TREVENA INC Form S-3 April 03, 2015

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As filed with the Securities and Exchange Commission on April 3, 2015

Registration No. 333-

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM S-3

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

TREVENA, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or organization)

26-1469215

(I.R.S. Employer Identification Number)

1018 West 8th Avenue, Suite A King of Prussia, PA 19406 (610) 354-8840

(Address, including zip code, and telephone number, including area code of registrant's principal executive offices)

John M. Limongelli, Esq.
Senior Vice President, General Counsel and Secretary
Trevena, Inc.
1018 West 8th Avenue, Suite A
King of Prussia, PA 19406
(610) 354-8840

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

Brent B. Siler, Esq.
Derek O. Colla, Esq.
Cooley LLP
1299 Pennsylvania Ave NW, Suite 700
Washington, DC 20001
Telephone: (202) 842-7800
Fax: (202) 842-7899

From time to time after the effective date of this Registration Statement (Approximate date of commencement of proposed sale to the public)

If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box. o

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box. \circ

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this Form is a registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box. o

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box.

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

Large accelerated	Accelerated filer	Non-accelerated filer o	Smaller reporting
filer o	o	(Do not check if a	company ý
		smaller reporting	
		company)	

CALCULATION OF REGISTRATION FEE

	Title of each class of securities to be registered	Amount to be Registered	Proposed Maximum Offering Price per Unit	Proposed Maximum Aggregate Offering Price	Amount of Registration Fee(1)
C	common Stock, par value \$0.001 per share	(2)	(3)	(3)	3 ··· ··· ·· · · · ()
P	referred Stock, par value \$0.001 per share	(2)	(3)	(3)	
D	bebt Securities	(2)	(3)	(3)	
V	Varrants	(2)	(3)	(3)	
Т	otal	(2)		\$150,000,000	\$17,430

(1) Calculated pursuant to Rule 457(o) under the Securities Act of 1933, as amended, or the Securities Act.

(2)

There are being registered hereunder such indeterminate number of shares of common stock and preferred stock, such indeterminate principal amount of debt securities and such indeterminate number of warrants to purchase common stock, preferred stock or debt securities as shall have an aggregate initial offering price not to exceed \$150,000,000. If any debt securities are issued at an original issue discount, then the principal amount of such debt securities shall be in such greater amount as shall result in an aggregate initial offering price not to exceed \$150,000,000, less the aggregate dollar amount of all securities previously issued hereunder. Any securities registered hereunder may be sold separately or as units with other securities registered hereunder. The securities registered also include such indeterminate number of shares of common stock and preferred stock and amount of debt securities as may be issued upon conversion of or exchange for preferred stock or debt securities that provide for conversion or exchange, upon exercise of warrants or pursuant to the antidilution provisions of any such securities. In addition, pursuant to Rule 416 under the Securities Act, the shares being registered hereunder include such indeterminate number of shares of common stock and preferred stock as may be issuable with respect to the shares being registered hereunder as a result of stock splits, stock dividends or similar transactions.

(3)	
	The proposed maximum aggregate offering price per class of security will be determined from time to time by the registrant in connection with the
	issuance by the registrant of the securities registered hereunder and is not specified as to each class of security pursuant to General Instruction II.D. of
	Form S-3 under the Securities Act.

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment that specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the registration statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

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EXPLANATORY NOTE

This registration statement contains:

a base prospectus which covers the offering, issuance and sale by the registrant of up to a maximum aggregate offering price of \$150,000,000 of the registrant's common stock, preferred stock, debt securities, warrants and/or units; and

a sales agreement prospectus covering the offering, issuance and sale by the registrant of up to a maximum aggregate offering price of \$40,000,000 of the registrant's common stock that may be issued and sold from time to time under a sales agreement with Cowen and Company, LLC.

The base prospectus immediately follows this explanatory note. The specific terms of any securities to be offered pursuant to the base prospectus will be specified in a prospectus supplement to the base prospectus. The sales agreement prospectus immediately follows the base prospectus. The \$40,000,000 of common stock that may be offered, issued and sold by the registrant under the sales agreement prospectus is included in the \$150,000,000 of securities that may be offered, issued and sold by the registrant under the base prospectus.

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The information in this prospectus is not complete and may be changed. We may not sell these securities or accept an offer to buy these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities, and it is not soliciting offers to buy these securities in any state where such offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED APRIL 3, 2015

PROSPECTUS

\$150,000,000

Common Stock Preferred Stock Debt Securities Warrants

From time to time, we may offer up to \$150,000,000 of any combination of the securities described in this prospectus in one or more offerings. We may also offer securities as may be issuable upon conversion, redemption, repurchase, exchange or exercise of any securities registered hereunder, including any applicable antidilution provisions.

This prospectus provides a general description of the securities we may offer. Each time we offer securities, we will provide specific terms of the securities offered in a supplement to this prospectus. We may also authorize one or more free writing prospectuses to be provided to you in connection with these offerings. The prospectus supplement and any related free writing prospectus may also add, update or change information contained in this prospectus. You should carefully read this prospectus, the applicable prospectus supplement and any related free writing prospectus, as well as any documents incorporated by reference, before you invest in any of the securities being offered.

This prospectus may not be used to consummate a sale of any securities unless accompanied by a prospectus supplement.

Our common stock is traded on the Nasdaq Global Select Market under the symbol "TRVN." On April 2, 2015, the last reported sale price of our common stock was \$7.09 per share. The applicable prospectus supplement will contain information, where applicable, as to any other listing on the Nasdaq Global Select Market or any securities market or other exchange of the securities, if any, covered by the prospectus supplement.

We will sell these securities directly to investors, through agents designated from time to time or to or through underwriters or dealers, on a continuous or delayed basis. For additional information on the methods of sale, you should refer to the section entitled "Plan of Distribution" in this prospectus. If any agents or underwriters are involved in the sale of any securities with respect to which this prospectus is being delivered, the names of such agents or underwriters and any applicable fees, commissions, discounts or over-allotment options will be set forth in a prospectus supplement. The price to the public of such securities and the net proceeds we expect to receive from such sale will also be set forth in a prospectus supplement.

Investing in our securities involves a high degree of risk. You should review carefully the risks and uncertainties described under the heading "Risk Factors" contained in the applicable prospectus supplement and any related free writing prospectus, and under similar headings in the other documents that are incorporated by reference into this prospectus.

NEITHER THE SECURITIES AND EXCHANGE COMMISSION NOR ANY STATE SECURITIES COMMISSION HAS
APPROVED OR DISAPPROVED OF THESE SECURITIES OR DETERMINED IF THIS PROSPECTUS IS TRUTHFUL OR
COMPLETE, ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.

The date of this prospectus is

, 2015.

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ABOUT THIS PROSPECTUS

This prospectus is a part of a registration statement on Form S-3 that we filed with the Securities and Exchange Commission, or SEC, utilizing a "shelf" registration process. Under this shelf registration process, we may sell any combination of the securities described in this prospectus in one or more offerings up to a total aggregate offering price of \$150,000,000. This prospectus provides you with a general description of the securities we may offer.

Each time we sell securities under this prospectus, we will provide a prospectus supplement that will contain specific information about the terms of that offering. We may also authorize one or more free writing prospectuses to be provided to you that may contain material information relating to these offerings. The prospectus supplement and any related free writing prospectus that we may authorize to be provided to you may also add, update or change information contained in this prospectus or in any documents that we have incorporated by reference into this prospectus. You should read this prospectus, any applicable prospectus supplement and any related free writing prospectus, together with the information incorporated herein by reference as described under the heading "Incorporation of Certain Information by Reference," before investing in any of the securities offered.

THIS PROSPECTUS MAY NOT BE USED TO CONSUMMATE A SALE OF SECURITIES UNLESS IT IS ACCOMPANIED BY A PROSPECTUS SUPPLEMENT.

Neither we, nor any agent, underwriter or dealer has authorized any person to give any information or to make any representation other than those contained or incorporated by reference in this prospectus, any applicable prospectus supplement or any related free writing prospectus prepared by or on behalf of us or to which we have referred you. This prospectus, any applicable supplement to this prospectus or any related free writing prospectus do not constitute an offer to sell or the solicitation of an offer to buy any securities other than the registered securities to which they relate, nor do this prospectus, any applicable supplement to this prospectus or any related free writing prospectus constitute an offer to sell or the solicitation of an offer to buy securities in any jurisdiction to any person to whom it is unlawful to make such offer or solicitation in such jurisdiction.

You should not assume that the information contained in this prospectus, any applicable prospectus supplement or any related free writing prospectus is accurate on any date subsequent to the date set forth on the front of the document or that any information we have incorporated by reference is correct on any date subsequent to the date of the document incorporated by reference, even though this prospectus, any applicable prospectus supplement or any related free writing prospectus is delivered, or securities are sold, on a later date.

This prospectus contains summaries of certain provisions contained in some of the documents described herein, but reference is made to the actual documents for complete information. All of the summaries are qualified in their entirety by the actual documents. Copies of some of the documents referred to herein have been filed, will be filed or will be incorporated by reference as exhibits to the registration statement of which this prospectus is a part, and you may obtain copies of those documents as described below under the heading "Where You Can Find More Information."

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SUMMARY

This summary highlights selected information from this prospectus and does not contain all of the information that you need to consider in making your investment decision. You should carefully read the entire prospectus, the applicable prospectus supplement and any related free writing prospectus, including the risks of investing in our securities discussed under the heading "Risk Factors" contained in the applicable prospectus supplement and any related free writing prospectus, and under similar headings in the other documents that are incorporated by reference into this prospectus. You should also carefully read the information incorporated by reference into this prospectus, including our financial statements, and the exhibits to the registration statement of which this prospectus is a part.

Unless the context requires otherwise, references in this prospectus to "Trevena," "we," "us" and "our" refer to Trevena, Inc.

Company Overview

Trevena, Inc. is a clinical stage biopharmaceutical company that discovers, develops and intends to commercialize therapeutics that use a novel approach to target G protein coupled receptors, or GPCRs. Unless the context otherwise requires, we use the terms "Trevena," "company," "we," "us" and "our" to refer to Trevena, Inc.

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

TRV130: We are developing TRV130 as a first-line treatment for patients experiencing moderate to severe pain where IV administration is preferred. We are currently conducting a second Phase 2 trial of TRV130 with the goal of evaluating analgesic efficacy following soft-tissue surgery and exploring TRV130's safety and tolerability profile benchmarked to morphine. We expect to report top-line data from this trial in mid-2015. In November 2014, we announced top-line data from our Phase 2a/b clinical trial of TRV130 in postoperative pain following bunionectomy surgery. At doses of 2 mg and 3 mg of TRV130 administered every three hours, the trial achieved its primary endpoint of statistically greater pain reduction than placebo for 48 hours, which we believe demonstrates proof of concept for TRV130. The 3 mg dose of TRV130 also showed statistically superior analgesic efficacy over the 48-hour trial period compared to 4 mg of morphine administered every four hours. There were no serious adverse events reported in the trial, which we believe suggests that these levels of pain relief can be achieved safely. Based on the data from the recently completed Phase 2a/b study, we plan to move into Phase 3 preparations, which we expect to occur in parallel with the second Phase 2 soft tissue trial for TRV130 that we commenced in December 2014. We also anticipate that we will initiate a Phase 3 clinical trial for TRV130 in the first quarter of 2016. We hold a U.S. patent covering the composition of matter and methods of use for TRV130. We have retained all worldwide development and commercialization rights to TRV130, and plan to commercialize it for use in acute care settings such as hospitals and ambulatory surgery centers if it receives regulatory approval.

TRV734: We are developing TRV734 as a first-line, orally administered compound for the treatment of moderate to severe acute and chronic pain. We have completed both a Phase 1 single ascending dose clinical trial and a Phase 1 multiple ascending dose clinical study and reported positive results from these studies in June 2014 and February 2015, respectively. We are commencing a pharmacokinetic study with various formulations of TRV734 to prepare for phase 2 development. We have retained all worldwide development and commercialization rights to TRV734.

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TRV027: We are developing TRV027 for the treatment of acute heart failure, or AHF. In early 2014 we initiated a Phase 2b clinical trial of TRV027 (BLAST-AHF) for the treatment of AHF. In January 2015, we conducted a planned interim analysis, evaluating data from approximately 250 patients. Upon reviewing the data, the data safety monitoring board (DSMB) and the BLAST-AHF Steering Committee recommended that future enrollment be weighted to the most promising dose of 5 mg/hr. We announced in March 2015 that remaining enrollment will be weighted 2:1:2:1 for placebo, 1 mg/hr, 5 mg/hr, and 25 mg/hr, respectively, and that we have increased target enrollment in the study from 500 patients to 620 patients. In addition, the DSMB and Steering Committee determined that patients with lower baseline systolic blood pressure could safely enroll in the study; inclusion criteria have been modified accordingly. Actavis plc, or Actavis, which holds an exclusive option to license TRV027, has fully funded this expansion of the study via a \$10 million payment to us to defray the external and internal costs of increasing the study sample size. As a result of the increased target enrollment, we now expect to release top-line data in the first half of 2016.

We also have identified a new product candidate, TRV250, from our preclinical δ -opioid receptor program focused on central nervous system, or CNS, indications and plan to advance TRV250 to preclinical studies in 2015 that would support our submission of an investigational new drug application, or IND, to the U.S. Food and Drug Administration, or FDA.

Corporate Information

We were incorporated under the laws of the State of Delaware in November 2007. Our principal executive office is located at 1018 West 8th Avenue, Suite A, King of Prussia, Pennsylvania 19406. Our telephone number is (610) 354-8840. Our website address is www.trevenainc.com. The information contained on our website is not incorporated by reference into this prospectus, and you should not consider any information contained on, or that can be accessed through, our website as part of this prospectus or in deciding whether to purchase our common stock.

"Trevena", the Trevena logo and other trademarks or service marks of Trevena, Inc. appearing in this prospectus are the property of Trevena, Inc. This prospectus contains additional trade names, trademarks and service marks of others, which are the property of their respective owners.

The Securities We May Offer

We may offer shares of our common stock and preferred stock, various series of debt securities and warrants to purchase any of such securities, up to a total aggregate offering price of \$150,000,000 from time to time in one or more offerings under this prospectus, together with any applicable prospectus supplement and any related free writing prospectus, at prices and on terms to be determined by market conditions at the time of the relevant offering. This prospectus provides you with a general description of the securities we may offer. Each time we offer a type or series of securities under this prospectus, we will provide a prospectus supplement that will describe the specific amounts, prices and other important terms of the securities, including, to the extent applicable:

designation or classification;
aggregate principal amount or aggregate offering price;
maturity, if applicable;
original issue discount, if any;
rates and times of payment of interest or dividends, if any;
redemption conversion exchange or sinking fund terms if any

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conversion or exchange prices or rates, if any, and, if applicable, any provisions for changes to or adjustments in the conversion or exchange prices or rates and in the securities or other property receivable upon conversion or exchange;	
ranking, if applicable;	
restrictive covenants, if any;	
voting or other rights, if any; and	
important U.S. federal income tax considerations.	

The prospectus supplement and any related free writing prospectus that we may authorize to be provided to you may also add, update or change information contained in this prospectus or in documents we have incorporated by reference. However, no prospectus supplement or free writing prospectus will offer a security that is not registered and described in this prospectus at the time of the effectiveness of the registration statement of which this prospectus is a part.