
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 8-K

**CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): **May 2, 2016**

TREVENA, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation)

001-36193
(Commission
File No.)

26-1469215
(IRS Employer
Identification No.)

**1018 West 8th Avenue, Suite A
King of Prussia, PA 19406**
(Address of principal executive offices and zip code)

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

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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Item 7.01 Regulation FD.

On May 2, 2016, Trevena, Inc. ("Trevena" or the "Company") announced that it will host a conference call and webcast at 5:30 pm EDT on May 2, 2016 (the "Event") to discuss the results of its recently completed End-of-Phase 2 ("EoP2") meeting with the U.S. Food and Drug Administration ("FDA") with respect to the Company's product candidate oliceridine (TRV130). To access the live webcast of the Event, please visit the "Investors" section of the Company's website at www.trevenainc.com. Following the conclusion, an archive of the Event will be available on the Company's website until June 1, 2016.

The Company will utilize a slide presentation during the Event, a copy of which is furnished hereto as Exhibit 99.2.

The information set forth in this Item 7.01 and furnished hereto as Exhibit 99.2 shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and is not incorporated by reference into any of the Company's filings under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, except as shall be expressly set forth by specific reference in any such filing.

Cautionary Note on Forward Looking Statements

Any statements in Item 7.01 of this Current Report on Form 8-K, including within Exhibit 99.2 hereto, regarding future expectations, plans and prospects for the Company, including statements about the Company's strategy, future operations, clinical development of its therapeutic candidates, plans for potential future product candidates and other statements containing the words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "suggest," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: uncertainties related to

the Company's intellectual property; the status, timing, costs, results and interpretation of the Company's clinical trials, including whether oliceridine will prove to be a differentiated analgesic for patients and caregivers seeking alternatives to conventional opioids; the uncertainties inherent in conducting clinical trials, including the timing around the initiation of the pivotal efficacy studies in the Phase 3 program, the release of top-line data and the potential filing of an NDA; whether interim results from a clinical trial will be predictive of the final results of the trial or results of early clinical trials, including the Phase 2 oliceridine studies and any post-hoc analysis of such trial results, will be indicative of the results of future trials; expectations for regulatory approvals, including the Company's assessment of the results of the End-of-Phase 2 meeting with FDA and whether the Company ultimately will achieve regulatory approval for oliceridine; availability of funding sufficient for the Company's foreseeable and unforeseeable operating expenses and capital expenditure requirements; other matters that could affect the availability or commercial potential of the Company's therapeutic candidates; and other factors discussed in the Risk Factors set forth in the Company's Annual Report on Form 10-K and Quarterly Reports on Form 10-Q filed with the Securities and Exchange Commission (SEC) and in other filings the Company makes with the SEC from time to time. In addition, the forward-looking statements included in this Current Report on Form 8-K, including Exhibit 99.2 hereto, represent the Company's views only as of the date hereof. The Company anticipates that subsequent events and developments may cause the Company's views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, it specifically disclaims any obligation to do so, except as may be required by law.

Item 8.01 Other Events.

On May 2, 2016, the Company issued a press release announcing completion of the EoP2 meeting with FDA and outlining the Company's plans for the Phase 3 program for oliceridine. A copy of the press release is furnished herewith as Exhibits 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

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Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

<u>Number</u>	<u>Description</u>
99.1	Press Release dated May 2, 2016
99.2*	Slides presentation for the Trevena, Inc. May 2, 2016 conference call and webcast

* Exhibit 99.2 is furnished as part of this Current Report on Form 8-K.

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

TREVENA, INC.

Date: May 2, 2016

By: /s/ John M. Limongelli
John M. Limongelli
Sr. Vice President, General Counsel & Chief Administrative Officer

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EXHIBIT INDEX

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Trevena Announces Successful End-of-Phase 2 Meeting with FDA and Outlines Phase 3 Program for Oliceridine

— 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 —

KING OF PRUSSIA, PA, May 2, 2016 — 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,” 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

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.
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- 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.

Conference Call and Webcast

The company will host a conference call and webcast to discuss its Phase 3 plans. The webcast will be available for replay for 30 days.

Date:	Monday, May 2 nd
Time:	5:30pm (EDT)
Telephone Access:	(855) 465-0180 (U.S. and Canada)
International:	(484) 756-4313 (International)
Conference ID:	5089524
Online Access:	http://edge.media-server.com/m/p/6cgu4kp

About oliceridine

Oliceridine (TRV130) is a new chemical entity (NCE) designed to optimize mu opioid receptor pharmacology to deliver an improved analgesic profile, and has been granted Breakthrough Therapy designation by the U.S. Food & Drug Administration. Oliceridine is the first mu receptor G protein pathway selective modulator (muGPS) — a biased mu opioid receptor ligand that in preclinical studies activated pathways associated with analgesia while avoiding pathways that can promote respiratory depression and gastrointestinal dysfunction and limit analgesia. In Phase 2, intravenous oliceridine demonstrated rapid and powerful analgesic efficacy with reduced frequency of opioid-related adverse events including nausea, vomiting, and hypoventilation compared to intravenous morphine. Trevena believes that oliceridine may offer an improved safety and tolerability profile compared to conventional

opioid analgesics while providing powerful pain relief to patients. Trevena anticipates that the initial market opportunity for oliceridine will be in the acute care settings, with

a focus on moderate to severe acute pain in the hospital.

About Trevena

Trevena, Inc. is a clinical stage biopharmaceutical company that discovers, develops and intends to commercialize therapeutics that use a novel approach to target G protein coupled receptors, or GPCRs. Using its proprietary product platform, Trevena has identified four biased ligand product candidates — oliceridine (TRV130) to treat moderate to severe acute pain intravenously (Phase 3), TRV027 to treat acute heart failure (Phase 2b), TRV734 to treat moderate to severe acute and chronic pain orally (Phase 1), and TRV250 for acute episodic migraine and other CNS disorders (preclinical).

Cautionary Note on Forward Looking Statements

Any statements in this press release about future expectations, plans and prospects for the Company, including statements about the Company’s strategy, future operations, clinical development of its therapeutic candidates, plans for potential future product candidates and other statements containing the words “anticipate,” “believe,” “estimate,” “expect,” “intend,” “may,” “plan,” “predict,” “project,” “suggest,” “target,” “potential,” “will,” “would,” “could,” “should,” “continue,” and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: uncertainties related to the Company’s intellectual property; the status, timing, costs, results and interpretation of the Company’s clinical trials, including whether oliceridine will prove to be a differentiated analgesic for patients and caregivers seeking alternatives to conventional opioids; the uncertainties inherent in conducting clinical trials, including the timing around the initiation of the pivotal efficacy studies in the Phase 3 program and the potential filing of an NDA; whether interim results from a clinical trial will be predictive of the final results of the trial or results of early clinical trials, including the Phase 2 oliceridine studies and any post-hoc analysis of such trial results, will be indicative of the results of future trials; expectations for regulatory approvals, including the Company’s assessment of the results of the End-of-Phase 2 meeting with FDA and whether the Company ultimately will achieve regulatory approval for oliceridine; availability of funding sufficient for the Company’s foreseeable and unforeseeable operating expenses and capital expenditure requirements; other matters that could affect the availability or commercial potential of the Company’s therapeutic candidates; and other factors discussed in the Risk Factors set forth in the Company’s Annual Report on Form 10-K and Quarterly Reports on Form 10-Q filed with the Securities and Exchange Commission (SEC) and in other filings the Company makes with the SEC from time to time. In addition, the forward-looking statements included in this press release represent the Company’s views only as of the date hereof. The Company anticipates that subsequent events and developments may cause the Company’s views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, it specifically disclaims any obligation to do so, except as may be required by law.

Contact:

Trevena, Inc.
Jonathan Violin, Ph.D.
Sr. Director, Investor Relations
(610) 354-8840 x231

jviolin@trevenainc.com



May 2, 2016





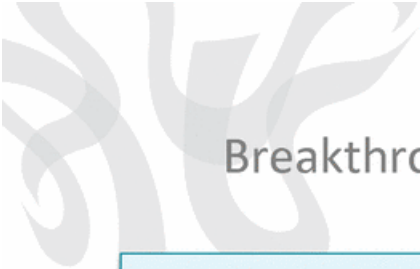
Forward looking statements and other important cautions

To the extent that statements contained in this presentation are not descriptions of historical facts regarding Trevena, Inc., they are forward-looking statements reflecting management's current beliefs and expectations. Forward-looking statements are subject to known and unknown risks, uncertainties, and other factors that may cause our or our industry's actual results, levels of activity, performance, or achievements to be materially different from those anticipated by such statements. You can identify forward-looking statements by terminology such as "may," "will," "should," "expects," "plans," "anticipates," "believes," "estimates," "predicts," "potential," "intends," or "continue," or the negative of these terms or other comparable terminology. Forward-looking statements contained in this presentation include, but are not limited to, (i) statements regarding the timing of anticipated clinical trials for our product candidates; (ii) the timing of receipt of clinical data for our product candidates; (iii) our expectations regarding the potential safety, efficacy, or clinical utility of our product candidates; (iv) the size of patient populations targeted by our product candidates and market adoption of our potential drugs by physicians and patients; (v) the timing or likelihood of regulatory filings and approvals; and (vi) our cash needs and potential payments under our agreements with Allergan plc.

Various factors may cause differences between our expectations and actual results, including unexpected safety or efficacy data, unexpected side effects observed during preclinical studies or in clinical trials, lower than expected enrollment rates in clinical trials, changes in expected or existing competition, changes in the regulatory environment for our drug candidates and our need for future capital, the inability to protect our intellectual property, and the risk that we become a party to unexpected litigation or other disputes. You should read our filings with the Securities and Exchange Commission, including the Risk Factors set forth in our Annual Report on Form 10-K and our Quarterly Reports on Form 10-Q filed with the Securities and Exchange Commission and other filings the Company makes with the Securities and Exchange Commission from time to time, completely and with the understanding that our actual future results may be materially different from what we expect. Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons why actual results could differ materially from those anticipated in the forward-looking statements, even if new information becomes available in the future.



INTRODUCTORY COMMENTS



Oliceridine: the first Breakthrough Therapy designation for pain

Breakthrough Therapy qualifying criteria:

“A drug that is intended to treat a serious condition AND preliminary clinical evidence indicates that the drug may demonstrate substantial improvement on a clinically significant endpoint(s) over available therapies”¹

Oliceridine program:

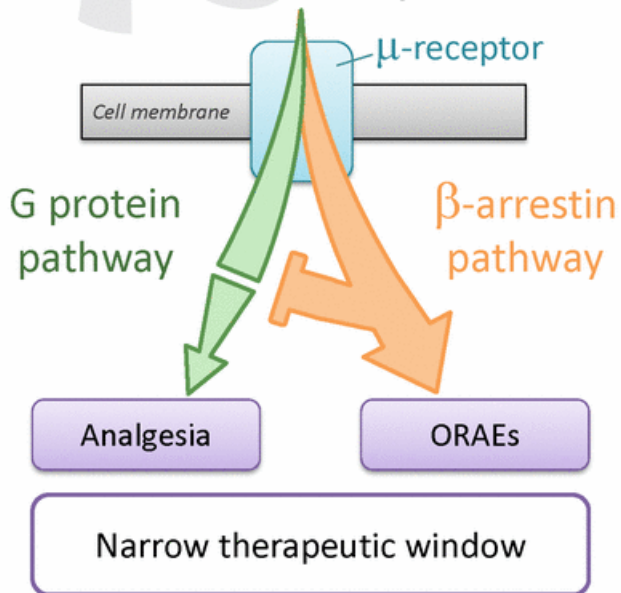
- Head-to-head comparisons to morphine throughout development
- Differentiation based on breakthrough science
- Rigorous and innovative trial design

(1) FDA Guidance for Industry; Expedited Programs for Serious Conditions – Drugs and Biologics. May 2014.

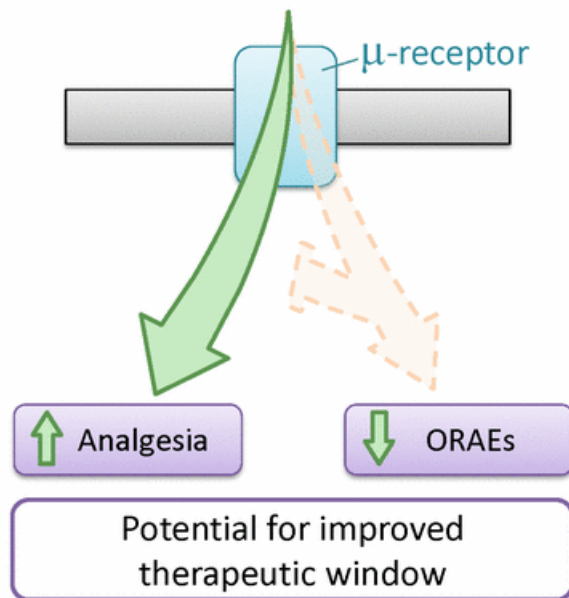
Oliceridine: a new mechanism of action

The first μ -GPS – μ receptor G protein P athway S elective modulator

Conventional opioids



Oliceridine



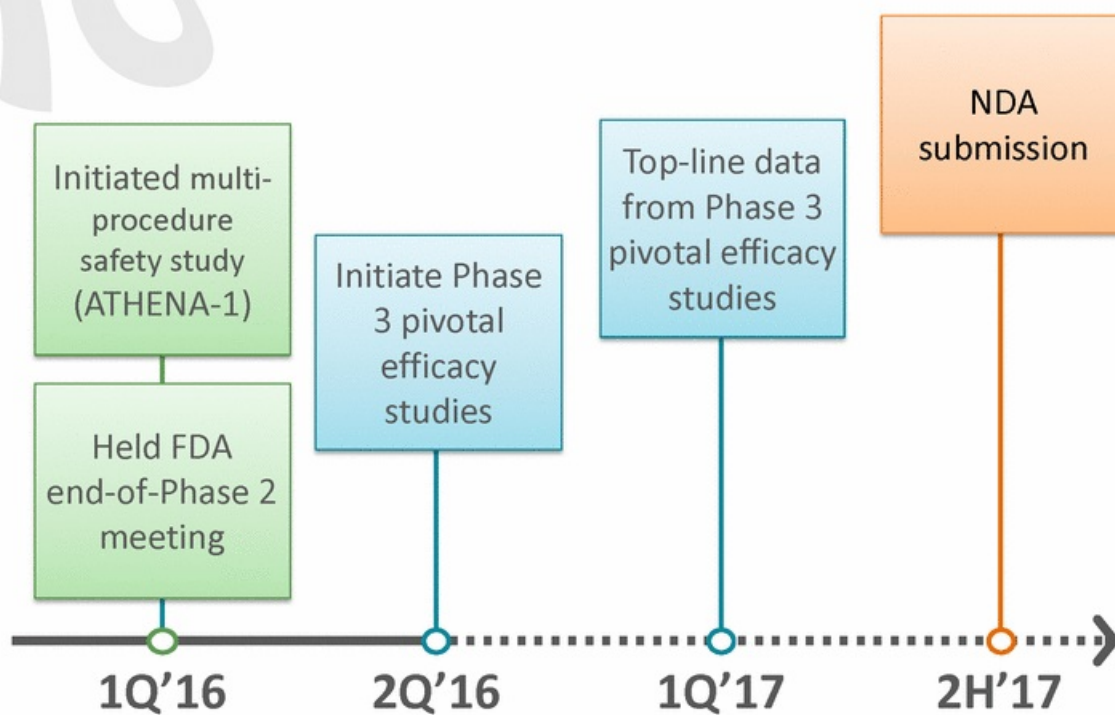
ORAE = opioid-related adverse events

Mechanism of action hypothesis based on preclinical research

- 1) Bohn LM et al *Science* 1999 Dec 24;286(5449):2495-8.
- 2) Raehal KM et al *JPET* 2005 Sep;314(3):1195-201
- 3) Dewire SM et al *JPET* 2013 Mar;344(3):708-17




Phase 3 program timing expectations





END-OF-PHASE 2 MEETING OUTCOME



Successful outcome for the end-of-phase 2 meeting for the oliceridine program

- General agreement was reached to move oliceridine in to Phase 3
- General agreement was reached that the oliceridine Phase 3 program could support an approval for the target indication
 - *Management of moderate-to-severe acute pain where parenteral therapy is warranted*
- Key elements of Phase 3 program:
 - Two pivotal efficacy studies with PCA dosing to support potential finding of efficacy
 - Bunionectomy and abdominoplasty populations appropriate for target indication
 - Safety database with PCA and bolus dosing $\geq 1,100$ patients
 - Including a sufficient number of patients with higher exposures and longer durations of oliceridine therapy
 - Key clinical pharmacology, nonclinical toxicology, CMC activities to support NDA



OLICERIDINE PHASE 3 PROGRAM OVERVIEW



Pivotal efficacy studies to support potential approval

- Two pivotal studies: same surgical models as in Phase 2
 - APOLLO-1: 48 hour treatment following bunionectomy
 - APOLLO-2: 24 hour treatment following abdominoplasty
 - Each study will include 375 patients, 75/group
- Primary endpoint: efficacy of oliceridine vs. placebo
- Secondary endpoints: oliceridine vs. morphine
 - Efficacy, including pain intensity difference and time to onset
 - Safety, including respiratory safety burden based on hypoventilation events
 - Tolerability, including nausea and vomiting

Phase 3 program dosing and administration

- Goal: dosing and administration labeling for as-needed dosing (bolus or PCA)
- APOLLO dosing: patient controlled analgesia (PCA), as in Phase 2b study
 - If PCA dosing does not adequately control pain, supplemental study drug can be given as often as every hour
 - If pain still not adequately controlled, rescue NSAID analgesic available
 - 3 oliceridine dose arms planned in each APOLLO study:

Regimen	N	Loading dose (mg)	Demand dose (mg)	Supplemental dose (mg)
Placebo	75	-	-	-
Oliceridine 0.1 mg	75	1.5	0.1	0.75
Oliceridine 0.35 mg	75	1.5	0.35	0.75
Oliceridine 0.5 mg	75	1.5	0.5	0.75
Morphine	75	4.0	1.0	2.0

- ATHENA safety study: PCA and as-needed bolus dosing intended to complement PCA dosing data from APOLLO studies

Pivotal efficacy studies: primary endpoint

- Same measure as Phase 2: pain intensity assessed with a visual analog scale
- Phase 3 will use a responder analysis as proposed by Trevena
 - Defined as $\geq 30\%$ improvement in sum of pain intensity difference from baseline (SPID) without early discontinuation and without rescue pain medication
 - Rationale:
 - More straightforward clinical interpretation than pain intensity difference
 - Incorporates an element of safety/tolerability
 - High power based on post-hoc analysis of Phase 2b abdominoplasty data

Post-hoc analysis of phase 2b abdominoplasty data using Phase 3 primary endpoint

	Placebo (n = 39) volume matched	Oliceridine (n = 39) 1.5 mg load, 0.1 mg demand	Oliceridine (n = 39) 1.5 mg load, 0.35 mg demand	Morphine (n = 83) 4.0 mg load, 1.0 mg demand
Responders, n (%)	12 (30.8%)	25 (64.1%)	28 (71.8%)	55 (66.3%)
p-value vs. placebo		0.0005	0.0004	0.0003



Pivotal efficacy studies: secondary endpoints

- Efficacy measures vs. placebo, including sum of pain intensity difference analyses and time to meaningful pain relief, to support primary analysis
- Efficacy, safety, and tolerability comparisons to morphine allow demonstration of potential clinical advantages of oliceridine
 - Efficacy measures vs. morphine include:
 - Responder rate: same evaluation as primary endpoint
 - Non-inferiority and superiority vs. morphine
 - Time to onset of meaningful pain relief
 - Time to use, total use, and prevalence of use for rescue analgesics
 - Safety/tolerability measures vs. morphine include:
 - Spontaneously reported nausea/vomiting and rescue anti-emetic use
 - Respiratory safety burden

Hypoventilation → respiratory safety burden

- Respiratory safety endpoint: based on hypoventilation, a clinical assessment as in Phase 2b study
- Phase 3 analysis: prevalence x duration = respiratory safety burden (RSB)
 - Provides more robust assessment of respiratory safety
 - Higher power than simple prevalence measure based on analysis of Phase 2b data
- In a post-hoc analysis of Phase 2b abdominoplasty data, hypoventilation was both more frequent and longer lasting with morphine than with oliceridine:

	Placebo (n = 39) Volume matched	Oliceridine (n = 39) 1.5 mg load, 0.1 mg demand	Oliceridine (n = 39) 1.5 mg load, 0.35 mg demand	Morphine (n = 83) 4.0 mg load, 1.0 mg demand
RSB, hr	1.3	1.0	2.2	6.5
p-value vs. placebo		0.7490	0.4025	< 0.0001
p-value vs. morphine	< 0.0001	< 0.0001	0.0003	

Phase 2b data: Hypoventilation frequency prespecified; duration is post-hoc from dose interruption data



Summary

- Successful end-of-phase 2 meeting
 - Appropriate to move oliceridine to Phase 3
 - Agreed upon key elements of Phase 3 program
 - Collaborative discussion with FDA
- Phase 3 program overview
 - APOLLO studies designed to support approval and differentiation
 - Endpoints and analysis are well informed by the Phase 2 program
 - ATHENA-1 study is underway
 - APOLLO studies to commence this quarter
- Breakthrough Therapy designation offers opportunity for ongoing dialogue



Biased Ligands. Better Drugs.