UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

WESLEY LOUIS, on Behalf of Himself and All Others Similarly Situated, Plaintiff, vs. TREVENA, INC., MAXINE GOWEN, DAVID SOERGEL, CARRIE BOURDOW, JONATHAN VIOLIN and ROBERTO CUCA, Defendants.	Civil Action No. COMPLAINT – CLASS ACTION DEMAND FOR JURY TRIAL

Plaintiff Wesley Louis ("Plaintiff"), on behalf of himself and all other persons similarly situated, by Plaintiff's undersigned attorneys, for Plaintiff's complaint against defendants, alleges the following based upon personal knowledge as to Plaintiff and Plaintiff's own acts, and upon information and belief as to all other matters based on the investigation conducted by and through Plaintiff's attorneys, which included, among other things, a review of Securities and Exchange Commission ("SEC") filings by Trevena, Inc. ("Trevena" or the "Company"), as well as conference call transcripts and media and analyst reports about the Company. Plaintiff believes that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. This is a securities class action on behalf of all purchasers of Trevena common stock between May 2, 2016 and October 9, 2018, inclusive (the "Class Period"), seeking to pursue remedies against Trevena and certain of its most senior executives under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act"), and Rule l0b-5 promulgated thereunder.

2. Defendant Trevena is a clinical stage biopharmaceutical company. At the start of the Class Period, the Company's most advanced drug under development was Olinvo (a/k/a "Oliceridine" and "TRV130"), an intravenous pain reliever which was undergoing a Phase III clinical trial for the treatment of moderate-to-severe postoperative pain after surgery. According to Trevena, its Phase II clinical trial for Olinvo had demonstrated that Olinvo was superior to the then-standard of care for post-surgery pain reduction, morphine. Trevena also claimed that once approved for commercial distribution, it planned to price Olinvo higher than morphine, because Olinvo purportedly caused less costly adverse effects than morphine, such as respiratory problems, nausea and vomiting.

3. Unbeknownst to investors, the U.S. Food and Drug Administration ("FDA") had expressly warned Trevena, however, prior to the start of the Class Period, of many defects in the design of its Phase III clinical trial – ***design defects Trevena refused to remedy*** – that threatened to render the data derived in the Phase III clinical trial worthless. As a result, the Company's prospects of obtaining FDA approval for commercial distribution of Olinvo, and its eventual commercial successes, were much lower than defendants were leading the market to believe throughout the Class Period.

4. Based on defendants' Class Period materially misleading statements and omissions concerning the strength of its clinical development program, the design of its Phase III Olinvo clinical trial and its prospects for obtaining FDA approval to commercially distribute Olinvo and the drug's financial prospects, the price of Trevena common stock traded at artificially inflated prices throughout the Class Period, trading above $8 per share on May 10, 2016.

5. When the Company disclosed the results of the Phase III clinical trial of Olinvo on February 21, 2017, the data did not show that Olinvo caused any meaningfully less adverse effects than morphine. On this news, the price of Trevena common stock plummeted approximately 40%, or $3 per share, on February 21, 2017, on unusually heavy trading of more than 10.5 million shares trading.

6. Then, on October 9, 2018, the FDA made public its prior criticisms of the design of the Phase III clinical trial and disclosed that its Advisory Committee was recommending that the FDA reject the Company's New Drug Application ("NDA") for Olinvo. On this news, the price of Trevena common stock plummeted another 64%, almost $2 per share, on October 9, 2018, again on unusually high trading of more than 40 million shares trading.

7. On October 11, 2018, trading in Trevena common stock was halted on pending news. Later that day, the Company disclosed that the FDA Advisory Committee had voted against approving Olinvo. While Trevena contended that "[t]he FDA [was] not bound by the Advisory Committee's recommendations" that day, it also acknowledged that the FDA "takes its advice into consideration when making its decision." When trading recommenced on October 12, 2018, the stock price dropped another 7%, closing below $1 per share, on unusually high trading of more than 12 million shares.

8. Finally, on Friday November 2, 2018, Trevena disclosed that the FDA had formally rejected its NDA for Olinvo, with the FDA stating in its complete response letter that the safety data was not adequate.

JURISDICTION AND VENUE

9. Jurisdiction is conferred by Section 27 of the Exchange Act. The claims asserted herein arise under Sections 10(b) and 20(a) of the Exchange Act, 15 U.S.C. §§ 78j(b) and 78t(a), and Rule 10b-5 promulgated thereunder, 17 C.F.R. § 240.10b-5. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. § 1331 and Section 27 of the Exchange Act, 15 U.S.C. § 78aa.

10. Venue is proper in this District pursuant to Section 27 of the Exchange Act, 15 U.S.C. § 78aa, and 28 U.S.C. § 1391(b) as many of the false and misleading statements alleged herein were disseminated from this District.

11. In connection with the acts alleged in this Complaint, defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications and the facilities of the national securities markets.

PARTIES

12. Plaintiff Wesley Louis, as set forth in the accompanying Certification, which is incorporated by reference herein, purchased Trevena common stock during the Class Period and has been damaged thereby.

13. Defendant Trevena is a development stage biopharmaceutical company. As of July 31, 2018, the Company had more than 76 million shares of common stock issued and outstanding, which trade in an efficient market on the NASDAQ under the ticker symbol "TRVN."

14. Defendant Maxine Gowen ("Gowen") was the Chief Executive Officer ("CEO") of Trevena from the beginning of the Class Period until she announced she was retiring on April 4, 2018, effective on or about October 1, 2018.

15. Defendant David Soergel ("Soergel") was the Chief Medical Officer of Trevena from the beginning of the Class Period until he announced he was resigning in July 2017.

16. Defendant Carrie Bourdow ("Bourdow") was the Senior Vice President and Chief Commercial Officer of Trevena until she was appointed its CEO upon Defendant Gowen's resignation, effective October 1, 2018.

17. Defendant Jonathan Violin ("Violin") is, and was throughout the Class Period, both a Co-Founder, a Senior Vice President of Scientific Affairs and the Senior Director of Investor Relations of Trevena.

18. Defendant Roberto Cuca ("Cuca") is, and was throughout the Class Period, a Senior Vice President and the Chief Financial Officer of Trevena.

19. Defendants Gowen, Soergel, Bourdow, Violin and Cuca are referred to herein as the "Individual Defendants." Trevena and the Individual Defendants are referred to herein, collectively, as "Defendants."

CLASS ACTION ALLEGATIONS

20. Plaintiff brings this action as a class action pursuant to Federal Rules of Civil Procedure 23(a) and (b)(3) on behalf of a class consisting of all purchasers of the common stock of Trevena during the Class Period (the "Class"). Excluded from the Class are Defendants, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

21. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Trevena common stock was actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can only be ascertained through appropriate discovery, Plaintiff believes that there are hundreds of thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Trevena and/or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

22. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

23. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation.

24. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

(a) whether the Exchange Act was violated by Defendants as alleged herein;

(b) whether statements made by Defendants misrepresented material facts about the business, operations and management of Trevena; and

(c) to what extent the members of the Class have sustained damages and the proper measure of damages.

25. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

SUBSTANTIVE ALLEGATIONS

26. Defendant Trevena is a clinical stage biopharmaceutical company headquartered in Chesterbrook, Pennsylvania. The Company is involved in the discovery and development of G-protein coupled receptors ("GPCR") biased ligands. Trevena claims that its expertise lies in engineering "biased ligands" that activate only the beneficial signaling pathways downstream of a GPCR to unlock new biology and purportedly avoid drug adverse effects.

27. At the start of the Class Period, Trevena's leading drug candidate was Olinvo, a G protein-biased ligand binding to the mu opioid receptor for the intravenous treatment of acute moderate-to-severe postoperative pain. On August 31, 2015, Trevena issued a press release announcing the Phase II clinical results, which purportedly demonstrated greater effectiveness than morphine in treating post-operative pain, with less opioid-related adverse effects ("ORAEs"), such as nausea, vomiting and respirtory problems. The August 31, 2015 release stated, in pertinent part, as follows:

> "The data from this trial showed that TRV130, when given on-demand, matched morphine efficacy for pain relief with a markedly improved safety and tolerability

profile," said Neil Singla, M.D., chief scientific officer of Lotus Clinical Research and lead investigator of the study.

"The challenges of safely and adequately titrating morphine are well recognized, and these data suggest that, if approved, TRV130 may provide a better option than currently available opioid analgesics."

28. The press release represented that the Phase II clinical trial "TRV130 demonstrated statistically significant pain reduction compared to placebo and comparable efficacy to morphine" and emphasized the drug's superiority in reducing side effects compared to morphine. The release also stated in pertinent part as follows:

Safety and tolerability

- In this study, the TRV130 groups had a significantly lower prevalence (percentage of patients) of hypoventilation events (a measure of respiratory safety), nausea, and vomiting than the morphine group (post hoc $p<0.05$ for both TRV130 regimens vs. morphine).

	Placebo	TRV130 0.1 mg	TRV130 0.35 mg	Morphine
Hypoventilation	10%	15%	31%	53%
Vomiting	8%	15%	15%	42%
Nausea	18%	41%	46%	72%

29. Defendant Gowen was quoted in the press release emphasizing that "[t]he positive data from this study continue the impressive accumulation of evidence suggesting meaningful differentiation of TRV130 from morphine," that "[t]he goal of new analgesic drug discovery has long been the provision of more powerful pain relief with reduced opioid-related adverse effects."

30. On January 19, 2016, Trevena issued a press release entitled "Trevena, Inc. Announces Initiation of Oliceridine Phase 3 Clinical Program." The release stated in pertinent part as follows:

Trevena … today announced the launch of the oliceridine (TRV130) Phase 3 clinical program with the enrollment of patients in the open label Phase 3 ATHENA-1 study. This study will evaluate the safety and tolerability of oliceridine in patients with acute moderate-to-severe pain in a variety of clinical settings.

ATHENA-1 is a Phase 3 open label, multicenter study evaluating the safety and tolerability of oliceridine in approximately 900 patients. The study will enroll eligible patients with moderate to severe pain caused by medical conditions or surgery.

> Patients will be treated with oliceridine on an as-needed basis via IV bolus, patient-controlled analgesia (PCA) administration, or both, as determined by the investigator. The primary objective is to assess the safety and tolerability of oliceridine. Pain intensity will be measured as a secondary endpoint.
>
> ***The Company also announced that an End-of-Phase 2 meeting with FDA has been scheduled for later this quarter. In the second quarter, the Company expects to communicate additional details of its Phase 3 development program, including details of its pivotal studies of oliceridine in acute moderate-to-severe pain.***
>
> "We are pleased to announce the start of our Phase 3 program with the initiation of ATHENA-1, which will provide data on the safety profile of oliceridine in a wide range of settings," said Maxine Gowen, Ph.D., chief executive officer. "We also look forward to discussing the oliceridine Phase 3 program with the FDA later this quarter, ***and remain on track to file an NDA for oliceridine in the second half of 2017***."

31. Unbeknownst to investors, Trevena had a series of meetings with the FDA during the last several months of 2015 and the first several months of 2016 to discuss the Company's clinical development plan, specifically the design of its Phase III clinical trial of Olinvo. During those meetings, the FDA delivered several pointed criticisms of the clinical development program and the design of the Phase III clinical trial for Olinvo – which threatened to render the Phase III clinical data for Olinvo less than satisfactory to the FDA for purposes of eventually supporting an NDA for Olinvo. According to the FDA's later-published description of those communications:

> **October 3, 2014 – Type C (written responses only)**
>
> FDA provided recommendations regarding the assessment of patients who are poor metabolizers at the CYP2D6 receptor and the proposed dosing paradigm for the Phase 2 study, CP130-2002.
>
> **December 2, 2015 – Fast Track Designation**
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> Fast track designation of oliceridine for the management of moderate-to-severe acute pain where use of IV opioid analgesics is appropriate was granted on December 2, 2015. Fast track was granted based on the potential ability to provide benefits similar to those of alternatives with a more favorable adverse event profile.

February 21, 2016 – Initial PSP

Non-agreement with the initial Pediatric Study Plan (iPSP) due to multiple issues, including the study design (which needed to be changed to an add-on design) and dose selection.

March 3, 2016 – Advice regarding ECGs – Written Advice

FDA issued written advice to the Applicant because QTcF prolongation exceeded the 10-ms regulatory threshold at clinically relevant exposures. The Applicant was instructed to submit amendments to modify all protocols for ongoing clinical trials to include the following safety assessments, and incorporate them into any future clinical trials:

1. Conduct safety ECG monitoring at baseline, following the first dose, and periodically thereafter. The timing of ECGs will need to reflect the delayed response relative to time of peak concentrations that was observed in the thorough QT study. Include additional ECG monitoring until ECGs return to baseline in patients discontinued from the trial or requiring dose reduction due to QTc interval prolongation.

2. Periodic monitoring of electrolytes (subjects already participating in the study with serum potassium, magnesium, or calcium levels outside of the central laboratory's reference range should be carefully monitored and brought to normal values).

3. Propose dose-modification and discontinuation criteria in subjects with posttreatment QTc > 500 ms or post-baseline increases > 60 ms.

March 29, 2016 (meeting minutes April 28, 2016) – End-of-Phase 2 Meeting

- FDA did not agree with the proposed dosing in the Phase 3 studies. The Sponsor proposed dosing up to 100 mg daily (including a 0.75 mg every 1 hour as needed clinician administered dose), but had only studied maximum daily doses of 36.8 mg. Further, the Sponsor did not have adequate non-clinical support for the proposed doses.

- FDA did not agree with the proposed primary endpoint, as it was unclear how a 30% improvement from baseline based on SPID correlates to an improvement in pain intensity scores on the NRS in the proposed setting of acute postoperative pain and if that change is clinically relevant.

- FDA did not agree with the proposed non-inferiority (NI) margin for comparing morphine to oliceridine.

- FDA noted that the safety database must include at least 350 patients exposed to the highest intended dose for the longest expected duration of use. It was

noted that the safety database requirements might change if safety signals arise during development that require further evaluation.

- Any comparative safety claims must be replicated, adequately justified for clinical relevance, and established in the setting of comparable efficacy between comparators to be considered for inclusion in labeling[.]

- The Applicant provided details of a proposed approach to missing data. This approach included replacing pain scores in the window determined dosing interval described in the label of the rescue medication following rescue with the pain score recorded immediately prior to rescue.

April 25, 2016 – Proprietary Name Request Conditionally Accepted

- The proposed proprietary name, Olinvo, was concluded to be conditionally acceptable.

32. The Class Period starts on May 2, 2016. On that day, Trevena issued a press release entitled "Trevena Announces ***Successful End-of-Phase 2 Meeting with FDA***[1] and Outlines Phase 3 Program for Oliceridine." The release stated in pertinent part as follows:

– Pivotal efficacy studies to start in 2Q 2016, with topline data expected in 1Q 2017, and NDA filing expected in 2H 2017 –

– Phase 3 program includes comparisons to both placebo and morphine –

– Webcast and call scheduled for today at 5:30 pm EDT –

. . . Trevena . . . 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," said 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

[1] Unless otherwise noted, all emphases herein are added.

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.

Overview of the Oliceridine Phase 3 program

- The oliceridine Phase 3 program includes two pivotal efficacy trials evaluating moderate-to-severe acute pain: the APOLLO-1 study will evaluate pain for 48 hours following bunionectomy, and the APOLLO-2 study will evaluate pain for 24 hours following abdominoplasty. In each trial, patients will be randomized to receive placebo, morphine, or one of three regimens of oliceridine by patient-controlled analgesia (PCA) for the management of their post-operative pain. Each study will enroll approximately 375 patients, allocated equally across study arms.

- ***The primary endpoint for both APOLLO studies will be a responder analysis proposed by the company comparing active treatment arms to placebo. A responder is defined as a patient experiencing a sum of pain intensity difference (SPID) at the end of the treatment period that corresponds to at least a 30% improvement from baseline without early discontinuation and without rescue pain medication.***

- ***Secondary endpoints in both APOLLO studies will include comparisons of oliceridine efficacy, safety, and tolerability to morphine.*** A respiratory safety endpoint will measure prevalence and duration of hypoventilation, which will be a clinical assessment as in the company's Phase 2b abdominoplasty study.

- The APOLLO study designs were informed in part by the company's Phase 2b abdominoplasty study, which also used PCA dosing. Powering assumptions included similar performance of PCA-administered oliceridine in both APOLLO studies as was observed in the Phase 2b study. In a post-hoc evaluation using the Phase 3 responder analysis, both doses in the company's Phase 2b study in abdominoplasty yielded analgesic efficacy similar to morphine, and significantly higher than placebo ($p \leq 0.0005$ for both oliceridine treatment arms). In addition, using the Phase 3 respiratory safety endpoint, both doses in the company's Phase 2b study showed significantly less respiratory safety burden for oliceridine than morphine ($p \leq 0.0003$ for both oliceridine treatment arms).

- The development program will include at least 1,100 patients exposed to oliceridine. The on-going open-label ATHENA-1 safety study is enrolling patients experiencing pain as a result of either a medical diagnosis or surgery. In this study, patients may receive oliceridine as-needed either as an intermittent bolus or via PCA device, with doses and durations appropriate to manage their pain.

Both APOLLO-1 and APOLLO-2 are expected to start in the second quarter of this year, and the company expects to report top-line data in the first quarter of 2017. The company continues to expect to file an NDA for oliceridine in the second half of 2017. The company also continues to expect that its available cash and investments will be sufficient to fund operations into 2018.

33. Defendants Violin, Gowen and Soergel conducted a conference with investors and stock analysts that same day. During her opening remarks, Defendant Gowen lauded the design of the Phase III clinical trial of Olinvo to demonstrate its efficacy and safety superiority over morphine, stating in pertinent part as follows:

> As many of you know, oliceridine is the first pain program awarded breakthrough therapy designation by the FDA. We were granted this important distinction on the basis of our Phase 2 data in which oliceridine matched the pain relieving power of morphine ***but with faster onset, less nausea and vomiting, and fewer respiratory safety events.***
>
> This has supported what we've long believed about oliceridine. It is a new class of analgesic molecule, muGPS, that harnesses innovative science to offer the potential for powerful pain relief with better safety and tolerability than conventional opioid analgesics like morphine. ***We welcome the opportunity to work with the FDA to finalize our Phase III plans. I am pleased to report that we had a very productive and collaborative and successful discussion of our oliceridine program with the FDA. This was the only helpful as we transition the program into Phase III, but I'm sure will be invaluable as we continue our conversation through the NDA.***

34. On May 5, 2016, Trevena issued a press release announcing its first quarter 2016 financial results for the interim period ended March 31, 2016. Concerning the status of the Company's Phase III clinical trial of Olinvo, the release stated in pertinent part as follows:

> "The first quarter set the stage for a critical year in Trevena's evolution," said Maxine Gowen, Ph.D., chief executive officer. "***We had a successful End-of-Phase 2 discussion of oliceridine with the FDA, and look forward to completing our ongoing Phase 3 program aimed at both approval and differentiation of oliceridine for moderate to severe acute pain.*** . . .

First Quarter and Recent Highlights

- **Received Breakthrough Therapy Designation for oliceridine.** In February, the U.S. Food and Drug Administration (FDA) granted Breakthrough Therapy designation to the company's lead product candidate, intravenous oliceridine (TRV130), for the management of moderate-to-severe acute pain. Breakthrough Therapy designation is granted by the FDA to new therapies intended to treat serious conditions, and for which preliminary clinical evidence indicates that the drug may demonstrate substantial clinical improvement over available therapies. The company believes this is the first Breakthrough Therapy designation for a pain therapy.

- ***Conducted a successful End-of-Phase 2 meeting for oliceridine with the FDA and announced details of the Phase 3 clinical program.*** Earlier this week, the company announced that it had ***reached agreement with the FDA on key elements of the Phase 3 program*** to support a New Drug Application (NDA) for oliceridine. The company also provided additional details of the Phase 3 clinical program, which will include two 375-patient, randomized, double-blind, placebo- and active-controlled, pivotal efficacy trials: the APOLLO-1 study, which will evaluate pain for 48 hours following bunionectomy; and the APOLLO-2 study, which will evaluate pain for 24 hours following abdominoplasty. In each trial, patients will be randomized to receive placebo, morphine, or one of three regimens of oliceridine by patient-controlled analgesia (PCA) for the management of their post-operative pain, with approximately 75 patients enrolled per study arm. ***The primary endpoint for both APOLLO studies will be a responder analysis comparing active treatment arms to placebo. Secondary endpoints in both APOLLO studies will include comparisons of oliceridine efficacy, safety, and tolerability to morphine.***

In January, the company initiated the Phase 3 clinical program with the enrollment of patients in the open label ATHENA study, which is evaluating the safety and tolerability of oliceridine in patients with moderate-to-severe acute pain caused by medical conditions or surgery. Patients will be treated with oliceridine on an as-needed basis via IV bolus, PCA administration, or both, as determined by the investigator.

The company expects to start the APOLLO studies in the second quarter of this year, and to report top-line data from these studies in the first quarter of 2017. The company continues to expect to file an NDA in the second half of 2017.

35. On May 6, 2016, unbeknownst to investors, Trevena met with the FDA concerning the design of its Phase III clinical trial, and according to the FDA's later-published description of those communications:

May 6, 2016 – The Applicant submitted a Justification for their Responder Definition

- Trevena provided their justification for a 30% improvement in pain from baseline. In an analysis of Study QS130-3002, the Applicant found an average percent improvement from baseline of 18% for placebo and 44% for morphine. Trevena justified the 30% improvement by stating that it was approximately the midpoint between the placebo and morphine.

36. On June 8, 2016, Trevena issued a press release entitled "Trevena, Inc. Announces First Patients Enrolled in the APOLLO-1 and APOLLO-2 Phase 3 Pivotal Efficacy Studies of Oliceridine in Acute Pain." The release stated in pertinent part as follows:

– Trials include comparisons of efficacy, safety and tolerability of oliceridine to both placebo and morphine –

– Top-line data for both studies expected in 1Q 2017 –

Trevena . . . today announced the enrollment of the first patients in the Phase 3 APOLLO-1 and APOLLO-2 studies of oliceridine in patients suffering moderate to severe acute pain following bunionectomy and abdominoplasty, respectively.

"We are pleased to announce the start of the APOLLO studies, ***which we designed both to support approval of oliceridine and to confirm the potential differentiation of oliceridine from conventional opioids***," commented Maxine Gowen, Ph.D., chief executive officer. ***"The trials recapitulate many features of our successful Phase 2 studies, with refinements based on the full Phase 2 data set that we believe strengthen the study designs and improve our probability of success.*** Together with the ongoing ATHENA Phase 3 safety study, ***we believe the APOLLO studies position us to deliver a robust data package to support regulatory approval and commercial success***."

The company continues to expect to report top-line data from both APOLLO studies in the first quarter of 2017, and to file an NDA for oliceridine in the second half of 2017. The company also continues to expect that its available cash and investments will be sufficient to fund operations into 2018.

About the APOLLO-1 and APOLLO-2 Studies

Both APOLLO trials are phase 3, multicenter, randomized, double-blind, placebo- and active-controlled studies of oliceridine for the treatment of moderate to severe acute pain. The APOLLO-1 study will evaluate pain for 48 hours following bunionectomy, and the APOLLO-2 study will evaluate pain for 24 hours following abdominoplasty. In each trial, patients will be randomized to receive placebo, morphine, or one of three regimens of oliceridine by patient-controlled analgesia

> (PCA) device for the management of their post-operative pain. Each study will enroll approximately 375 patients, allocated equally across study arms. ***The primary objective in each study is to evaluate the analgesic efficacy of oliceridine compared to placebo. Secondary endpoints will include comparisons of oliceridine efficacy, safety, and tolerability to morphine.***

37. Later that day, Defendant Gowen presented for Trevena at the Jefferies Healthcare Conference. During her opening remarks, Defendant Gowen again emphasized that the "statistically significant" improvement in efficacy and safety in the Phase II results supported the design of the Phase III clinical trial, stating in pertinent part as follows:

> So this breakthrough therapy designation was the first that had ever been given to a pain drug . . . .
>
> Just to remind you of the qualifying criteria, that the drug is intended to treat a serious condition, clearly pain falls into that category. ***And there is preliminary clinical evidence indicating the drug may demonstrate substantial improvement on a clinically significant endpoint or endpoints over available therapies***. ***And here the FDA was considering its differentiation to conventional opioid drugs.***
>
> So there is still a strong need that physicians express for better and safer options to treat acute pain. It still remains undertreated despite the introduction of so-called multimodal therapy, which is the addition of other therapies onto opioid therapies.
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> * * *
>
> One of the reasons for this under treatment of pain is because conventional opioids, which are the foundation of pain therapy, are used sparingly because of their side effects. Post-operatively we see nausea and vomiting in a high percentage of patients. This is very distressing and uncomfortable for the patients.
>
> But we also see a safety issue with respect to respiratory depression. And there is a high incidence of respiratory depression or rather a high number even though the incidence is relatively low. And this can certainly be fatal and it is fatal in tens of thousands of patients every year in the United States.
>
> So, oliceridine, acting through this biased ligand approach, activates the G protein pathway in this case, which is the pathway leading to analgesic efficacy, very low levels of activation of the beta-arrestin pathway. And this leads to an enhancement of analgesia, a decrease in the opioid-related adverse events, significantly increasing the therapeutic window of the drug.
>
> So the goal is to find doses of the drug that are highly efficacious but have significantly reduced side effects. And that is indeed what we showed recently in a Phase 2b clinical trial.

* * *

So we are looking at three effects: nausea, vomiting and hypoventilation. And hypoventilation is a measure of respiratory suppression. So these were a lot less prevalent in the oliceridine treated patients than with morphine for all three of these. And they were indeed statistically significantly less than the incidence with morphine.

And these are both statistically meaningful and clinically very meaningful reductions inside -- in these key side effects. ***So, we really believe that we have breakthrough potential of oliceridine versus the conventional IV opioids. We have great efficacy. We have excellent precision.***

…. And in terms of safety we are seeing less hypoventilation, less nausea and less vomiting with oliceridine.

So, we had an end of Phase 2 meeting with the FDA at the very end of March. ***And we reached agreement with them that we have shown sufficient data to move into Phase 3. The program that we proposed to them they agreed would support an approval -- could support, I should say given that the data are correct, could support an approval for the target indication.***

* * *

The key elements of the Phase 3 program are two pivotal efficacy studies with PCA dosing as I -- in the study that I just showed you in Phase 2, to support efficacy. And these two studies will be performed in the two surgical types that we already studied in Phase 2 with successful outcomes. So, bunionectomy is a hard tissue, abdominoplasty a soft tissue. And this is what allows us to get this broad label.

38. On June 21, 2016, Defendants Soergel and Violin presented for Trevena at the JPM Securities Life Sciences Conference making additional positive statements about how the Phase III clinical trial had been designed to demonstrate comparably as strong of efficacy and safety results as those demonstrated in the Phase II clinical trial, the design to which the FDA had purportedly agreed.

39. On August 4, 2016, Trevena issued a press release announcing its second quarter 2016 financial results for the interim period ended June 30, 2016. Concerning the status of the Company's Phase III clinical trial of Olinvo, the release stated in pertinent part as follows:

"This quarter marked an important milestone for the company's oliceridine program with the initiation of our two Phase 3 pivotal efficacy trials," said Maxine Gowen, Ph.D., chief executive officer. "***Following our successful End-of-Phase-2 and Breakthrough Therapy designation meeting with the FDA in the first quarter***, we were able to rapidly initiate the pivotal efficacy trials, which are enrolling well."

Second Quarter and Recent Highlights

- **Enrolled first patients in APOLLO-1 and APOLLO-2 Phase 3 trials of oliceridine.** In June, the company announced the enrollment of the first patients in the APOLLO-1 and APOLLO-2 pivotal Phase 3 efficacy studies. APOLLO-1 is studying patients suffering moderate to severe pain for 48 hours after undergoing bunionectomy, while APOLLO-2 is studying patients suffering moderate to severe pain for 24 hours after undergoing abdominoplasty; both are 375-patient, multicenter, randomized, double-blind, placebo- and active-controlled studies. Patients are randomized to receive placebo, morphine, or one of three oliceridine regimens, all dosed as needed via patient-controlled analgesia (PCA) device for the management of their post-operative pain, with approximately 75 patients per study arm. ***The primary objective of both trials is to evaluate the analgesic efficacy of oliceridine versus placebo. Secondary endpoints compare the efficacy, safety, and tolerability of oliceridine to morphine***. The company continues to expect to release top-line data in the first quarter of 2017 and to file an NDA in the second half of 2017.

40. On November 3, 2016, Trevena issued a press release announcing its third quarter 2016 financial results for the interim period ended October 31, 2016. Concerning the status of the Company's Phase III clinical trial of Olinvo, the release stated in pertinent part as follows:

"This quarter saw important progress for our company, ***with continued execution of our Phase 3 program for oliceridine***. We had extensive engagement with the medical community to discuss the challenges of acute pain management in the hospital and how oliceridine may provide an important treatment option to patients and physicians," said Maxine Gowen, Ph.D., chief executive officer. "We look forward to sharing top-line data from both Phase 3 APOLLO pivotal efficacy studies in the first quarter of 2017, and filing an NDA in the second half of next year."

Third Quarter and Recent Highlights

• **APOLLO-1 and APOLLO-2 Phase 3 efficacy trials of oliceridine remain on track for first quarter 2017 topline data release.** The APOLLO-1 trial includes patients suffering moderate to severe pain after undergoing bunionectomy, while the APOLLO-2 trial includes patients suffering moderate to severe pain after undergoing abdominoplasty; both are 375-patient, multicenter, randomized, double-blind, placebo- and active-controlled studies. Patients are randomized to receive placebo,

> morphine, or one of three oliceridine regimens, all dosed as needed via patient-controlled analgesia (PCA) device for the management of their post-operative pain, with approximately 75 patients per study arm. ***The primary objective of both trials is to evaluate the analgesic efficacy of oliceridine versus placebo***. ***Secondary endpoints compare the efficacy, safety, and tolerability of oliceridine to morphine***.

41. On November 8, 2016, unbeknownst to investors, Trevena met with the FDA concerning the design of its Phase III clinical trial, and according to the FDA's later-published description of those communications:

> **November 8, 2016 (meeting minutes December 19, 2016) – Type C teleconference**
>
> - FDA did not agree with Trevena's proposal to evaluate the respiratory safety of oliceridine as compared to morphine because the definition of Respiratory Safety Events (RSEs) was not clearly defined and the determination of the presence of an RSE relied largely on clinical acumen. Even though the parameters proposed in the evaluation of an RSE (respiratory rate, oxygen saturation, and MRPSS somnolence/sedation scores) are well accepted criteria used for the assessment of patients at risk for experiencing an RSE, it is unclear that a small change in these parameters is of clinical significance. Trevena was told to specify a clinically meaningful definition of an RSE, such as patients who require a clinical intervention after meeting a specific criterion (e.g., naloxone administration and/or oxygen administration with a reduction in oxygen saturation). Further, FDA did not agree with inclusion of sedation and somnolence in the RSE definition.
>
> - FDA stated that the statistical model proposed to evaluate the respiratory safety of oliceridine incorporates both the population prevalence of RSEs and the population conditional mean cumulative duration of RSEs to describe respiratory safety burden (RSB). Based on this model, a small change in event duration could result in a statistically significant result without clinical significance. In addition, the RSB endpoint is difficult to interpret and apply directly to clinical practice. Trevena was asked to analyze and report event duration separately from the event prevalence.

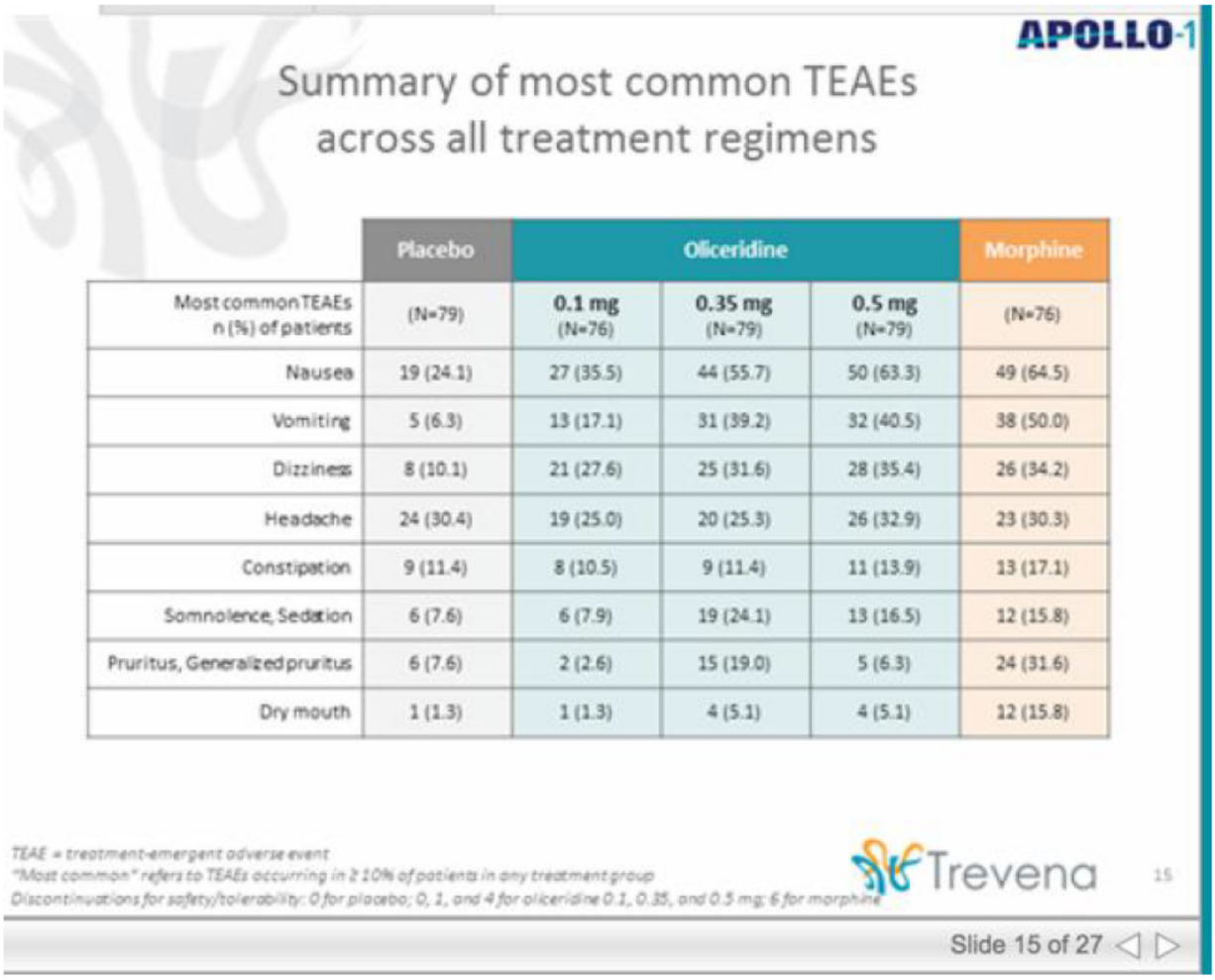
42. On January 4, 2017, Trevena issued a press release entitled "Trevena Completes Enrollment of Phase 3 APOLLO Pivotal Efficacy Trials of Oliceridine for Moderate-to-Severe Acute Pain." The press release stated in pertinent part as follows:

> *- Top-line results expected later this quarter -*

> Trevena . . . today announced that it has completed enrollment of its Phase 3 APOLLO-1 and APOLLO-2 pivotal efficacy studies of oliceridine (TRV130) in moderate-to-severe acute pain following bunionectomy and abdominoplasty, respectively.
>
> "***We are pleased to have completed enrollment in these important studies*** and to confirm that the APOLLO trials remain on schedule to report top-line results in the first quarter of 2017," said Maxine Gowen, Ph.D., chief executive officer. "***We look forward to sharing these data when they become available***."
>
> ***The APOLLO studies were designed based on the Phase 2 clinical trials of oliceridine that were successful in showing potential differentiation of oliceridine from morphine. The Company expects top-line results to include measures of efficacy, safety, and tolerability of oliceridine compared to both placebo and morphine.***
>
> In addition, the Company announced that patient enrollment for the Phase 3 ATHENA multi-procedure safety study remains on track. The Company continues to anticipate filing a New Drug Application (NDA) for oliceridine with the U.S. Food & Drug Administration (FDA) in the second half of 2017.
>
> **About the APOLLO-1 and APOLLO-2 Studies**
>
> Both APOLLO trials are Phase 3, multicenter, randomized, double-blind, placebo- and active-controlled studies of oliceridine for the treatment of moderate to severe acute pain. The APOLLO-1 study is evaluating pain for 48 hours following bunionectomy, and the APOLLO-2 study is evaluating pain for 24 hours following abdominoplasty. In each trial, patients were randomized to receive placebo, morphine, or one of three regimens of oliceridine by patient-controlled analgesia (PCA) device for the management of their post-operative pain. Each study enrolled approximately 375 patients, allocated equally across study arms. ***The primary objective in each study is to evaluate the analgesic efficacy of oliceridine compared to placebo. Secondary endpoints include comparisons of efficacy, safety, and tolerability of oliceridine to morphine.***

43. Before the opening of trading on February 21, 2017, Trevena issued a press release announcing the clinical results of the APOLLO-1 and APOLLO-2 Phase 3 clinical trials of Olinvo. While the Company claimed that the highest of the three doses of Olinvo demonstrated a statistically superior rate of pain relief compared to morphine, it conceded that the lowest dose had not. It further claimed that all three doses of Olinvo showed lower rates of depressed breathing compared to morphine, while acknowledging that only the lowest, least efficacious dose was statistically

significant. Likewise, it claimed that Olinvo caused less vomiting and nausea compared to morphine, while acknowledging that the improved tolerability was not statistically significant at all three dose levels. Some in the market feared that this negated the best selling point for Olinvo to hospitals because Olinvo would remain more expensive than morphine without providing the contemplated safety and tolerability advantages.


APOLLO-1

Summary of most common TEAEs across all treatment regimens

	Placebo	Oliceridine			Morphine
Most common TEAEs n (%) of patients	(N=79)	0.1 mg (N=76)	0.35 mg (N=79)	0.5 mg (N=79)	(N=76)
Nausea	19 (24.1)	27 (35.5)	44 (55.7)	50 (63.3)	49 (64.5)
Vomiting	5 (6.3)	13 (17.1)	31 (39.2)	32 (40.5)	38 (50.0)
Dizziness	8 (10.1)	21 (27.6)	25 (31.6)	28 (35.4)	26 (34.2)
Headache	24 (30.4)	19 (25.0)	20 (25.3)	26 (32.9)	23 (30.3)
Constipation	9 (11.4)	8 (10.5)	9 (11.4)	11 (13.9)	13 (17.1)
Somnolence, Sedation	6 (7.6)	6 (7.9)	19 (24.1)	13 (16.5)	12 (15.8)
Pruritus, Generalized pruritus	6 (7.6)	2 (2.6)	15 (19.0)	5 (6.3)	24 (31.6)
Dry mouth	1 (1.3)	1 (1.3)	4 (5.1)	4 (5.1)	12 (15.8)

TEAE = treatment-emergent adverse event
"Most common" refers to TEAEs occurring in ≥ 10% of patients in any treatment group
Discontinuations for safety/tolerability: 0 for placebo; 0, 1, and 4 for oliceridine 0.1, 0.35, and 0.5 mg; 6 for morphine

Trevena

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44. During a conference call all of the Individual Defendants held with investors and stock analysts later that day, Defendant Gowen opened her remarks lamenting – for the first time – that "[a] particular challenge was including morphine as a comparator in the trial, not the norm in our industry . . . ." During his opening remarks, Defendant Soergel disclosed that the Company was

no longer on track to file its NDA between July and September 2017, and would instead not be in a position to file it until October 2017 at the earliest.

45. On this news, the price of Trevena common stock plummeted approximately 40%, or $3 per share, on February 21, 2017, on unusually heavy trading of more than 10.5 million shares trading, or approximately 17x the average daily trading volume over the preceding ten trading days.

46. On March 8, 2017, Trevena issued a press release announcing its fourth quarter and fiscal year 2016 financial results for the period ended December 31, 2016. The release highlighted the purportedly "**Successful End-of-Phase 2 meeting with FDA**," stating that:

> In May 2016, ***the Company announced that it had reached general agreement with the FDA on key elements of the Phase 3 OLINVO program to support a New Drug Application (NDA), including that the APOLLO-1 and APOLLO-2 pivotal efficacy trials in bunionectomy and abdominoplasty included appropriate patient populations to support an indication for moderate-to-severe acute pain***.

47. The release also quoted Defendant Gowen stating in pertinent part that "***[t]he recent successful completion of the pivotal efficacy studies for OLINVO put[] [Trevena] in a strong position to bring this innovative analgesic to physicians and patients in need of a new option for managing moderate-to-severe acute pain in the hospital***," adding that Trevena then "believe[d] the data from these studies highlight the potential for OLINVO to reduce the burden of opioid-related adverse effects, particularly for those patients who [were] at elevated risk for serious consequences from post-operative nausea and vomiting or opioid-induced respiratory depression."

48. On March 8, 2017, Trevena filed its Annual Report on Form 10-K with the SEC for the fiscal year ended December 31, 2016. The 10-K was signed and certified pursuant the Sarbanes Oxley Act of 2002 by Defendants Gowen and Cuca. Concerning the Phase III clinical trial and anticipated commercialization of Olinvo, the 10-K stated in pertinent part as follows:

Phase 3 development program

In January 2016, we initiated the Phase 3 clinical program for OLINVO with the enrollment of patients in the ATHENA study, a Phase 3, open label, multicenter study evaluating the safety and tolerability of OLINVO in approximately 900 patients. The study is enrolling eligible patients with moderate-to-severe pain caused by medical conditions or surgery. Patients are treated with OLINVO on an as-needed basis via IV bolus, patient-controlled analgesia, or PCA, or both, as determined by the investigator. ***The primary objective is to assess the safety and tolerability of OLINVO. Pain intensity is being measured as a secondary endpoint.*** As of February 15, 2017, over 400 patients have been treated in the ATHENA study, with no apparent off-target or unexpected adverse effects.

In the first quarter of 2016, we discussed our Phase 3 development program with the FDA at an 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 across the development program for the purposes of evaluating safety and tolerability and that the trials should include a 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.

* * *

Commercialization

We intend to build hospital commercial capabilities in the United States and retain full U.S. rights to OLINVO. We expect to seek collaborators to commercialize OLINVO outside the United States to offset risk and preserve capital.

To commercialize OLINVO in the United States, we intend to utilize a hospital-focused specialty sales force targeting surgeons, anesthesiologists, hospitalists, and other healthcare providers with acute post-surgical or medical pain management responsibility. Within the inpatient setting, we believe that there will be opportunities for OLINVO in the post-anesthesia care unit, the emergency department, the intensive/critical care unit, and the medical/surgical floor. Based on market research conducted to date with key customers, we currently expect to focus on multiple surgical and medical procedures in which OLINVO may be a good clinical fit due to patient or procedure characteristics. In targeted hospitals, we will work to secure Pharmacy and Therapeutics Committee approval and subsequent pull-through utilization of OLINVO. Given the changing dynamics in the hospital marketplace and the increased emphasis on clinical and economic outcomes, we expect our commercialization plans also will include health economic information designed to demonstrate the value OLINVO could provide to the healthcare system

through a potential reduction in adverse events related to the use of conventional IV opioids. ***Because many of our targeted customers also provide care in other hospital settings, we anticipate that we will also target a select number of hospital outpatient departments and ambulatory surgery centers.***

49. On April 11, 2017, unbeknownst to investors, Trevena met with the FDA concerning the design of its Phase III clinical trial, and according to the FDA's later-published description of those communications:

April 11, 2017 (meeting minutes April 19, 2017) – Pre-NDA CMC-Only Meeting

- Discussion of drug substance, drug product, and presentations[.]

50. On May 4, 2017, Trevena issued a press release announcing its first quarter 2017 financial results for the interim period ended March 31, 2017. The release stated in pertinent part as follows:

"***This quarter marked a key milestone for our OLINVO program, with the delivery of robust data that we believe will support our new drug application and demonstrates the potential value of OLINVO for the management of moderate-to-severe acute pain in the hospital***," said Maxine Gowen, Ph.D., chief executive officer. "There remains a critical unmet need for patients who require IV opioids to manage pain but are at risk for poor outcomes from opioid-related adverse effects. ***Our successful Phase 3 data showed not only significant efficacy of OLINVO versus placebo to support approval, but also showed the potential for fewer gastrointestinal and respiratory adverse effects while providing comparable pain relief to a commonly used morphine regimen***."

First quarter and recent corporate highlights

- **Announced positive top-line results from two Phase 3 pivotal efficacy studies of OLINVO™ (oliceridine injection) for moderate-to-severe pain.** In February, the Company announced ***positive data*** from the APOLLO-1 and APOLLO-2 studies of OLINVO in moderate-to severe-acute pain following hard tissue and soft tissue surgeries, respectively. OLINVO demonstrated significant analgesic efficacy compared to placebo in both studies for all three tested dosing regimens. ***Consistent with Phase 2b results, a 0.35 mg dose regimen provided comparable pain relief to a common IV morphine regimen and showed potential to reduce opioid-related adverse effects on multiple measures of respiratory safety and gastrointestinal tolerability.***

- **OLINVO program remains on track for a new drug application (NDA) submission in 4Q 2017.** As of March 31, 2017, approximately 600 patients have been treated with OLINVO in the ongoing open-label, multi-procedure ATHENA safety study. In addition, the Company has successfully completed a chemistry, manufacturing, and controls Type B pre-NDA meeting with the U.S. Food and Drug Administration (FDA), and ***all pre-NDA activities remain on track*** to support an NDA submission to the FDA in the fourth quarter of 2017.

51. Between May 5, 2017 and June 22, 2017, unbeknownst to investors, Trevena met with the FDA concerning the design of its Phase III clinical trial, and according to the FDA's later-published description of those communications:

May 5, 2017 – Advice on Integrated Statistical Analysis Plan (ISAP) for the Integrated Summary of Safety

- Agency agreed with the proposed pooling for the ISAP, the planned subgroups for analysis of intrinsic and extrinsic factors, and planned summarization of adverse events.

- FDA reiterated the concerns noted at the November 8, 2016, teleconference regarding the assessment of respiratory safety. It was noted that the RSE as described in the ISS statistical plan would be considered exploratory and would not be acceptable for a proposed labeling claim.

June 22, 2017 – Agreed iPSP

- FDA agreed with Trevena's Agreed Ipsp[.]

May 25, 2017 – Pre-NDA Meeting

- Need for an adequate nonclinical assessment of potential extractables/leachables and qualification data for metabolites, impurities, and degradation products[.]

- FDA stated that the safety database must include at least 350 patients exposed to the highest intended dose for the longest expected duration of use. FDA stated that the NDA must be complete, including a complete safety database, at the time of NDA submission.

- The Sponsor was informed that positive results from the primary endpoints for the two key efficacy studies, along with support from the secondary endpoints will likely be adequate to demonstrate efficacy of the proposed product, but the final determination would be made following review of the entire NDA submission.

- FDA requested and the sponsor agreed to conduct analyses of the components of the responder definition and sensitivity analyses using the SPID endpoints.

- There was discussion on the what [sic] methods of handling missing data in the key efficacy studies would be appropriate.

- Agreement reached that a REMS did not need to be included in the NDA submission[.]

52. On July 20, 2017, Trevena announced that Defendant Soergel, its Chief Medical Officer, was resigning.

53. On August 3, 2017, Trevena issued a press release reporting its second quarter 2017 financial results for the interim period ended June 30, 2017. The release stated in pertinent part as follows:

> "The second quarter saw ***continued progress towards our goal of delivering*** an innovative new option for patients who are at risk of adverse events associated with IV opioids like morphine," said Maxine Gowen, Ph.D., chief executive officer. "***We have now completed our Phase 3 clinical development for OLINVO and successfully completed our pre-NDA meetings with the FDA***. In addition, we have refined our commercial strategy to lay the groundwork for a successful commercial launch. ***With the comparative data from our successful APOLLO pivotal efficacy studies, as well as data and investigator observations from more real-word use in the ATHENA open label study, we believe the value of OLINVO will resonate with potential prescribers who want to improve the care of hospital patients suffering severe pain***."
>
> **Second quarter and recent corporate highlights**
>
> - **OLINVO™ (oliceridine injection) program remains on track for a new drug application (NDA) submission in September/October 2017.** In July 2017, the Company announced that enrollment in the ATHENA open-label safety study was complete to support the NDA file, with 772 patients treated with OLINVO across more than 40 sites. ***In addition, the Company successfully completed a chemistry, manufacturing, and controls (CMC) Type B pre-NDA meeting and a preclinical and clinical Type B pre-NDA meeting with the U.S. Food and Drug Administration (FDA). All pre-NDA activities remain on track*** to support an NDA submission to the FDA in September/October of 2017.

54. On November 7, 2017, Trevena issued a press release reporting its third quarter 2017 financial results for the interim period ended September 30, 2017. The release stated in pertinent part as follows:

> "The recent submission of the OLINVO NDA capped a transformative period for our Company," said Maxine Gowen, Ph.D., chief executive officer. "***We are now focused on preparing for the approval and commercialization of OLINVO***, while continuing to advance our development pipeline following our recent strategic decision to halt our discovery research efforts. ***To this end, new results continue to highlight the potential value of OLINVO for patients in a real world setting who require IV opioids but are at risk of opioid-related adverse events.*** Positive interim Phase 1 data for TRV250 bode well for future clinical development of this exciting potential migraine therapy."
>
> **Third quarter and recent corporate highlights**
>
> - **OLINVO New Drug Application submitted. The Company recently submitted its New Drug Application (NDA) for OLINVO to the U.S. Food and Drug Administration (FDA).** OLINVO is the first G protein biased ligand of the mu opioid receptor, a new class of opioid receptor modulator, and the first pain program to receive Breakthrough Therapy designation from the FDA. ***The submission includes data showing that intravenous OLINVO demonstrated analgesic efficacy in all three dosing regimens tested in the two Phase 3 APOLLO pivotal efficacy studies. These trials were designed to support an indication for the management of moderate-to-severe acute pain in adult patients for whom an intravenous opioid is warranted. The filing also includes safety and tolerability data for over 1,100 patients administered OLINVO across Phase 2 and Phase 3 studies, including the ATHENA open label safety study. Additional pharmacokinetic data, clinical pharmacology data, and results from five randomized controlled trials with head to head comparisons to morphine, support potential differentiation of OLINVO.***

55. On March 7, 2018, Trevena issued a press release reporting its fourth quarter and fiscal 2018 financial results for the interim period ended December 31, 2017. The release stated in pertinent part as follows:

> "***2017 marked important progress for Trevena as we completed our Phase 3 program and NDA submission for OLINVO and prepared to support commercial launch***," said Maxine Gowen, Ph.D., chief executive officer. "***We look forward to potential approval of OLINVO later this year***, as well as advancement of our earlier R&D programs. We remain committed to bringing patients innovative medicines for safer and more successful pain management."

2017 and recent corporate highlights

- **New Drug Application (NDA) for OLINVO submitted and accepted.** ***In January 2018, the Company announced that the FDA has accepted the Company's NDA for OLINVO***. OLINVO is an investigational product for the management of moderate to severe acute pain. It is the first G protein biased ligand of the mu receptor designed to provide IV opioid pain relief with fewer associated adverse effects. ***The FDA has informed the Company that it intends to convene an advisory committee meeting to discuss the OLINVO NDA ahead of the Prescription Drug User Fee Act (PDUFA) review date of November 2, 2018. If approved, the Company expects commercial launch of OLINVO in the first quarter of 2019 following DEA scheduling.***

56. On March 7, 2018, Trevena filed its Annual Report on Form 10-K with the SEC for the fiscal year ended December 31, 2017. The 10-K was signed and certified pursuant the Sarbanes Oxley Act of 2002 by Defendants Gowen and Cuca. Concerning the Phase III clinical trial and anticipated commercialization of Olinvo, the 10-K stated in pertinent part as follows:

Clinical development

We are developing OLINVO for the management of moderate-to-severe acute pain where IV administration is preferred. In the future, we also may explore other formulations, such as transmucosal administration for breakthrough pain in additional, separate clinical trials. ***In the second quarter of 2017, we held a successful Type B meeting with the FDA regarding the Chemistry, Manufacturing and Controls data package of our NDA submission for OLINVO. We also held a successful pre-NDA meeting with the FDA regarding the clinical and non-clinical data package of the NDA in the second quarter of 2017.***

Below is a summary of the clinical development work undertaken for OLINVO.

* * *

APOLLO-1 and APOLLO-2 Phase 3 Studies

We have conducted two pivotal efficacy trials evaluating OLINVO in patients with moderate-to-severe acute pain: the APOLLO-1 study, which evaluated pain for 48 hours following bunionectomy, and the APOLLO-2 study, which evaluated pain for 24 hours following abdominoplasty. ***In February 2017, we announced positive top-line results from the APOLLO-1 and APOLLO-2 studies. In both studies, all dose regimens achieved the primary endpoint of statistically greater analgesic efficacy than placebo, as measured by responder rate.***

* * *

Regulatory

In December 2015, the FDA granted Fast Track designation to OLINVO for the management of moderate-to-severe acute pain. The Fast Track program is designed to facilitate the development and review of drugs intended to treat serious conditions with unmet medical needs by providing sponsors with the opportunity for frequent interactions with the FDA. In February 2016, the FDA granted Breakthrough Therapy designation to OLINVO for the management of moderate-to-severe acute pain. Breakthrough Therapy designation is granted by the FDA to new therapies intended to treat serious conditions and for which preliminary clinical evidence indicates that the drug may demonstrate substantial clinical improvement over available therapies. Breakthrough Therapy designation provides all the benefits of the Fast Track program, as well as more intensive FDA guidance on preparing an efficient drug development program. ***In January 2018, we announced that the FDA had accepted for review the NDA we submitted for OLINVO.*** The FDA also indicated that the PDUFA review date for the OLINVO NDA is November 2, 2018 and that it plans to hold an advisory committee meeting to discuss the NDA.

Commercialization

According to 2015 IMS data, approximately 51 million patients in the United States were treated with an IV opioid in the hospital setting. The majority of use is in the inpatient setting where approximately 16 million patients are treated for an average of two days. The World Health Organization estimates that over 230 million major surgical procedures are performed each year worldwide. The Centers for Disease Control and Prevention, or CDC, estimate that 100 million surgical and invasive diagnostic procedures occur annually in the United States. ***Accordingly, if approved, we believe that there is a large potential commercial opportunity for OLINVO in the management of both surgical and medical acute pain.***

If OLINVO ultimately receives regulatory approval, we plan to commercialize it in the United States, either on our own or with a commercial partner. ***Assuming approval on the November 2, 2018 PDUFA review date and allowing for DEA scheduling of OLINVO within 90 days of FDA approval (as mandated by the Improving Regulatory Transparency for New Medicinal Therapies Act), we anticipate launching OLINVO in the first quarter of 2019.*** Outside the United States, we expect to seek collaborators to commercialize OLINVO to offset risk and preserve capital.

57. On April 4, 2018, Defendant Gowen formally notified the Company's Board of Directors of her intention to retire as CEO effective as of October 1, 2018. The Company issued a press release on April 5, 2018 announcing she was retiring.

58. On May 3, 2018, Trevena issued a press release reporting its first quarter 2018 financial results for the interim period ended March 31, 2018. The release stated in pertinent part as follows:

> "In 2018, we have made important progress in Trevena's evolution," said Maxine Gowen, Ph.D., president and chief executive officer. . . . "***We continue to have an ongoing productive dialogue with the FDA as they review our oliceridine NDA, and look forward to an advisory committee meeting later this year and potential approval in November***."
>
> **First quarter and recent corporate highlights**
>
> - **New Drug Application (NDA) for oliceridine submitted and accepted**. In January 2018, the Company announced that ***the FDA has accepted the Company's NDA for oliceridine***, an investigational product for the management of moderate to severe acute pain. Oliceridine is the first G protein biased ligand of the mu receptor, and was designed to provide IV opioid pain relief with fewer associated adverse effects. ***The FDA has informed the Company that it intends to convene an advisory committee meeting to discuss the oliceridine NDA ahead of the Prescription Drug User Fee Act (PDUFA) review date of November 2, 2018. If approved, the Company expects commercial launch of oliceridine in the first quarter of 2019, following DEA scheduling.***

59. On June 29, 2018, Trevena announced that it had entered into a Sales Agreement with Cowen and Company LLC ("Cowen") pursuant to which it would issue to Cowen and Cowen would sell up to $50 million of Trevena common stock at market prices. Trevena filed a prospectus with the SEC in connection with this anticipated offering that expressly incorporated by reference the Company's 2017 10-K and its first quarter 2018 10-Q, among other filings the Company had made with the SEC. It also expressly incorporated by reference all of the filings Trevena made with the SEC until the offering was complete.

60. On August 2, 2018, Trevena issued a press release announcing its second quarter 2018 financial results for the interim period ended June 30, 2018. The release stated in pertinent part as follows:

> "The second quarter saw important progress towards Trevena's long-term success," said Maxine Gowen, Ph.D., President and Chief Executive Officer. "***We remain confident that the oliceridine NDA remains on track for an FDA decision by the November 2, 2018 PDUFA date, and we look forward to discussing the oliceridine data at an Advisory Committee meeting, likely in October***. . . ."
>
> **Second quarter and recent corporate highlights**
>
> - **Prescription Drug User Fee Act (PDUFA) date for oliceridine**: **November 2, 2018.** Oliceridine is an investigational product under FDA review for the management of moderate to severe acute pain where parenteral opioid analgesia is warranted and was designed to provide the pain relief of IV opioids with fewer associated adverse effects. ***The FDA has informed the Company that it intends to convene an advisory committee meeting, likely in October, to discuss the oliceridine NDA. If oliceridine is approved by the FDA, and following DEA scheduling, the Company expects the commercial launch of oliceridine in the first half of 2019.***

61. The statements referenced above in ¶¶ 32-34, 36-42, 46-47, 49, 52-55, 57 and 59 were each materially false and misleading when made as they failed to disclose and misrepresented the following adverse facts, which were known to Defendants or recklessly disregarded by them as follows:

(a) during its meetings with the FDA prior to the start of the Class Period, Trevena had been advised that the FDA did not agree with certain aspects of the design of the Phase III clinical trial of Olinvo, including the proposed dosing, the proposed primary endpoint and the proposed non-inferiority margin for comparing morphine to Olinvo;

(b) unless Trevena demonstrated that Olinvo was at least equally effective to morphine in treating post-operative pain in the Phase III clinical trial, the FDA would be unwilling to consider any secondary benefits Olinvo might confer in terms of reduced ORAEs;

(c) the FDA disagreed with how the safety data was being compiled in the Phase II clinical trial of Olinvo;

(d) because the FDA did not agree with major tenants of the design of the Phase III clinical trial of Olinvo, it was highly unlikely that the FDA would find the data obtained from that clinical trial sufficient to support Trevena's NDA;

(e) because the Phase III clinical trial data being derived would not likely be deemed sufficient to support the NDA for Olinvo, the Company would not be able to market Olinvo as soon as it was leading the market to expect, if ever; and

(f) as a result of the foregoing, the Company was not on track to achieve the commercial sales revenues from Olinvo as soon as Defendants had led the market to expect during the Class Period, if ever.

62. On October 9, 2018, the FDA's Anesthetic and Analgesic Drug Products Advisory Committee issued a Briefing Document in advance of its previously scheduled October 11, 2018 meeting to vote on its recommendation to the FDA concerning its approval of Olinvo. Among other things, the Briefing Document contained the minutes of the previously undisclosed details concerning the FDA's communications with Trevena during the last several months of 2015 and the first several months of 2016 detailed above in ¶ 30, along with other covert communications the Company had with the FDA during the Class Period that had not been accurately – if at all – communicated to investors, as detailed above in ¶¶ 35, 41, 48 and 50. Among other things, the Briefing Document revealed for the first time that the FDA had communicated to Trevena at a March 29, 2016 meeting, ***prior to the start of the Class Period***, 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." It also determined that an adequate database demonstrating safety had not been compiled. As a result, the Briefing Document disclosed that the Advisory Committee was not

recommending that the FDA approve Olinvo for commercial use, including stating in pertinent part as follows:

> *Efficacy*: In FDA's analysis of efficacy for Study 3001, all three doses of oliceridine (0.1 mg, 0.35 mg, and 0.5 mg) demonstrated a statistically greater reduction in pain intensity than placebo. ***However, morphine demonstrated a greater reduction in pain intensity than all three doses of oliceridine that was also statistically significant.*** In FDA's analysis for Study 3002, two of the three doses of oliceridine (0.35 mg and 0.5 mg) demonstrated a statistically greater reduction in pain intensity than placebo, but the 0.1 mg dose did not. In Study 3002, ***morphine demonstrated a greater reduction in pain intensity relief than two of the doses of oliceridine (0.1 mg and 0.35 mg) that was statistically significant***. The reduction in pain intensity by morphine was not greater than that of the highest oliceridine dose (0.5 mg). Currently, Trevena is only seeking approval of the 0.1 mg and 0.35 mg doses.
>
> A secondary objective of the studies was to demonstrate the superiority of oliceridine to morphine in terms of respiratory safety burden. ***FDA did not agree with Trevena's proposed endpoint due to concerns with its clinical meaningfulness. Further, when evaluating this endpoint in both studies, none of the oliceridine treatment arms demonstrated a significant reduction in the expected cumulative duration of respiratory safety events compared to morphine. Further, any numeric trends in terms of respiratory safety must be considered in the context of the observed efficacy. A conclusion of benefit in a dose-related safety outcome cannot be made without a demonstration of similar efficacy.***
>
> *Safety*: Opioids are typically administered as needed (PRN) for acute pain. In the Phase 3 studies, the oliceridine dosing regimen included a clinician-administered loading dose, patient-delivered PRN dosing via patient-controlled analgesia (PCA) pump, clinician-administered PRN supplemental dosing, or some combination of these. ***This complex PRN dosing resulted in a wide range of patient exposures and added complexity to the safety analyses.*** Given the variability in doses administered, the Applicant and Agency analyzed safety in a variety of ways, including by randomized treatment regimen and by cumulative oliceridine exposure.
>
> The agency analysis of the safety of oliceridine in the Phase 3, double-blind studies focused on comparisons of the randomized oliceridine treatment arms by study, so that the safety results could be considered in the context of the efficacy of the evaluated doses. ***Many adverse events in the clinical program were consistent with opioid-related adverse events, including respiratory depression and hypoxia, and nausea and vomiting.*** When evaluating the controlled Phase 3 data by randomized treatment group, many of the adverse events were dose-related, including respiratory effects. ***While there were trends showing a decreased percentage of respiratory events as defined by the applicant with oliceridine than morphine for some parameters, this was not consistent across all parameters.*** Notable safety issues in the clinical program included hepatic adverse events and QT prolongation. ***An***

additional consideration is whether the safety database is adequate to support the proposed dosing.

63. On this news, the price of Trevena common stock plummeted on October 9, 2018, declining by 64% on unusually high trading of more than 40 million shares trading, more than five times the average daily volume over the preceding ten trading days.

64. On October 11, 2018, Trevena filed a Current Report on Form 8-K with the SEC disclosing pursuant to Regulation F-D, in pertinent part as follows, concerning its prior communications with the FDA about the design of its Phase III clinical trial of Olinvo:

> Trevena, Inc. (the "Company" or the "Sponsor") is providing the following information to clarify and further expand upon the interactions between Trevena and the U.S. Food and Drug Administration ("FDA") with respect to the primary endpoint for the two pivotal Phase 3 studies, APOLLO-1 and APOLLO-2, conducted by the Company with respect to oliceridine.
>
> ***Prior to the Company's End-of-Phase 2 meeting, the Division of Anesthesia, Analgesia, and Addiction Products (the "Division"), Center for Drug Evaluation and Research of FDA indicated to the Company that it did not agree with the proposed primary efficacy endpoint for the APOLLO-1 and APOLLO-2 studies. Following this, the Company submitted additional analyses to, and had further discussions with, the Division. In the meeting minutes dated April 28, 2016 from the End-of-Phase 2 meeting between the Division and the Company, the Division indicated the following to the Company:***
>
> > "Regarding the relevance of the proposed primary endpoint, the Sponsor plans to include multiple secondary endpoints in their analyses to reflect appropriate endpoints of clinical importance. They have tried patient global assessments, but these have limitations in the acute setting. ***The Division stated that while a 30% improvement in summed pain intensity difference (SPID) is acceptable statistically, the clinical relevance of a 30% improvement in this setting using this measure is not clear. Interpretability of SPIDs can be challenging because the value is dependent on the formula for calculating the SPID and has no obvious meaning. Further, the SPID may be different for the two treatment groups, but the difference can reflect only an early or late effect. The Division stated that a 30% decrease in pain has typically been used as a marker to determine a clinically-meaningful difference in chronic pain settings.*** The Division has no objection to use of a responder rate as an endpoint, however, the Sponsor must incorporate those patients who discontinue into the analysis as non-responders." (emphasis added).

> In its analysis of the primary endpoint of the APOLLO-1 and APOLLO-2 studies of oliceridine, the Company treated any patient who discontinued for any reason as non-responders, as requested by the Division.

65. Later, on October 11, 2018, the Company also announced that the FDA's Analgesic Drug Products Advisory Committee voted, that day, "8 against, and 7 in favor of, the approval of oliceridine for the management of moderate to severe acute pain in adult patients for whom an intravenous (IV) opioid is warranted." According to the Company's press release issued that afternoon, the entire FDA would consider the NDA by November 2, 2018. While Trevena contended that "[t]he FDA [was] not bound by the Advisory Committee's recommendations," it also acknowledged that the FDA "takes its advice into consideration when making its decision."

66. Trading in Trevena common stock was halted throughout October 11, 2018 on pending news. When trading recommenced on October 12, 2018, the stock price dropped another 7%, closing below $1 per share, on unusually high trading of more than 12 million shares trading.

67. Finally, on Friday November 2, 2018, Trevena disclosed that the FDA had formally rejected its NDA for Olinvo, with the FDA stating in its complete response letter that the safety data was not adequate.

68. The market for Trevena common stock was open, well-developed and efficient at all relevant times. As a result of these materially false and misleading statements and omissions as set forth above, Trevena common stock traded at artificially inflated prices during the Class Period. Plaintiff and other members of the Class purchased or otherwise acquired Trevena common stock relying upon the integrity of the market price of Trevena common stock and market information relating to Trevena, and have been damaged thereby.

69. During the Class Period, Defendants materially misled the investing public, thereby inflating the price of Trevena common stock, by publicly issuing false and misleading statements and omitting to disclose material facts necessary to make Defendants' statements, as set forth herein,

not false and misleading. Said statements and omissions were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about the Company, its business and operations, as alleged herein.

70. At all relevant times, the material misrepresentations and omissions particularized in this Complaint directly or proximately caused, or were a substantial contributing cause, of the damages sustained by Plaintiff and other members of the Class. As described herein, during the Class Period, Defendants made or caused to be made a series of materially false or misleading statements about Trevena's business, prospects, and operations. These material misstatements and omissions had the cause and effect of creating, in the market, an unrealistically positive assessment of Trevena and its business, prospects, and operations, thus causing the Company's securities to be overvalued and artificially inflated at all relevant times. Defendants' materially false and misleading statements during the Class Period resulted in Plaintiff and other members of the Class purchasing Trevena common stock at artificially inflated prices, thus causing the damages complained of herein. When the true facts about the Company were revealed to the market, the inflation in the price of Trevena common stock was removed and the price of Trevena common stock declined dramatically, causing losses to Plaintiff and the other members of the Class.

ADDITIONAL SCIENTER ALLEGATIONS

71. As alleged herein, Trevena and the Individual Defendants acted with scienter in that they knew that the public documents and statements issued or disseminated in the name of the Company were materially false and misleading; knew that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the federal securities laws. As set forth elsewhere herein in detail, these Defendants, by virtue of their receipt of information reflecting the true facts regarding Trevena, their control over, and/or

receipt and/or modification of Trevena's allegedly materially misleading statements and/or their associations with the Company which made them privy to confidential proprietary information concerning Trevena, participated in the fraudulent scheme alleged herein.

NO SAFE HARBOR

72. The "Safe Harbor" warnings accompanying Trevena's reportedly forward-looking statements ("FLS") issued during the Class Period were ineffective to shield those statements from liability. To the extent that projected revenues and earnings were included in the Company's financial reports prepared in accordance with GAAP, including those filed with the SEC on Form 8-K, they are excluded from the protection of the statutory Safe Harbor. *See* 15 U.S.C. § 78u-5(b)(2)(A).

73. Defendants are also liable for any false or misleading FLS pleaded because, at the time each FLS was made, the speaker knew the FLS was false or misleading and the FLS was authorized and/or approved by an executive officer of Trevena who knew that the FLS was false. None of the historic or present tense statements made by Defendants were assumptions underlying or relating to any plan, projection or statement of future economic performance, as they were not stated to be such assumptions underlying or relating to any projection or statement of future economic performance when made, nor were any of the projections or forecasts made by Defendants expressly related to or stated to be dependent on those historic or present tense statements when made.

APPLICATION OF PRESUMPTION OF RELIANCE:
FRAUD ON THE MARKET

74. Plaintiff will rely upon the presumption of reliance established by the fraud on the market doctrine in 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) Trevena common stock traded in an efficient market;

(d) The misrepresentations alleged would tend to induce a reasonable investor to misjudge the value of Trevena common stock; and

(e) Plaintiff and other members of the Class purchased Trevena common stock between the time Defendants misrepresented or failed to disclose material facts and the time the true facts were disclosed, without knowledge of the misrepresented or omitted facts.

75. At all relevant times, the market for Trevena common stock was efficient for the following reasons, among others:

(a) As a regulated issuer, Trevena filed periodic public reports with the SEC; and

(b) Trevena 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.

LOSS CAUSATION/ECONOMIC LOSS

76. During the Class Period, as detailed herein, Defendants made false and misleading statements and engaged in a scheme to deceive the market and a course of conduct that artificially inflated the price of Trevena common stock and operated as a fraud or deceit on Class Period purchasers of Trevena common stock by misrepresenting the value of the Company's business and financial prospects. As Defendants' misrepresentations and fraudulent conduct became apparent to the market, the price of Trevena common stock fell precipitously, as the prior artificial inflation came out of the price. As a result of their purchases of Trevena common stock during the Class Period, Plaintiff and other members of the Class suffered economic loss, *i.e.*, damages, under the federal securities laws.

COUNT I

For Violations of Section 10(b) of the Exchange Act and Rule 10b-5 Against All Defendants

77. Plaintiff incorporates ¶¶ 1-76 by reference.

78. 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.

79. Defendants violated Section 10(b) of the Exchange Act and Rule 10b-5 in that they: (a) employed devices, schemes and artifices to defraud; (b) made untrue statements of material facts or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; or (c) engaged in acts, practices and a course of business that operated as a fraud or deceit upon Plaintiff and others similarly situated in connection with their purchases of Trevena common stock during the Class Period.

80. Plaintiff and the Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for Trevena common stock. Plaintiff and the Class would not have purchased Trevena common stock at the prices they 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

For Violations of Section 20(a) of the Exchange Act Against the Individual Defendants

81. Plaintiff incorporates ¶¶ 1-80 by reference.

82. The Individual Defendants acted as control persons of Trevena within the meaning of Section 20(a) of the Exchange Act as alleged herein. By virtue of their intimate knowledge of the

false and misleading statements made during the Class Period, they had the power to influence and control, and did influence and control, directly or indirectly, the decision-making of Trevena, including the content and dissemination of the false and misleading statements alleged herein.

83. The Individual Defendants were provided with or had unlimited access to copies of the statements alleged to be misleading prior to and/or shortly after those statements were issued, and had the ability to prevent the issuance of those statements or cause those statements to be corrected.

84. As set forth above, the Individual Defendants had the ability to exercise control over, and did control, Trevena, which violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder, in connection with the false and materially misleading Class Period statements as alleged herein.

85. By virtue of these facts, the Individual Defendants have violated Section 20(a) of the Exchange Act and are liable to Plaintiff and the other members of the Class.

PRAYER FOR RELIEF

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

A. Determining that this action is a proper class action, designating Plaintiff as Lead Plaintiff and certifying Plaintiff as a Class representative under Rule 23 of the Federal Rules of Civil Procedure and Plaintiff's counsel as Lead Counsel;

B. Awarding compensatory 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 interest thereon;

C. Awarding Plaintiff and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees;

D. Awarding rescission or a rescissory measure of damages; and

E. Awarding such equitable/injunctive or other relief as deemed appropriate by the Court.

JURY DEMAND

Plaintiff demands a trial by jury.

DATED: November 5, 2018

KESSLER TOPAZ MELTZER & CHECK, LLP
NAUMON A. AMJED (PA #309520)

NAUMON A. AMJED

280 King of Prussia Road
Radnor, PA 19087
Telephone: 610/667-7706
610/667-7056 (fax)
Email: namjed@ktmc.com

ROBBINS GELLER RUDMAN
& DOWD LLP
SAMUEL H. RUDMAN
MARY K. BLASY
58 South Service Road, Suite 200
Melville, NY 11747
Telephone: 631/367-7100
631/367-1173 (fax)
srudman@rgrdlaw.com
mblasy@rgrdlaw.com

JOHNSON FISTEL, LLP
MICHAEL I. FISTEL, JR.
40 Powder Springs Street
Marietta, GA 30064
Telephone: 770/200-3104
770/200-3101 (fax)

Attorneys for Plaintiff