**UNITED STATES DISTRICT COURT**
**EASTERN DISTRICT OF PENNSYLVANIA**

, INDIVIDUALLY and ON BEHALF OF ALL OTHERS SIMILARLY SITUATED,

Plaintiff,

v.

TREVENA, INC., MAXINE GOWEN and ROBERTO CUCA,

Defendants.

Case No. 18cv4378

**CLASS ACTION COMPLAINT FOR VIOLATION OF THE FEDERAL SECURITIES LAWS**

**Jury Trial Demanded**

Plaintiff ("Plaintiff"), by and through his attorneys, alleges upon personal knowledge as to himself, and upon information and belief as to all other matters, based upon the investigation conducted by and through his attorneys, which included, among other things, a review of documents filed by Defendants (as defined below) with the United States Securities and Exchange Commission (the "SEC"), news reports, press releases issued by Defendants, and other publicly available documents, as follows:

## NATURE AND SUMMARY OF THE ACTION

1. This is a federal securities class action on behalf of all investors who purchased or otherwise acquired Defendant Trevena, Inc. ("Trevena" or the "Company") common stock between May 2, 2016 through October 8, 2018, inclusive (the "Class Period"). This action is brought on behalf of the Class for violations of Sections 10(b) and 20(a) of the Securities

Exchange Act of 1934 (the "Exchange Act"), 15 U.S.C. §§ 78j(b) and 78t(a) and Rule 10b-5 promulgated thereunder by the SEC, 17 C.F.R. § 240.10b-5.

2. Trevena 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. Using its proprietary product platform, Trevena has identified four biased ligand product candidates, including oliceridine (TRV130) to treat moderate to severe acute pain intravenously.

3. Throughout the Class Period, Defendants made false and/or misleading statements, as well as failed to disclose material adverse facts about the Company's interactions with the FDA. Specifically, Trevena misled its shareholders to believe that its April 28, 2016 End-of-Phase 2 Meeting with the United States Food and Drug Administration ("FDA") was far more successful than it actually was. The Company did so by issuing a press release entitled "Trevena Announces Successful End-of-Phase 2 Meeting with FDA and Outlines Phase 3 Program for Oliceridine," on May 2, 2016, in which it announced that it had "reached general agreement" with the FDA on key elements of its Phase 3 program for oliceridine (TRV130) and was "very pleased" with the outcome of its discussions with the FDA. In reality, the FDA disagreed with Trevena on several key factors relating to whether oliceridine would ultimately be approved for commercial distribution. Trevena's filings therefore concealed the true risks faced by the Company in gaining ultimate FDA approval.

4. On October 9, 2018, two days ahead of Trevena's meeting with the FDA to determine whether oliceridine would be granted approval, the FDA released a Briefing Document related to Trevena. Contained in the Briefing Document are the minutes from the

FDA's April 28, 2016 meeting with Trevena which reveal, in stark contrast to the Company's prior statements, that the FDA:

- "did not agree with the proposed dosing in the Phase 3 studies";
- "did not agree with the proposed primary endpoint"; and
- "did not agree with the proposed non-inferiority (NI) margin for comparing morphine to oliceridine."

5. On this news, the Company's stock plummeted by $1.91 or 64%, to close at $1.07, eliminating over $145 million of Trevena's market capitalization.

6. Rather than stay silent regarding the April 28, 2016 meeting with the FDA, or disclosing the full picture to its investors, Defendants chose to present the investing public with the false impression that the meeting was successful, while concealing the negative information that was necessary to make the Company's statements about the meeting not misleading.

7. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class Members have suffered significant losses and damages.

## JURISDICTION AND VENUE

8. The federal law claims asserted herein arise under §§ 10(b) and 20(a) of the Exchange Act, 15 U.S.C. § 78j(b) and 78t(a), and Rule 10b-5 promulgated thereunder by the SEC, 17 C.F.R. § 240.10b-5, as well as under the common law.

9. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §1331 and § 27 of the Exchange Act, 15 U.S.C. § 78aa.

10. This Court has jurisdiction over each Defendant named herein because each Defendant is an individual or corporation who has sufficient minimum contacts with this District

so as to render the exercise of jurisdiction by the District Court permissible under traditional notions of fair play and substantial justice.

11. Venue is proper in this District pursuant to § 27 of the Exchange Act, 15 U.S.C. § 78aa and 28 U.S.C. § 1931(b), as the Company has its principal executive offices located in this District and conducts substantial business here.

12. In connection with the acts, omissions, conduct and other wrongs in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce including but not limited to the United States mail, interstate telephone communications and the facilities of the national securities exchange.

**PARTIES**

13. Plaintiff is an individual residing in North Carolina. Plaintiff acquired and held shares of the Company at artificially inflated prices during the class period and has been damaged by the revelation of the Company's material misrepresentations and material omissions.

14. Defendant Trevena is a Delaware corporation with its principal place of business in Chesterbrook, Pennsylvania. The Company trades on the NASDAQ stock exchange under the ticker symbol "TRVN" and claims that it 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."

15. Defendant Maxine Gowen ("Gowen") was the President, Chief Executive Officer and a director of Trevena from November 2007 until her retirement on October 1, 2018. Defendant Gowen continues to serve as a director for Trevena.

16. Defendant Roberto Cuca ("Cuca") was the Senior Vice President and Chief Financial Officer of Trevena from September 17, 2013 until his resignation on May 3, 2018.

17. Collectively, Gowen and Cuca are referred to throughout this complaint as the "Individual Defendants".

18. The Individual Defendants, because of their positions at the Company, possessed the power and authority to control the content and form of the Company's annual reports, quarterly reports, press releases, investor presentations, and other materials provided to the SEC, securities analysts, money and portfolio managers and investors, *i.e.*, the market. The Individual Defendants authorized the publication of the documents, presentations, and materials alleged herein to be misleading prior to its issuance and had the ability and opportunity to prevent the issuance of these false statements or to cause them to be corrected. Because of their position with the Company and access to material non-public information available to them but not to the public, the Individual Defendants knew that the adverse facts specified herein had not been disclosed to and were being concealed from the public and that the positive representations being made were false and misleading. The Individual Defendants are liable for the false statements pleaded herein.

## SUBSTANTIVE ALLEGATIONS

19. Trevena 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. Using its proprietary product platform, Trevena has identified four biased ligand product candidates, including oliceridine (TRV130) to treat moderate to severe acute pain intravenously.

20. The Class Period begins on May 2, 2016. On that day, Trevena issued a press release entitled "Trevena Announces Successful End-of-Phase 2 Meeting with FDA and Outlines Phase 3 Program for Oliceridine" and filed the same with the SEC on Form 8-K in which the Company announced that it had "reached general agreement" with the FDA on key elements of its Phase 3 program for oliceridine (TRV130) and was "very pleased" with the outcome of its discussions with the FDA. The May 2, 2016 press release provided:

> Trevena, Inc. (NASDAQ: TRVN), a clinical stage biopharmaceutical company focused on the discovery and development of biased ligands targeting G protein coupled receptors, today announced the successful completion of the End-of-Phase 2 Meeting Process with the United States Food and Drug Administration (FDA). **The company has reached general agreement with the FDA on key elements of the Phase 3 program** to support a New Drug Application (NDA) for oliceridine (TRV130), to which the FDA has granted Breakthrough Therapy designation.
>
> **"We are very pleased with the outcome of our End-of-Phase 2 discussion with the FDA,"** Maxine Gowen, Ph.D., chief executive officer. "We appreciate the valuable guidance the FDA has provided, and look forward to continuing a constructive relationship as we advance our Phase 3 registration program. We remain focused on bringing oliceridine to market as a new and potentially differentiated analgesic for patients and caregivers seeking alternatives to conventional opioids."
>
> **End-of-Phase 2 meeting**
>
> The FDA agreed that pivotal efficacy trials in bunionectomy and abdominoplasty patients include appropriate patient populations to support an indication for moderate to severe acute pain. The agency also confirmed the need for at least 1,100 patients exposed to oliceridine across the development program for the purposes of evaluating safety and tolerability. This database should include a sufficient number of patients with higher exposures and longer durations of oliceridine therapy. **In addition, general agreement was reached on the company's planned clinical, nonclinical,**

**clinical pharmacology, and chemistry, manufacturing and control (CMC) activities to support the planned NDA.**

21. These statements, including calling the meeting "successful," and stating that the Company was "pleased with the outcome" of the meeting were materially false and misleading when made, as they failed to disclose that at the meeting the FDA did not agree with the proposed dosing in the Phase 3 studies, did not agree with the proposed primary endpoint, and did not agree with the proposed non-inferiority (NI) margin for comparing morphine to oliceridine. Furthermore, the statement that the "company has reached general agreement with the FDA on key elements of the Phase 3 program," was false at the time it was made.

22. On May 5, 2016, Trevena filed with the SEC its Quarterly Report on Form 10-Q for the quarter ended March 31, 2016, in which the Company reiterated that "On May 2, 2016, the company announced the FDA's agreement to certain key elements of the company's Phase 3 program for oliceridine to support a proposed indication for the management of moderate-to-severe acute pain." These representations omitted the FDA's disagreements on key elements as revelated by the FDA on October 9, 2018. The omitted information was necessary in order to make the statements not misleading.

23. The Company's May 5, 2016 Form 10-Q was signed by Defendant Cuca and contained certifications pursuant to the Sarbanes-Oxley Act of 2002 ("SOX"), signed by Defendants Gowen and Cuca, who each certified:

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.

24. On August 4, 2016, Trevena filed with the SEC its Quarterly Report on Form 10-Q for the quarter ended June 30, 2016, in which the Company again stated, "On May 2, 2016, we announced U.S. Food and Drug Administration, or FDA, agreement to certain key elements of our Phase 3 program for oliceridine." These representations omitted the FDA's disagreements on key elements as revelated by the FDA on October 9, 2018. The omitted information was necessary in order to make the statements not misleading.

25. The Company's August 4, 2016 Form 10-Q was signed by Defendant Cuca and contained certifications pursuant to SOX, signed by Defendants Gowen and Cuca, substantially similar to the certifications described in ¶23, *supra*.

26. On March 8, 2017, Trevena filed with the SEC its Annual Report on Form 10-K for the year ended December 31, 2016, in which the Company stated:

> In the first quarter of 2016, we discussed our Phase 3 development program with the FDA at and End of Phase 2 meeting. At this meeting, the FDA agreed that pivotal efficacy trials in bunionectomy and abdominoplasty patients include appropriate patient populations to support an indication for the management of moderate-to-severe acute pain.
>
> The FDA also confirmed the need for at least 1,100 patients exposed to OLINVO[1] across the development program for the purposes of evaluating safety and tolerability and that the trials should include a

[1] OLINVO is the name that Trevena hopes to market oliceridine under.

> sufficient number of patients with higher exposures and longer durations of OLINVO therapy. **In addition, general agreement was reached on our planned clinical, nonclinical, clinical pharmacology, and chemistry, manufacturing and control activities to support the planned NDA.**

These representations omitted the FDA's disagreements on key elements as revealed by the FDA on October 9, 2018. The omitted information was necessary in order to make the statements not misleading.

27. The Company's March 8, 2017 Form 10-K was signed by Defendant Gowen and contained certifications pursuant to SOX, signed by Defendants Gowen and Cuca, substantially similar to the certifications described in ¶23, *supra*.

***The Truth is Revealed***

28. The truth was finally revealed October 9, 2018, when the FDA issued its Briefing Document ahead of its scheduled meeting with Trevena to determine whether oliceridine would be granted approval for commercial use. Among other items, the Briefing Document contained the minutes from the FDA's April 28, 2016 meeting with Trevena—the meeting that Trevena used as the basis for its May 2, 2016 press release. Far from being a great success with general agreement on key elements, the FDA minutes revealed that the agency:

- "did not agree with the proposed dosing in the Phase 3 studies";
- "did not agree with the proposed primary endpoint"; and
- "did not agree with the proposed non-inferiority (NI) margin for comparing morphine to oliceridine."

29. An article entitled "Trevena shares sink on FDA concerns ahead of key panel meeting," published in BioPharma Dive: Biotech and Pharma Industry News on October 9, 2018, explains:

> **Investors typically pore over FDA briefing documents, which are published by the agency two days before advisory committee meetings.** Staffed by experts, the panels make recommendations to the FDA for or against approval of certain experimental drugs. **Sometimes these documents offer few new insights into the agency's thinking on a particular drug. In this case, it was clear FDA staff had several concerns about Trevena's trial design and results.**
> . . .
>
> But key to Trevena's case is the company's claim that oliceridine's more selective mechanism of action makes it safer than conventional opioids, with less respiratory depression and nausea.
>
> On this point, **it turns out, the FDA never agreed to Trevena's plans for measuring the superiority of oliceridine to morphine in terms of respiratory safety burden**. Further, in both randomized studies, Trevena's drug did not demonstrate a significant lowering in the expected cumulative duration of respiratory safety events versus morphine, FDA staff wrote.
>
> . . .
>
> **Respiratory safety burden wasn't the only thing the FDA saw differently than Trevena either. The documents disclosed the agency had a number of disagreements with the biotech in an April 2016 meeting** and a November 2016 teleconference.
>
> **An announcement made by Trevena following the April sit-down gave investors no hints of the differences in view.**

30. These adverse facts, which stand in stark contrast to the Company's May 2, 2016 press release, were known to Defendants for more than two years and hidden from the investing public until the FDA disclosed the information.

31. Trevena's stock price cratered in the aftermath of these disclosures. After closing at $2.98 on October 8, 2018, the Company's stock price dropped to $1.07 per share on October 9, 2018—a 64% drop.

## CLASS ACTION ALLEGATIONS

32. Plaintiff brings this action as a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of a class of all persons and entities who purchased or otherwise acquired Trevena common stock between May 2, 2016 and October 8, 2018, inclusive. Excluded from the Class are Defendants, directors and officers of the Company, as well as their families and affiliates.

33. The members of the Class are so numerous that joinder of all members is impracticable. The disposition of their claims in a class action will provide substantial benefits to the parties and the Court.

34. There is a well-defined community of interest in the questions of law and fact involved in this case. Questions of law and fact common to the members of the Class which predominate over questions which may affect individual Class members include:

a. Whether the Exchange Act was violated by Defendants;

b. Whether Defendants omitted and/or misrepresented material facts;

c. Whether Defendants' statements omitted material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading;

d. Whether Defendants knew or recklessly disregarded that their statements were false and misleading;

e. Whether the price of the Company's stock was artificially inflated; and

f. The extent of damage sustained by Class members and the appropriate measure of damages.

35. Plaintiff's claims are typical of those of the Class because Plaintiff and the Class sustained damages from Defendants' wrongful conduct alleged herein.

36. Plaintiff will adequately protect the interests of the Class and has retained counsel who are experienced in class action securities litigation. Plaintiff has no interests that conflict with those of the Class.

37. A class action is superior to other available methods for the fair and efficient adjudication of this controversy.

**FRAUD ON THE MARKET**

38. Plaintiff will rely upon the presumption of reliance established by the fraud-on-the-market doctrine that, among other things:

a. Defendants made public misrepresentations or failed to disclose material facts during the Class Period;

b. The omissions and misrepresentations were material;

c. The Company's common stock traded in efficient markets;

d. The misrepresentations alleged herein would tend to induce a reasonable investor to misjudge the value of the Company's common stock; and

e. Plaintiff and other members of the class purchased the Company's common stock between the time Defendants misrepresented or failed to disclose material facts and the time that the true facts were disclosed, without knowledge of the misrepresented or omitted facts.

39. At all relevant times, the markets for the Company's stock were efficient for the following reasons, among others: (i) the Company filed periodic public reports with the SEC;

and (ii) the Company regularly communicated with public investors via established market communication mechanisms, including through regular disseminations of press releases on the major news wire services and through other wide-ranging public disclosures such as communications with the financial press, securities analysts, and other similar reporting services. Plaintiff and the Class relied on the price of the Company's common stock, which reflected all information in the market, including the misstatements by Defendants.

**NO SAFE HARBOR**

40. The statutory safe harbor provided for forward-looking statements under certain conditions does not apply to any of the allegedly false statements pleaded in this Complaint. The specific statements pleaded herein were not identified as forward-looking statements when made.

41. To the extent there were any forward-looking statements, there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements.

**LOSS CAUSATION**

42. Prior to the market opening, on October 9, 2018, the FDA disclosed disagreements from its April 28, 2016 meeting with Trevena, contrary to the Company's public statements made beginning on May 2, 2016 and described above. By the time the market closed on October 9, 2018, the Company's stock had declined by $1.91, or 64%. This decline is directly attributable to the October 9, 2018 corrective FDA Briefing Document.

## CAUSES OF ACTION

### Count I
### Violation of § 10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder (Against All Defendants)

43. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein.

44. During the Class Period, Defendants disseminated or approved the false statements specified above, which they knew or deliberately disregarded were misleading in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

45. Defendants violated § 10(b) of the Exchange Act and Rule 10b-5 in that they (i) employed devices, schemes, and artifices to defraud; (ii) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and (iii) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon those who purchased or otherwise acquired the Company's securities during the class period.

46. Plaintiff and the Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for the Company's common stock. Plaintiff and the Class would not have purchased the Company's common stock at the price paid, or at all, if they had been aware that the market prices had been artificially and falsely inflated by Defendants' misleading statements.

**Count II**
**Violation of § 20(a) of the Exchange Act**
**(Against The Individual Defendants)**

47. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein.

48. The Individual Defendants acted as controlling persons of the Company within the meaning of § 20(a) of the Exchange Act as alleged herein. By virtue of their high-level positions at the Company, the Individual Defendants had the power and authority to cause or prevent the Company from engaging in the wrongful conduct complained of herein. The Individual Defendants were provided with or had unlimited access to the documents were false or misleading statements were made and other statements alleged by Plaintiffs to be false or misleading both prior to and immediately after their publication, and had the ability to prevent the issuance of those materials or to cause them to be corrected so as not to be misleading.

**PRAYER FOR RELIEF**

WHEREFORE, Plaintiff prays for relief and judgment, as follows:

(a) determining that this action is a proper class action pursuant to Rule 23(a) and 23(b)(3) of the Federal Rules of Civil Procedure on behalf of the Class as defined herein, and a certification of Plaintiff as class representative pursuant to Rule 23 of the Federal Rules of Civil Procedure and appointment of Plaintiff's counsel as Lead Counsel;

(b) awarding compensatory and punitive damages in favor of Plaintiff and the other class members against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including pre-judgment and post-judgment interest thereon.