
**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): January 3, 2017

Inotek Pharmaceuticals Corporation
(Exact name of registrant as specified in its charter)

DELAWARE
(State or other jurisdiction
of incorporation)

001-36829
(Commission
File Number)

04-3475813
(I.R.S. Employer
Identification No.)

91 Hartwell Avenue
Lexington, MA
(Address of principal executive offices)

02421
(Zip Code)

Registrant's telephone number, including area code (781) 676-2100

Not Applicable
(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 8.01 Other Events.

On January 3, 2017, Inotek Pharmaceuticals Corporation (the “Company”) issued a press release announcing the top-line results of MATrX-1, the first pivotal Phase 3 trial of *trabodenoson* for the treatment of primary open-angle glaucoma or ocular hypertension. The full text of the press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release issued by Inotek Pharmaceuticals Corporation on January 3, 2017, furnished herewith.

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.

Date: January 3, 2017

INOTEK PHARMACEUTICALS CORPORATION

By: /s/ Dale Ritter
Dale Ritter
Vice President —Finance

EXHIBIT INDEX

Exhibit No.

Description

99.1

Press release issued by Inotek Pharmaceuticals Corporation on January 3, 2017, furnished herewith.



Inotek Announces Top-line Results for MATrX-1, First Phase 3 Trial of *Trabodenoson* for Glaucoma

- Trial Did Not Achieve Superiority to Placebo at All 12 Time Points-

- Diurnal IOP Reduction of 4.25mmHg at Three Months with *Trabodenoson* 6% Once-a-day Dose, Statistically Superior to Placebo -

- Safety and Tolerability Similar to Placebo-

- Conference Call Scheduled for 8:30am EST Today -

Lexington, MA — January 3, 2017 — Inotek Pharmaceuticals Corporation (NASDAQ: ITEK), a clinical stage biopharmaceutical company focused on the discovery, development and commercialization of therapies for ocular diseases, today announced top-line results of MATrX-1, the first pivotal Phase 3 trial of *trabodenoson* for the treatment of primary open-angle glaucoma (POAG) or ocular hypertension (OHT). The trial did not achieve its primary endpoint of superiority in reduction of intraocular pressure (IOP) compared with placebo at all 12 time points. This was, in part, due to a placebo response that was 2-3 mmHg greater than that observed in Phase 2. *Trabodenoson*, the Company's lead clinical candidate, is a first-in-class, highly selective adenosine mimetic targeting the A₁ subreceptor. *Trabodenoson* lowers IOP by augmenting the eye's natural function of the trabecular meshwork, the primary outflow pathway for aqueous humor and a site of pathology in glaucoma.

"We are disappointed that the primary endpoint of superiority at all 12 time points was not achieved," commented David P. Southwell, President and Chief Executive Officer of Inotek. "This result was driven primarily by the unexpectedly stronger placebo response at the 8AM time point. However, MATrX-1 did achieve several clinically meaningful secondary endpoints- the 6% dose was significant versus placebo in the daily IOP change from diurnal baseline at all days tested. Additionally, an analysis of responders (subjects with IOP reduction of 5mmHg or greater from baseline) indicated a statistically higher proportion of responders in the 6% *trabodenoson* group than the placebo group at all visits. The safety, tolerability and low discontinuation rate in MATrX-1 continues to suggest that *trabodenoson* is an active molecule with a unique safety profile. Later this quarter, we expect to receive additional data beyond the top-line results reported today. Once we have the additional data, we will determine next steps in the *trabodenoson* monotherapy program."

The primary endpoint of the MATrX-1 trial was the IOP reduction of *trabodenoson* compared to that of placebo on Days 28, 42 and 84 and at four time points during each of these days: 8AM, 10AM, 12PM, and 4PM. The 8AM time point did not achieve

statistical separation with any *trabodendoson* dose. This was primarily due to an unexpectedly high placebo response compared to that observed in Phase 2, as well as a published meta-analysis by Raber et al¹.

The 6%/2000 mcg QD dose of *trabodendoson* was statistically superior to placebo at Days 84, 42, 14 and marginally superior at Day 28. The daily IOP reduction from diurnal baseline at three months for this dose was 4.25 mmHg compared to 2.38 mmHg for placebo, and 5.29 mmHg for the timolol 0.5% twice daily control arm. The normal response observed with the timolol control arm supports that the trial was properly conducted.

There were no significant safety or tolerability events reported. The safety profile of *trabodendoson* was comparable to placebo. Notably, there was minimal drug related hyperemia. Only 4 subjects (2.2%) discontinued the trial due to a treatment-related adverse event.

“The results of the MATrX-1 trial demonstrate that *trabodendoson*, operating through a novel mechanism of action, actively lowers IOP with a tolerability profile that, remarkably, was similar to that observed in the placebo arm,” commented Rudolf Baumgartner, MD, Executive Vice President and Chief Medical Officer of Inotek.

Southwell commented, “Looking ahead, 2017 is an important year for the *trabodendoson* development program. We will wait for the full results from MATrX-1 to better understand the behavior of the placebo arm. We look forward to the results of the FDC Phase 2 trial, which is substantially enrolled and for which we expect to report top-line data mid-year.”

MATrX-1 Phase 3 Trial Design

MATrX-1 was a Phase 3 randomized, double-masked, placebo-controlled trial of *trabodendoson* in 303 subjects diagnosed with POAG or OHT. MATrX-1 assessed the efficacy, safety and tolerability of *trabodendoson* over three months of treatment. The primary endpoint was reduction of IOP as compared to the placebo treatment arm. In addition, the study contained a timolol 0.5% arm to validate the sensitivity of the patient population and serve as an internal control. IOP was measured at four time points during the day: 8AM, 10AM, 12PM, and 4PM on days 14, 28, 42 and 84. Three doses of *trabodendoson* ophthalmic suspension were administered: 3%/1000 mcg once daily, 4.5%/1500 mcg twice daily, and 6%/2000 mcg once daily. The trial enrolled patients with a diagnosis of POAG or OHT and an IOP greater than or equal to 24 mmHg and less than or equal to 34 mmHg.

Conference Call Information

Inotek will host a conference call and webcast today, January 3, 2017, at 8:30am EST to discuss the top-line results from the MATrX-1 Phase 3 trial. To participate in the



conference call, please dial (844) 358-9183 in the U.S. or (478) 219-0400 outside of the U.S. five minutes prior to the start of the call and provide the Conference ID: 46680576, or access the listen-only webcast by visiting the Company's website www.inotekpharma.com.

An archive of today's conference call will be available shortly after the conclusion of the call and accessed by dialing (855) 859-2056 in the U.S. or (404) 537-3406 outside of the U.S. and referencing the Conference ID: 46680576, or by visiting Inotek's website. The audio replay will be available for two weeks following the call and the webcast for thirty days.

About Inotek Pharmaceuticals Corporation

Inotek Pharmaceuticals is a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of therapies for glaucoma and other eye diseases. The Company's lead product candidate, *trabodенoson*, is a first-in-class selective adenosine mimetic currently in Phase 3 development. *Trabodенoson* was developed in Inotek's laboratories and is designed to restore the eye's natural pressure control mechanism. Additionally, the Company is evaluating the potential for selective adenosine mimetics to address optic neuropathies and other degenerative retinal diseases. For more information, please visit www.inotekpharma.com. The inclusion of our website address here and elsewhere in this press release does not include or incorporate by reference the information on our website into this press release.

Forward-Looking Statements

Various statements in this release concerning Inotek's future expectations, plans and prospects, including without limitation, Inotek's expectations regarding the use of *trabodенoson* and its fixed-dose combination (FDC) program with latanoprost as treatments for POAG or OHT, Inotek's expectations regarding reporting top-line data of its Phase 2 trial for its FDC, Inotek's expectations with respect to the timing and success of its clinical studies and pre-clinical studies for *trabodенoson*, its FDC, orphan diseases, and the possibility of selective adenosine mimetics to address optic neuropathies and other degenerative retinal diseases, may constitute forward-looking statements for the purposes of the safe harbor provisions under The Private Securities Litigation Reform Act of 1995 and other federal securities laws and are subject to substantial risks, uncertainties and assumptions. You should not place reliance on these forward looking statements, which often include words such as "believe," "expect," "anticipate," "intend," "plan," "will give," "estimate," "seek," "will," "may" "suggest" or similar terms, variations of such terms or the negative of those terms. Although the Company believes that the expectations reflected in the forward-looking statements are reasonable, the Company cannot guarantee such outcomes. Actual results may differ materially from those indicated by these forward-looking statements as a result of various important factors, including, without limitation, Inotek's ability to successfully demonstrate the efficacy and safety of *trabodенoson*, its FDC program, its pre-clinical studies for orphan

diseases, or selective adenosine mimetics to address optic neuropathies and other degenerative retinal diseases, the pre-clinical and clinical results for its product candidates, which may not support further development and marketing approval, the potential advantages of Inotek's product candidates, actions of regulatory agencies, which may affect the initiation, timing and progress of pre-clinical studies and clinical trials of its product candidates, Inotek's ability to obtain, maintain and protect its intellectual property, Inotek's ability to enforce its patents against infringers and defend its patent portfolio against challenges from third parties, the timing, cost or other aspects of a potential commercial launch of Inotek's product candidates and potential future sales of our current product candidates or any other potential products if any are approved for marketing, competition from others developing products for similar uses, Inotek's ability to manage operating expenses, Inotek's ability to obtain additional funding to support its business activities and establish and maintain strategic business alliances and new business initiatives, Inotek's dependence on third parties for development, manufacture, marketing, sales and distribution of product candidates, the outcome of litigation, and unexpected expenditures, as well as those risks more fully discussed in the section entitled "Risk Factors" in Inotek's most recent Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission, as well as discussions of potential risks, uncertainties, and other important factors in Inotek's subsequent filings with the Securities and Exchange Commission. Accordingly, you should not place undue reliance on these forward-looking statements. All such statements speak only as of the date made, and the Company undertakes no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

¹Raber S, Mandema JW, Li H, Nickens D. A Model-Based Dose-Response Meta-Analysis of Ocular Hypotensive Agents as a Drug Development Tool to Evaluate New Therapies in Glaucoma. *J Ocul Pharmacol Ther.* 2015; 31:189-97

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