March 31, 2022

Trevena Reports Fourth Quarter and Full Year 2021 Results

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OLINVYK® utilization gaining traction in key target markets

Seasoned Biopharma Leader Patricia Drake appointed new Chief Commercial Officer

Topline data of OLINVYK vs IV morphine in high-risk subjects demonstrates statistically significant benefit in lowering respiratory depression

$66.9M of cash at year end 2021

$40M OLINVYK ex-US royalty-based financing with R-Bridge Healthcare Fund

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Company to host conference call today, March 31st, 2022, at 8:00 a.m. ET

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CHESTERBROOK, Pa., March 31, 2022 (GLOBE NEWSWIRE) -- **Trevena, Inc. (Nasdaq: TRVN)**, a biopharmaceutical company focused on the development and commercialization of novel medicines for patients with central nervous system (CNS) disorders, today reported its financial results for the fourth quarter and full year ended December 31, 2021, and provided an overview of its 2021 and 2022 year-to-date operational highlights.

“2021 was an important year for Trevena as we launched OLINVYK in the hospital setting. Our sales and marketing team, led by our new CCO Pattie Drake, adapted to the pandemic headwinds and we are confident the foundation we established positions us well in 2022,” said Carrie Bourdow, President and CEO of Trevena. “We also continued to build upon the supportive profile for OLINVYK with positive topline respiratory physiology data announced today, and two additional post-approval studies underway. In addition, TRV027 is being studied in COVID patients by the NIH, with enrollment expanding to international sites, and our novel S1P modulator TRV045 entered clinical studies to support development for diabetic neuropathic pain. We also solidified our financial position and recognized value for an important asset through our ex-US royalty-based financing of up to $40 million. We are pleased with the continued progress and look forward to discussing results in the near future.”

2021 and 2022 YTD Corporate Highlights:

Commercial Launch of OLINVYK® (oliceridine) injection

- **Launched OLINVYK and further strengthened commercial efforts with a focus on core target markets.** Trevena launched OLINVYK in February 2021 and, in the last year, the field and medical teams have met with over 700 target accounts and held over 200 in-service educational programs, where Trevena presented OLINVYK's in-depth clinical, health economic and overall value proposition data to key hospital staff and formulary decision-makers. The team focused on anesthesiologists, colorectal surgeons and critical care physicians who are managing complex patients.

- **Appointed Patricia Drake as Chief Commercial Officer.** In November 2021, the Company welcomed Ms. Drake, a global leader with more than 30 years of experience successfully launching multiple products in the hospital market. Ms. Drake held numerous US and international commercial roles in marketing, sales, and strategy. At Merck, she served as Managing Director and CEO of Merck, Sharp & Dohme (MSD) Finland; Leader of US and global Market Operations and Strategy Realization; and Hospital Business Unit Leader in Canada where she led the successful launch of multiple commercial products, including Bridion®, a highly successful post-surgical product with over $1 billion worldwide sales in 2020.

- **Leveraged expected OLINVYK approval and commercialization in China to raise up to $40 million in royalty and revenue interest financing.** The Company today announced a financing with R-Bridge Healthcare Fund focused on OLINVYK royalties expected from Trevena's partner in China, Jiangsu Nhwa Pharmaceutical. Trevena will receive $15 million upfront, $15 million upon first commercial sale of OLINVYK in China and an additional $10 million based on a financing or commercial milestone. If approved by year-end 2023, repayment will be limited to Chinese royalties from Nhwa, plus a 4% royalty (capped at $10 million) on OLINVYK US net sales. Trevena retains all milestones from its partnership with Nhwa, including a potential $3 million milestone on Chinese approval.

Compelling Clinical Support for OLINVYK

- **Generated positive topline data from OLINVYK Respiratory Physiology study.** Today, the Company announced positive topline data from a study evaluating the physiologic impact of OLINVYK on respiratory function in high-risk subjects including elderly and obese subjects (mean age of 71.2 years). In this study OLINVYK, at similar levels of analgesia compared to IV morphine, demonstrated a statistically significant reduced impact on respiratory depression. The study was initiated in July 2021 and led by a recognized expert in risk/benefit analysis, Albert Dahan, M.D., Ph.D., Professor of Anesthesiology at the Leiden University Medical Center. The data from this study is consistent with prior data involving younger (mean age of 26.9 years) subjects showing a favorable risk/benefit profile for OLINVYK compared to IV morphine. As with all opioids, serious, life-threatening, or fatal respiratory depression may occur in patients treated with OLINVYK.

- **Advanced two additional post-approval clinical studies focused on respiratory and gastrointestinal (GI) safety outcomes and a potential reduced effect on cognitive function.** In May 2021, the Company announced initiation of a study with Cleveland Clinic to further evaluate the potential impact of OLINVYK on respiratory, GI, and cognitive function outcomes in the postoperative setting. Wake Forest Baptist

Health joined the study in August 2021, and topline data is expected in 2H 2022.

In November 2021, the Company also announced a new study designed to assess the potential reduced effect of OLINVYK on cognitive function compared to IV morphine, being conducted in collaboration with the Netherlands-based Center for Human Drug Research. Cognitive function will be assessed using NeuroCart, a validated neurocognitive test methodology, and will also include pain model testing. Topline data from this study is expected by mid-2022.

- **Presented robust health economic models and analyses.** In 2021, the Company published and presented data supporting substantial overall cost savings for hospitals when using OLINVYK compared to IV morphine in postoperative care. These head-to-head data versus IV morphine and the accompanying health economic models can provide valuable information for decision-making by hospital formulary committees. These health economic analyses support our belief that using OLINVYK versus IV morphine may provide substantial economic value to a hospital.

- **Supported clinical and regulatory progress by Jiangsu Nhwa, Trevena's commercial partner in China.** In July 2021, the Company announced that Jiangsu Nhwa had enrolled its first patient in a bridging Phase 3 clinical trial for OLINVYK in China. Based on supportive data from this study, Jiangsu Nhwa submitted a New Drug Application for OLINVYK to China's National Medical Products Administration (NMPA) in January 2022.

Broad Pipeline Advancement

- **Established proof-of-concept data for TRV027 in COVID-19 patients.** In September 2021, the Company announced positive data from 30 patients enrolled in a proof-of-concept study in collaboration with Imperial College London (ICL) to investigate TRV027, a novel AT_1 receptor selective agonist, as a potential treatment for acute lung damage / abnormal clotting associated with COVID-19. Among TRV027 treated patients, 70% (7 of 10) experienced a reduction in circulating 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). Elevation of D-dimer is a validated marker of disease morbidity and mortality in patients with COVID-19 infection. These results provide initial evidence of the therapeutic potential of TRV027 to improve COVID-19 patient outcomes.

- **Initiated enrollment in a large NIH ACTIV-4 trial for TRV027 in COVID-19 patients.** In July 2021, the Company announced the first patient enrolled in the NIH-funded ACTIV-4 host tissue trial of TRV027 for COVID-19 and currently anticipate topline data in 2H 2022. The study is a multi-site, randomized, placebo-controlled, clinical trial with approximately 300 COVID-19 patients dosed with TRV027. The Company announces participation in the international expansion of the ACTIV-4 study and will continue to supply TRV027 in collaboration with the NIH Team.

- **Advanced TRV045 into clinical development for diabetic neuropathic pain.** In December 2021, the Company announced advancement of TRV045 into clinical development, following receipt of a notification from the US Food and Drug

Administration that the study may proceed. TRV045 is the Company's novel $S1P_1$ receptor modulator being developed as a potential treatment for diabetic neuropathic pain. In addition, through a collaboration with the NIH, the Company is also exploring TRV045 as a potential treatment for epilepsy.

Financial Results for Fourth Quarter and Full Year 2021

The Company today reported $66.9 million in cash and cash equivalents as of December 31, 2021, which it believes will be sufficient to fund operating expenses and capital expenditure requirements through the fourth quarter of 2022. This cash balance does not include proceeds from the R Bridge Financing, announced today. For the fourth quarter of 2021, the Company reported a net loss attributable to common stockholders of $14.7 million, or $0.09 per share, compared to $11.9 million, or $0.08 per share, for the fourth quarter of 2020. For the full year ended December 31, 2021, net loss attributable to common stockholders was $52.3 million, or $0.32 per share, compared to $29.4 million, or $0.23 per share, for the year ended December 31, 2020. This increase is primarily due to activities around the commercial launch of OLINVYK.

Conference Call and Webcast Information

The Company will host a conference call and webcast with the investment community on March 31st, 2022, at 8:00 a.m. Eastern Time featuring remarks by Carrie Bourdow, President and Chief Executive Officer, Patricia Drake, Chief Commercial Officer, Mark Demitrack, M.D., Senior Vice President and Chief Medical Officer, and Barry Shin, Senior Vice President and Chief Financial Officer.

Title:	Trevena Fourth Quarter & Full Year 2021 Financial Results
Date:	Thursday, March 31, 2022
Time:	8:00 a.m. ET
Conference Call Details:	Toll-Free: (855) 465-0180 International: (484) 756-4313 Conference ID: 8874745
Webcast:	https://www.trevena.com/investors/events-presentations/ir

About OLINVYK® (oliceridine) injection

OLINVYK is a new chemical entity approved by the FDA in August 2020. OLINVYK contains oliceridine, an opioid, which is a Schedule II controlled substance with a high potential for abuse similar to other opioids. It is indicated in adults for the management of acute pain severe enough to require an intravenous opioid analgesic and for whom alternative treatments are inadequate. OLINVYK is available in 1 mg/1 mL and 2 mg/2 mL single-dose vials, and a 30 mg/30 mL single-patient-use vial for patient-controlled analgesia (PCA). Approved PCA doses are 0.35 mg and 0.5 mg and doses greater than 3 mg should not be administered. The cumulative daily dose should not exceed 27 mg. Please see Important Safety Information, including the BOXED WARNING, and full prescribing information at www.OLINVYK.com.

Important Safety Information

WARNING: ADDICTION, ABUSE, AND MISUSE; LIFE-THREATENING RESPIRATORY DEPRESSION; NEONATAL OPIOID WITHDRAWAL SYNDROME; and RISKS FROM CONCOMITANT USE WITH BENZODIAZEPINES OR OTHER CENTRAL NERVOUS SYSTEM (CNS) DEPRESSANTS

ADDICTION, ABUSE, AND MISUSE – OLINVYK exposes patients and other users to the risks of opioid addiction, abuse, and misuse, which can lead to overdose and death. Assess each patient's risk before prescribing OLINVYK, and monitor all patients regularly for the development of behaviors or conditions.

LIFE-THREATENING RESPIRATORY DEPRESSION – Serious, life-threatening, or fatal respiratory depression may occur with use of OLINVYK. Monitor for respiratory depression, especially during initiation of OLINVYK or following a dose increase.

NEONATAL OPIOID WITHDRAWAL SYNDROME – Prolonged use of OLINVYK during pregnancy can result in neonatal opioid withdrawal syndrome, which may be life-threatening if not recognized and treated, and requires management according to protocols developed by neonatology experts. If opioid use is required for a prolonged period in a pregnant woman, advise the patient of the risk of neonatal opioid withdrawal syndrome and ensure that appropriate treatment will be available.

RISK FROM CONCOMITANT USE WITH BENZODIAZEPINES OR OTHER CNS DEPRESSANTS – Concomitant use of opioids with benzodiazepines or other CNS depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death. Reserve concomitant prescribing for use in patients for whom alternative treatment options are inadequate; limit dosages and durations to the minimum required; and follow patients for signs and symptoms of respiratory depression and sedation.

INDICATIONS AND USAGE
OLINVYK is an opioid agonist indicated in adults for the management of acute pain severe enough to require an intravenous opioid analgesic and for whom alternative treatments are inadequate.

Limitations of Use
Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, reserve OLINVYK for use in patients for whom alternative treatment options [e.g., non-opioid analgesics or opioid combination products]:

- Have not been tolerated, or are not expected to be tolerated
- Have not provided adequate analgesia, or are not expected to provide adequate analgesia.

The cumulative total daily dose should not exceed 27 mg, as total daily doses greater than 27 mg may increase the risk for QTc interval prolongation.

CONTRAINDICATIONS
OLINVYK is contraindicated in patients with:

- Significant respiratory depression

- Acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment
- Known or suspected gastrointestinal obstruction, including paralytic ileus
- Known hypersensitivity to oliceridine (e.g., anaphylaxis)

WARNINGS AND PRECAUTIONS

- OLINVYK contains oliceridine, a Schedule II controlled substance, that exposes users to the risks of addiction, abuse, and misuse. Although the risk of addiction in any individual is unknown, it can occur in patients appropriately prescribed OLINVYK. Assess risk, counsel, and monitor all patients receiving opioids.
- Serious, life-threatening respiratory depression has been reported with the use of opioids, even when used as recommended, especially in patients with chronic pulmonary disease, or in elderly, cachectic and debilitated patients. The risk is greatest during initiation of OLINVYK therapy, following a dose increase, or when used with other drugs that depress respiration. Proper dosing of OLINVYK is essential, especially when converting patients from another opioid product to avoid overdose. Management of respiratory depression may include close observation, supportive measures, and use of opioid antagonists, depending on the patient's clinical status.
- Opioids can cause sleep-related breathing disorders including central sleep apnea (CSA) and sleep-related hypoxemia with risk increasing in a dose-dependent fashion. In patients who present with CSA, consider decreasing the dose of opioid using best practices for opioid taper.
- Prolonged use of opioids during pregnancy can result in withdrawal in the neonate that may be life-threatening. Observe newborns for signs of neonatal opioid withdrawal syndrome and manage accordingly. Advise pregnant women using OLINVYK for a prolonged period of the risk of neonatal opioid withdrawal syndrome and ensure that appropriate treatment will be available.
- Profound sedation, respiratory depression, coma, and death may result from the concomitant use of OLINVYK with benzodiazepines or other CNS depressants (e.g., non-benzodiazepine sedatives/hypnotics, anxiolytics, tranquilizers, muscle relaxants, general anesthetics, antipsychotics, other opioids, or alcohol). Because of these risks, reserve concomitant prescribing of these drugs for use in patients for whom alternative treatment options are inadequate, prescribe the lowest effective dose, and minimize the duration.
- OLINVYK was shown to have mild QTc interval prolongation in thorough QT studies where patients were dosed up to 27 mg. Total cumulative daily doses exceeding 27 mg per day were not studied and may increase the risk for QTc interval prolongation. Therefore, the cumulative total daily dose of OLINVYK should not exceed 27 mg.
- Increased plasma concentrations of OLINVYK may occur in patients with decreased Cytochrome P450 (CYP) 2D6 function or normal metabolizers taking moderate or strong CYP2D6 inhibitors; also in patients taking a moderate or strong CYP3A4 inhibitor, in patients with decreased CYP2D6 function who are also receiving a moderate or strong CYP3A4 inhibitor, or with discontinuation of a CYP3A4 inducer. These patients may require less frequent dosing and should be closely monitored for

respiratory depression and sedation at frequent intervals. Concomitant use of OLINVYK with CYP3A4 inducers or discontinuation of a moderate or strong CYP3A4 inhibitor can lower the expected concentration, which may decrease efficacy, and may require supplemental doses.

- Cases of adrenal insufficiency have been reported with opioid use (usually greater than one month). Presentation and symptoms may be nonspecific and include nausea, vomiting, anorexia, fatigue, weakness, dizziness, and low blood pressure. If confirmed, treat with physiologic replacement doses of corticosteroids and wean patient from the opioid.
- OLINVYK may cause severe hypotension, including orthostatic hypotension and syncope in ambulatory patients. There is increased risk in patients whose ability to maintain blood pressure has already been compromised by a reduced blood volume or concurrent administration of certain CNS depressant drugs (e.g., phenothiazines or general anesthetics). Monitor these patients for signs of hypotension. In patients with circulatory shock, avoid the use of OLINVYK as it may cause vasodilation that can further reduce cardiac output and blood pressure.
- Avoid the use of OLINVYK in patients with impaired consciousness or coma. OLINVYK should be used with caution in patients who may be susceptible to the intracranial effects of CO_2 retention, such as those with evidence of increased intracranial pressure or brain tumors, as a reduction in respiratory drive and the resultant CO_2 retention can further increase intracranial pressure. Monitor such patients for signs of sedation and respiratory depression, particularly when initiating therapy.
- As with all opioids, OLINVYK may cause spasm of the sphincter of Oddi, and may cause increases in serum amylase. Monitor patients with biliary tract disease, including acute pancreatitis, for worsening symptoms.
- OLINVYK may increase the frequency of seizures in patients with seizure disorders and may increase the risk of seizures in vulnerable patients. Monitor patients with a history of seizure disorders for worsened seizure control.
- Do not abruptly discontinue OLINVYK in a patient physically dependent on opioids. Gradually taper the dosage to avoid a withdrawal syndrome and return of pain. Avoid the use of mixed agonist/antagonist (e.g., pentazocine, nalbuphine, and butorphanol) or partial agonist (e.g., buprenorphine) analgesics in patients who are receiving OLINVYK, as they may reduce the analgesic effect and/or precipitate withdrawal symptoms.
- OLINVYK may impair the mental or physical abilities needed to perform potentially hazardous activities such as driving a car or operating machinery.
- Although self-administration of opioids by patient-controlled analgesia (PCA) may allow each patient to individually titrate to an acceptable level of analgesia, PCA administration has resulted in adverse outcomes and episodes of respiratory depression. Health care providers and family members monitoring patients receiving PCA analgesia should be instructed in the need for appropriate monitoring for excessive sedation, respiratory depression, or other adverse effects of opioid medications.

ADVERSE REACTIONS
Adverse reactions are described in greater detail in the Prescribing Information.
The most common (incidence ≥10%) adverse reactions in Phase 3 controlled clinical trials were nausea, vomiting, dizziness, headache, constipation, pruritus, and hypoxia.

MEDICAL INFORMATION
For medical inquiries or to report an adverse event, other safety-related information or product complaints for a company product, please contact the Trevena Medical Information Contact Center at **1-844-465-4686** or email **MedInfo@Trevena.com**.
You are encouraged to report suspected adverse events of prescription drugs to the FDA. Visit **www.fda.gov/medwatch** or call **1-800-FDA-1088**.
Please see Full Prescribing Information, including Boxed Warning.

About Trevena

Trevena, Inc. is a biopharmaceutical company focused on the development and commercialization of innovative medicines for patients with CNS disorders. The Company has one approved product in the United States, OLINVYK® (oliceridine) injection, indicated in adults for the management of acute pain severe enough to require an intravenous opioid analgesic and for whom alternative treatments are inadequate. The Company's novel pipeline is based on Nobel Prize winning research and includes four differentiated investigational drug candidates: TRV250 for the acute treatment of migraine, TRV734 for maintenance treatment of opioid use disorder, TRV045 for diabetic neuropathic pain and epilepsy, and TRV027 for acute respiratory distress syndrome and abnormal blood clotting in COVID-19 patients.

For more information, please visit www.Trevena.com

About R-Bridge (CBC Group)
CBC Group is Asia's largest and most active healthcare-dedicated investment firm with over US$5 billion AUM, focused on platform-building, buyout opportunities, and alternative financing across three core areas: pharmaceutical & biotech, medtech, and healthcare services. CBC has a leading team of investment, industry and portfolio management professionals, headquartered in Singapore with offices in New York, Shanghai, Beijing, and Hong Kong and presence in Boston, San Diego, San Francisco and Tokyo.

Founded in February 2020, R-Bridge Healthcare Fund is an affiliate of CBC Group and it is dedicated in providing alternative, non-dilutive financing backed by royalties, revenue interest and other cash flows generated by the sale of healthcare products and services in China, the first of its kind for the asset class and the region. R-Bridge provides additional sources of capital to leading healthcare companies to continue their extraordinary growth trajectories, commercializing their products and services in China and on a global scale.

About Jiangsu Nhwa Pharmaceuticals

Jiangsu Nhwa Pharmaceutical Co., Ltd. (SZ002262), founded in 1978, is a leading CNS company in China. Over the past 40 years, Nhwa has focused on developing an innovative and differentiated pipeline in the areas of anesthesia, analgesia, psychiatry, and neurology via its own in-house R&D and via global partnerships.

As a fully integrated pharmaceutical company with more than 4000 employees, Nhwa has comprehensive capabilities in discovery, clinical development, manufacturing, and commercialization of CNS drugs. In recent years, Nhwa has further strengthened its leadership in CNS field in China by providing precision diagnostic services for CNS disorders, as well as establishing the largest Chinese CNS internet health platform.

Forward-Looking Statements

Any statements in this press release about future expectations, plans and prospects for the Company, including statements about the Company's strategy, future operations, clinical development and trials of its therapeutic candidates and approved product, plans for potential future product candidates and other statements containing the words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "suggest," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the status, timing, costs, results and interpretation of the Company's clinical trials or any future trials of any of the Company's investigational drug candidates; the uncertainties inherent in conducting clinical trials; expectations for regulatory interactions, submissions and approvals, including the Company's assessment of discussions with FDA; available funding; uncertainties related to the Company's intellectual property; uncertainties related to the ongoing COVID-19 pandemic, other matters that could affect the availability or commercial potential of the Company's therapeutic candidates and approved product; and other factors discussed in the Risk Factors set forth in the Company's Annual Report on Form 10-K and Quarterly Reports on Form 10-Q filed with the Securities and Exchange Commission (SEC) and in other filings the Company makes with the SEC from time to time. In addition, the forward-looking statements included in this press release represent the Company's views only as of the date hereof. The Company anticipates that subsequent events and developments may cause the Company's views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, it specifically disclaims any obligation to do so, except as may be required by law.

For more information, please contact:

Investor Contact:

Dan Ferry
Managing Director
LifeSci Advisors, LLC
daniel@lifesciadvisors.com
(617) 430-7576

Company Contact:

Bob Yoder
SVP and Chief Business Officer
Trevena, Inc.
(610) 354-8840

TREVENA, INC.
Condensed Statements of Operations
(Unaudited, in thousands except share and per share data)

	Three Months Ended Dec 31,		Year Ended Dec 31,	
	2021	**2020**	**2021**	**2020**
Product revenue	$ (1)	$ 69	$ 498	$ 69
License revenue	-	-	69	3,000
Total revenue	(1)	69	567	3,069
Operating expenses:				
Cost of goods sold	334	182	954	182
Selling, general and administrative	9,761	8,227	38,112	19,248
Research and development	3,937	3,674	13,426	13,124
Total operating expenses	14,032	12,083	52,492	32,554
Loss from operations	(14,033)	(12,014)	(51,925)	(29,485)
Other income	80	143	337	416
Loss before income tax expense	(13,953)	(11,871)	(51,588)	(29,069)
Foreign income tax expense	-	-	-	(300)
Net loss	$ (13,953)	$ (11,871)	$ (51,588)	$ (29,369)
Per share information:				
Net loss per share of common stock, basic and diluted	$ (0.08)	$ (0.08)	$ (0.32)	$ (0.23)
Weighted average shares outstanding, basic and diluted	164,724,051	158,012,954	163,293,296	127,623,859

TREVENA, INC.
Condensed Balance Sheets
(Unaudited, in thousands)

	December 31, 2021	December 31, 2020
Assets		

Current assets:		
Cash and cash equivalents	$ 66,923	$ 109,403
Accounts receivable, net	-	71
Inventories	2,352	-
Insurance recovery	-	9,000
Prepaid expenses and other current assets	1,448	570
Total current assets	70,723	119,044
Restricted cash	1,311	1,310
Property and equipment, net	1,841	2,253
Right-of-use lease assets	4,706	5,119
Other assets	1,543	13
Total assets	$ 80,124	$ 127,739
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable, net	$ 4,547	$ 1,693
Accrued expenses and other current liabilities	3,847	5,168
Estimated settlement liability	-	9,000
Current portion of lease liabilities	792	703
Total current liabilities	9,186	16,564
Leases, net of current portion	6,309	7,101
Warrant liability	-	6
Total liabilities	15,495	23,671
Common stock	165	160
Additional paid-in capital	558,566	546,422
Accumulated deficit	(494,102)	(442,514)
Total stockholders' equity	64,629	104,068
Total liabilities and stockholders' equity	$ 80,124	$ 127,739

Source: Trevena Inc.