
Cost of goods sold	9	—	29	—
Total stock-based compensation	$ 978	$ 787	$ 3,271	$ 2,444

Stock Options

A summary of stock option activity and related information through September 30, 2021 follows:

	Options Outstanding		
	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)
Balance, December 31, 2020	9,564,519	$ 3.07	7.17
Granted	2,657,642	1.86	
Exercised	(146,559)	1.28	
Forfeited/Cancelled	(521,726)	2.77	
Balance, September 30, 2021	11,553,876	$ 2.83	6.99
Vested or expected to vest at September 30, 2021	11,553,876	$ 2.83	6.99
Exercisable at September 30, 2021	6,917,596	$ 3.45	5.69

The aggregate intrinsic value of options exercisable as of September 30, 2021 was $0.5 million, based on the difference between the Company's closing stock price of $1.23 and the exercise price of each stock option. At September 30, 2021, there was $5.9 million of total unrecognized compensation expense related to unvested options that will be recognized over the weighted average remaining vesting period of 3.01 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, 2021 and 2020 was estimated at $1.45 and $0.73 per share, respectively, on the date of grant using the Black-Scholes option pricing model with the following weighted-average assumptions:

	September 30, 2021	September 30, 2020
Expected term of options (in years)	6.1	5.7
Risk-free interest rate	0.9 %	0.7 %
Expected volatility	97.8 %	96.1 %
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 year:

	Number of Awards	Weighted Average Grant Date Fair Value
Non-vested at December 31, 2020	3,771,342	$ 1.66
Granted	27,500	1.20
Vested	(143,750)	0.85
Forfeited	(624,075)	1.61
Non-vested at September 30, 2021	3,031,017	$ 1.71

For the nine months ended September 30, 2021, the Company recorded $1.4 million in stock-based compensation expense related to RSUs, which is reflected in the statement of operations and comprehensive loss.

As of September 30, 2021, there was $3.8 million of total unrecognized compensation expense related to unvested RSUs that will be recognized over the weighted average remaining period of 3.08 years.

Shares Available for Future Grant

At September 30, 2021, the Company has the following shares available to be granted under its equity incentive plans:

	2013 Plan	Inducement Plan
Available at December 31, 2020	4,053,501	252,500
Authorized	6,399,997	—
Granted	(2,685,142)	—
Shares withheld for taxes not issued	49,915	—
Forfeited/Cancelled	1,145,801	—
Available at September 30, 2021	8,964,072	252,500

Shares Reserved for Future Issuance

At September 30, 2021, the Company has reserved the following shares of common stock for issuance:

Stock options outstanding under 2013 Plan	11,306,376
Restricted stock units outstanding under 2013 Plan	3,031,017
Shares reserved for future issuance under 2013 Plan	8,964,072
Stock options outstanding under Inducement Plan	247,500
Shares reserved for future issuance under Inducement Plan	252,500
Shares reserved for future issuance under 2013 Employee Stock Purchase Plan	225,806
Warrants outstanding	295,591
Total shares of common stock reserved for future issuance	24,322,862

6. 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 of37 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 statements of operations and comprehensive loss as other income (expense).

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

	September 30, 2021	December 31, 2020
Operating leases:		
Operating lease right-of-use assets	$ 4,815	$ 5,119
Other current liabilities	765	696
Operating lease liabilities	6,516	7,097
Total operating lease liabilities	$ 7,281	$ 7,793
Finance leases:		
Property and equipment, at cost	$ 44	$ 45
Accumulated depreciation	(38)	(34)
Property and equipment, net	6	11
Other current liabilities	5	7
Other long-term liabilities	—	4
Total finance lease liabilities	$ 5	$ 11

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Operating lease costs:				
Operating lease rental expense	$ 309	$ 277	$ 1,362	$ 950
Other income	(305)	(303)	(881)	(904)
Total operating lease costs	$ 4	$ (26)	$ 481	$ 46
Finance lease costs:				
Amortization of right-of-use assets	2	2	6	7
Interest on lease liabilities	—	—	—	1
Total finance lease costs	$ 2	$ 2	$ 6	$ 8

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

	Nine Months Ended September 30,	
	2021	2020
Cash paid for amounts included in the measurement of lease liabilities		
Operating cash flows from operating leases	$ (647)	$ (117)
Operating cash flows from finance leases	—	—
Financing cash flows from finance leases	(6)	(8)

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

	Operating Leases	Financing Leases
2021 (October 1 - December 31)	$ 348	$ 1
2022	1,401	4
2023	1,425	—
2024	1,450	—
2025	1,474	—
2026 and beyond	3,661	—
Total minimum lease payments	$ 9,759	$ 5
Interest Expense	(2,478)	—
Lease liability	$ 7,281	$ 5

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

	Sublease
2021 (October 1 - December 31)	$ 276
2022	1,118
2023	1,139
2024	996
2025	—
2026 and beyond	—
Total minimum lease payments	$ 3,529

Lease term and discount rates are as follows:

	Nine Months Ended September 30,	
	2021	2020
Weighted average remaining lease term (years)		
Operating leases	7	8
Finance leases	1	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 inthree 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, and on May 29, 2019, the District Court appointed a group of five individual investors as lead plaintiffs. A consolidated amended complaint was filed on August 2, 2019, alleging, among other things, that the Company and two former officers made false and misleading statements regarding the Company's business, operations, and prospects, including certain statements made relating to the Company's End-of-Phase 2 meeting with the FDA, and certain statements concerning top-line results from the Company's Phase 3 studies. The plaintiffs sought, among other remedies, unspecified damages, attorneys' fees and other costs, and unspecified equitable or injunctive relief. On August 28, 2020, the EDPA granted in part and denied in part the defendants' motion to dismiss. On October 2, 2020, the Company and the individual defendants filed their answer to the amended complaint, denying all liability. 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 issued its preliminary approval of the settlement on May 3, 2021 and finally 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, which involved facts similar to the consolidated securities lawsuits, asserted claims against the individual defendants for, among other things, breach of fiduciary duty, waste of corporate assets, violations of the federal securities laws, and unjust enrichment, and they make a number of demands, including for monetary damages and other equitable and injunctive relief. The parties agreed to a settlement, which was preliminarily approved by the Court on May 27, 2021, and finally 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. As expected, the $0.5 million was paid by the Company's insurance carriers, and the litigation is now resolved.

7. 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.

Concentration of Revenue

The Company's three customers account for 100% of total product revenue for the nine months ended September 30, 2021.

Sales-Related Deductions

The following table presents a rollforward of the major categories of sales-related deductions included in trade receivable allowances for the nine months ended September 30, 2021 (in thousands):

	Sales Discounts	Chargebacks	Fee for Service
Balance, January 1, 2021	$ 2	$ 5	$ 10
Provision related to current period sales	22	37	74
Adjustment related to prior period sales	—	—	—
Credit or payments made during the period	(10)	(1)	(33)
Balance, September 30, 2021	$ 14	$ 41	$ 51

8. 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 payment 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. As part of the agreement, 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.

9. Net Loss Per Common Share

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Basic and diluted net loss per common share calculation:				
Net loss	$ (13,771)	$ (5,551)	$ (37,635)	$ (17,498)
Weighted average common shares outstanding	164,510,570	144,335,143	162,811,136	117,420,221
Net loss per share of common stock - basic and diluted	$ (0.08)	$ (0.04)	$ (0.23)	$ (0.15)

The following outstanding securities at September 30, 2021 and 2020 have been excluded from the computation of diluted weighted shares outstanding, as they would have been anti-dilutive:

	September 30,	
	2021	2020
Options outstanding	11,553,876	7,848,738
RSUs outstanding	3,031,017	3,008,435
Warrants	295,591	295,591
Total	14,880,484	11,152,764

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 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, 2020, which are included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission, or SEC, on March 9, 2021. 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. We initiated commercial launch of OLINVYK in the first quarter of 2021, deploying approximately 40 customer-facing roles, including Key Account Managers, Institutional Account Managers and other professionals by the end of February 2021. OLINVYK is an opioid agonist for use in adults for the management of acute pain severe enough to require an intravenous opioid analgesic and for whom alternative treatments are inadequate. We are also developing a pipeline of product candidates based on our proprietary product platform, including TRV027 for the treatment of acute lung injury contributing to acute respiratory distress syndrome and abnormal blood clotting in patients with COVID-19; TRV250 for acute migraines; TRV734 for moderate-to-severe acute and chronic pain and opioid use disorders; and TRV045 for chronic pain and epilepsy.

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 OLINVYK. We have financed our operations primarily through private placements and public offerings of our equity securities and debt borrowings. As of September 30, 2021, we had an accumulated deficit of $480.1 million. Our net loss was $37.6 million and $17.5 million for the nine months ended September 30, 2021 and 2020, 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 TRV027, TRV250, TRV734, or TRV045.

We expect to incur significant expenses and operating losses for the foreseeable future as we begin 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

Appointment of Executive Officer

On November 10, 2021, our board of directors appointed Patricia Drake as our Chief Commercial Officer. Ms. Drake comes to the Trevena with over 30 years of experience in a variety of U.S. and global commercial roles in marketing, sales and strategy.

OLINVYK Cognition Study

In October 2021, we entered into an agreement with the Center for Human Drug Research in Leiden, Netherlands to initiate a new study evaluating the impact of OLINVYK on cognitive function and pain thresholds in healthy volunteer subjects.

Interest in the formal assessment of cognitive function outcomes was prompted by informal clinician observations in both the Phase 3 ATHENA open-label safety study, and in early clinical use of OLINVYK. The study is a randomized, double-blind, placebo-controlled, dose-ranging crossover study and will investigate the effect of intravenous OLINVYK on both cognitive functioning and nociceptive thresholds compared to intravenous morphine. All subjects will receive two doses of OLINVYK and two doses of IV morphine to obtain a range of plasma concentrations that span the clinically relevant range for each medication. Cognitive function will be evaluated using tests contained within the NeuroCart® test battery, a validated neurocognitive test methodology developed by CHDR scientists. A broad array of cognitive outcomes will be evaluated including motor performance, attention, reaction time, memory and executive function. Analgesia will be determined by assessment of pain thresholds using the cold pressor test. Pharmacokinetic measures will be obtained and the data analyzed through PK/PD modeling of analgesia and cognitive outcomes. The study is planned to include approximately 20 healthy subjects. Enrollment is expected to begin in the first quarter of 2022, and we expect data to be reported by mid-year 2022.

Results of TRV027 Proof-of-Concept Study in COVID-19 Patients

In September 2021, we announced the results of the TRV027 Proof-of-Concept Study in COVID-19 patients, sponsored by Imperial College London. The primary endpoint was mean change from baseline in D-dimer levels at three days following the start of drug administration. D-dimer is a biomarker used to monitor the risk of abnormal clotting throughout the vascular system, and has been used as a predictor of critical disease progression and mortality in hospitalized COVID-19 patients.

Among TRV027 treated patients, 70% (7 of 10) experienced a reduction in circulating levels of D-dimer, compared to 27% (3 of 11) of patients on placebo. TRV027 was associated with a 92% probability of a potential beneficial treatment effect, based on a Bayesian model analysis recommended by the study's Data Monitoring and Safety Committee (DMSC). In addition, a post-hoc analysis indicated that patients receiving TRV027 experienced an average 12-day reduction in time to discharge compared to placebo (11.4 vs. 23.3 days), with a median reduction of 4 days (8 vs. 12 days).

TRV045 Program for Diabetic Neuropathic Pain

In September 2021, we submitted an IND for TRV045, our selective S1P modulator for diabetic neuropathic pain. In October 2021, we received a clinical hold letter from the FDA regarding certain Phase 1 study design elements. Responding to the FDA's comments, we refiled the IND and are prepared to initiate the Phase 1 program once the FDA provides final feedback.

Litigation

In October and November 2018, we 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, and on May 29, 2019, the EDPA appointed a group of five individual investors as lead plaintiffs. A consolidated amended complaint was filed on August 2, 2019, alleging, among other things, that we and two former officers made false and misleading statements regarding our business, operations, and prospects, including certain statements made relating to our End-of-Phase 2 meeting with the FDA related to OLINVYK, and certain statements concerning top-line results from our Phase 3 studies related to OLINVYK. The plaintiffs sought, among other remedies, unspecified damages, attorneys' fees and other costs, and unspecified equitable or injunctive relief. On August 28, 2020, the EDPA granted in part and denied in part defendants' motion to dismiss. On October 2, 2020, we and the individual defendants filed our answer to the amended complaint, denying all liability. 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 issued its preliminary approval of the settlement on May 3, 2021 and finally approved the settlement on August 2, 2021. We and the individual defendants did not acknowledge any wrongdoing as part of the settlement. Upon entry into the agreement in principle, our liability related to this settlement became estimable and probable. Accordingly, we recorded in the fourth quarter of 2020 an estimated liability of $8.5 million and a corresponding insurance recovery of the same amount. As expected, the $8.5 million was paid by our insurance carriers, and the litigation is now resolved. We continue to believe that the claims were without merit.

In December 2018, a shareholder derivative action was filed on behalf of us 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, which involved facts similar to the consolidated securities lawsuits, asserted claims against the individual defendants for, among other things, breach of fiduciary duty, waste of corporate assets, violations of the federal securities laws, and unjust enrichment, and they make a number of demands, including for monetary damages and other equitable and injunctive relief. The parties agreed to a settlement, which was preliminarily approved by the Court on May 27, 2021, and finally approved by the Court on August 2, 2021. The individual defendants did not acknowledge any wrongdoing as part of the settlement. We 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. We recorded in the fourth quarter of 2020 an estimated liability of $0.5 million and a corresponding insurance recovery of the same amount. As expected, the $0.5 million was paid by the Company's insurance carriers, and the litigation is now resolved.

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. 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, 2021, 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 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, 2020 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 5, 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, 2021 and 2020 (in thousands)

	Three Months Ended 2021	Three Months Ended 2020	Change	Nine Months Ended 2021	Nine Months Ended 2020	Change
Revenue:						
Product revenue	$ 112	$ —	$ 112	$ 499	$ —	$ 499
License revenue	69	3,000	(2,931)	69	3,000	(2,931)
Total revenue	181	3,000	(2,819)	568	3,000	(2,432)
Operating expenses:						
Cost of goods sold	199	—	199	620	—	620
Selling, general and administrative	10,438	4,089	6,349	28,351	11,021	17,330
Research and development	3,404	4,301	(897)	9,489	9,450	39
Total operating expenses	14,041	8,390	5,651	38,460	20,471	17,989
Loss from operations	(13,860)	(5,390)	(8,470)	(37,892)	(17,471)	(20,421)
Other income (expense):						
Change in fair value of warrant liability	1	(14)	15	6	(17)	23
Other income, net	51	75	(24)	127	170	(43)
Interest income	39	78	(39)	130	146	(16)
Interest expense	—	—	—	—	(29)	29
Loss on foreign currency exchange	(2)	—	(2)	(6)	3	(9)
Total other income	89	139	(50)	257	273	(16)
Loss before income tax expense	(13,771)	(5,251)	(8,520)	(37,635)	(17,198)	(20,437)
Foreign income tax expense	—	(300)	300	—	(300)	300
Net loss attributable to common stockholders	$ (13,771)	$ (5,551)	$ (8,220)	$ (37,635)	$ (17,498)	$ (20,137)

Revenue

To date, we have derived revenue mainly from activities pursuant to our licensing agreements related to the development and commercialization of OLINVYK in China and South Korea. For the three and nine months ended September 30, 2021, we recorded $0.1 million and $0.5 million, respectively, in product revenue from the shipment of drug product to wholesalers. There was no product revenue recorded for the three or nine months ended September 30, 2020. For the three months ended September 30, 2021, we recorded $0.1 million in license revenue related to materials shipped to Nhwa to support the development of oliceridine efforts in China.

Cost of goods sold

Cost of goods sold for product revenue includes third party logistics costs, shipping costs, third party manufacturing variances 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, 2021	Three Months Ended September 30, 2020	Nine Months Ended September 30, 2021	Nine Months Ended September 30, 2020
Cost of goods sold	$ 199	$ —	$ 620	$ —

Cost of goods sold increased by $0.2 million and $0.6 million for the three and nine months ended September 30, 2021, respectively, compared to the same period in 2020, primarily related to distribution and indirect costs following the regulatory approval and DEA scheduling of OLINVYK.

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, 2021 increased by $6.3 million or 155% as compared to the same period in 2020, and increased by $17.3 or 157% for the nine months ended September 30, 2021, as compared to the same period in 2020. The increase in both the three and nine month periods was primarily related to increases in commercialization activities.

Research and development expense

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

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

Research and development expenses decreased by $0.9 million, or 21%, for the three months ended September 30, 2021, as compared to the same period in 2020, and decreased by less than $0.1 million, or less than 1%, for the nine months ended September 30, 2021 as compared to the same period in 2020. The following table summarizes our research and development expenses (in thousands):

	Three Months Ended		Nine Months Ended	
	2021	2020	2021	2020
Personnel-related costs	$ 1,481	$ 1,272	$ 4,125	$ 4,050
OLINVYK	420	898	1,026	1,729
TRV027	383	51	606	422
TRV045	431	640	2,384	945
TRV250	476	1,254	673	1,784
Other research and development	213	186	675	520
	$ 3,404	$ 4,301	$ 9,489	$ 9,450

The lower research and development expenses incurred during the three months ended September 30, 2021 compared to the same period in 2020 were the result of higher expenditures in 2020 on activities to support TRV250 and producing OLINVYK validation batches, partially offset by expenditures in 2021 on TRV045 and TRV027. Research and development expenses for the nine months ended September 30, 2021 were comparable to the same period in 2020.

Total other income

Total other income, net for the three months ended September 30, 2021 was lower than prior year primarily because of lower interest income and was comparable to prior year for the nine months ended September 30, 2021.

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, 2021, we had an accumulated deficit of $480.1 million, working capital of $75.0 million, cash and cash equivalents of $78.6 million, and restricted cash of $1.3 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, 2021.

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 nine months ended September 30, 2021 as compared to the same period in 2020 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 $37.6 million and $14.3 million for the nine months ended September 30, 2021 and 2020, respectively. We incurred net losses of $37.6 million and $17.5 million for those same periods.

Cash Flows

The following table summarizes our cash flows for the nine months ended September 30, 2021 and 2020 (in thousands):

	September 30, 2021	September 30, 2020
Net cash (used in) provided by:		
Operating activities	$ (37,581)	$ (14,262)
Investing activities	(1,180)	3,500
Financing activities	8,005	91,140
Net increase (decrease) in cash, cash equivalents and restricted cash	$ (30,756)	$ 80,378

Net cash used in operating activities

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 operating activities was $14.3 million for the nine months ended September 30, 2020 and consisted primarily of a net loss of $17.5 million, partially offset by stock-based compensation of $2.4 million and depreciation expense of $0.4 million, and changes in operating assets and liabilities of $0.1 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)/provided by investing activities

Net cash used in investing activities was $1.2 million for the nine months ended September 30, 2021 and net cash provided by investing activities was $3.5 million for the nine months ended September 30, 2020. Investing activities for the nine months ended September 30, 2021 consisted of an increase in long-term deposits on commercial contracts. Investing activities for the nine months ended September 30, 2020 consisted primarily of purchases and maturities of marketable securities.

Net cash provided by financing activities

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.

Net cash provided by financing activities was $91.1 million for the nine months ended September 30, 2020, which was primarily due to net proceeds of $53.7 million from the registered underwritten public offering and net proceeds of $42.5 million from the ATM Program partially offset by principal repayments on our Term Loans of $3.2 million and an additional final fee payment of $1.9 million.

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 commercialize OLINVYK, advance clinical development of TRV027, continue clinical development of TRV250, and continue IND-enabling work for TRV045. Over the next twelve months, we anticipate that our total operating expenses will increase compared to the previous twelve months.

We believe that our cash and cash equivalents as of September 30, 2021, together with interest thereon, will be sufficient to fund our operating expenses and capital expenditure requirements through the fourth quarter of 2022. 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, 2021, 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

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, and on May 29, 2019, the District Court appointed a group of five individual investors as lead plaintiffs. A consolidated amended complaint was filed on August 2, 2019, alleging, among other things, that the Company and two former officers made false and misleading statements regarding the Company's business, operations, and prospects, including certain statements made relating to the Company's End-of-Phase 2 meeting with the FDA, and certain statements concerning top-line results from the Company's Phase 3 studies. The plaintiffs sought, among other remedies, unspecified damages, attorneys' fees and other costs, and unspecified equitable or injunctive relief. On August 28, 2020, the EDPA granted in part and denied in part the defendants' motion to dismiss. On October 2, 2020, the Company and the individual defendants filed their answer to the amended complaint, denying all liability. 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 issued its preliminary approval of the settlement on May 3, 2021 and finally 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 over. 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, which involved facts similar to the consolidated securities lawsuits, asserted claims against the individual defendants for, among other things, breach of fiduciary duty, waste of corporate assets, violations of the federal securities laws, and unjust enrichment, and they make a number of demands, including for monetary damages and other equitable and injunctive relief. The parties agreed to a settlement, which was preliminarily approved by the Court on May 27, 2021, and finally 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. As expected, the $0.5 million was paid by the Company's insurance carriers, and the litigation is now resolved.

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

ITEM 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. The risk factors disclosed in our Annual Report are incorporated herein by reference.

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, 2021, formatted in Inline XBRL (eXtensible Business Reporting Language): (i) Balance Sheets as of September 30, 2021 and December 31, 2020, (ii) Statements of Operations and Comprehensive Income (Loss) for the three and nine months ended September 30, 2021 and 2020, (iii) Statement of Stockholders' Equity for the period from January 1, 2021 to September 30, 2021, (iv) Statements of Cash Flows for the nine months ended September 30, 2021 and 2020 and (v) Notes to Unaudited Financial Statements, tagged as blocks of text.
104#	Cover Page Interactive Data File – The cover page interactive data file does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.

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

\# Filed herewith.

SIGNATURES

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

Date: November 15, 2021

TREVENA, INC.

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

Exhibit 31.1

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 15, 2021

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

Exhibit 31.2

Certification of Principal Financial Officer of Trevena, Inc.
Pursuant to 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 15, 2021

/s/ BARRY SHIN
Barry Shin
Chief Financial Officer

Exhibit 32.1

Certification Of
Principal Executive Officer
Pursuant To 18 U.S.C. Section 1350,
As Adopted Pursuant To
Section 906 Of The Sarbanes-Oxley Act Of 2002

In connection with the Quarterly Report of Trevena, Inc. (the “Company”) on Form 10-Q for the period ended September 30, 2021, 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 15, 2021

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

This certification accompanies the Report and shall not be deemed “filed” by the Company with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Report), irrespective of any general incorporation language contained in such filing.

Exhibit 32.2

Certification Of
Principal Financial Officer
Pursuant To 18 U.S.C. Section 1350,
As Adopted Pursuant To
Section 906 Of The Sarbanes-Oxley Act Of 2002

In connection with the Quarterly Report of Trevena, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2021, 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 15, 2021

/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.