# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

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

Date of Report (Date of Earliest Event Reported): July 12, 2016

# **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)

ck 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 risions:
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))

# Item 8.01 Other Events.

On July 12, 2016, Inotek Pharmaceuticals Corporation (the "Company") issued a press release announcing the initiation of its Phase 2 dose-ranging trial of a fixed-dose combination of *trabodenoson* and *latanoprost* for the treatment of glaucoma. A copy of the press release is filed as Exhibit 99.1 hereto and is hereby incorporated by reference into this Item 8.01.

# **Item 9.01 Financial Statements and Exhibits**

(d) Exhibits.

Exhibit No. Description

99.1 Press Release, dated July 12, 2016

# **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: July 14, 2016

# INOTEK PHARMACEUTICALS CORPORATION

By: /s/ Dale Ritter

Dale Ritter

Vice President — Finance

# EXHIBIT INDEX

Exhibit No. Description

99.1 Press Release, dated July 12, 2016



# Inotek Pharmaceuticals Initiates Phase 2 Dose-ranging Trial of a Fixed-Dose Combination of *Trabodenoson*, a Novel Treatment for Glaucoma, and *Latanoprost*

-Data Expected in 2017-

**LEXINGTON, Mass** – July 12, 2016 – <u>Inotek Pharmaceuticals Corporation</u> (NASDAQ: ITEK), a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of therapies for glaucoma and other eye diseases, today announced the initiation of a Phase 2 dose-ranging trial of a fixed-dose combination (FDC) of *trabodenoson* and *latanoprost*. Glaucoma is one of the leading causes of blindness, and occurs when there is damage to the optic nerve as a result of elevated eye pressure. While the goal of glaucoma treatment is to preserve vision; lowering intraocular pressure (IOP) —a risk-factor for glaucoma—has been shown to prevent progressive vision loss.

*Trabodenoson*, the Company's lead clinical candidate, is a first-in-class, highly selective adenosine A1 mimetic which has been observed in Phase 2 clinical trials to reduce IOP. *Latanoprost* is a prostaglandin analog and the most commonly used drug for lowering IOP. Approximately 50% of glaucoma patients that receive a prostaglandin require a second, adjunctive therapy to achieve sufficient IOP-lowering. However, no combination product with a prostaglandin has been approved in the United States.

"The Phase 2 trial of *trabodenoson* and *latanoprost* as a fixed-dose combination in a single eye drop substantially broadens the scope of Inotek's *trabodenoson* development program," said Rudolf Baumgartner, MD, Chief Medical Officer of Inotek. "*Trabodenoson* is designed to restore the eye's natural pressure by increasing aqueous humor outflow via the trabecular meshwork, the primary outflow apparatus of the eye and a site of pathology in glaucoma. Existing therapies, including prostaglandin analogs, primarily regulate eye pressure through other mechanisms such as the uveoscleral or secondary pathway. We believe that a fixed-dose combination of *trabodenoson* with *latanoprost* has the potential to provide patients and physicians with a novel treatment option that offers the convenience of a single daily drop, with two complementary eye pressure lowering mechanisms, and an optimized safety and efficacy profile."

#### About the Phase 2 Fixed-dose Combination Study of Trabodenoson and Latanoprost

The randomized, double-masked, Phase 2 dose-ranging trial will assess the overall benefit/risk profile of binocular topical application of different daily doses of trabodenoson (3.0% and 6.0%) when combined with latanoprost (0.005% or 0.0025%) for eight weeks in patients with ocular hypertension or primary open-angle glaucoma.

Three treatment combinations of trabodenoson and latanaprost will be investigated as well as two separate concentrations of latanaprost alone. The treatments are: *trabodenoson* 6%/*latanaprost* 0.005%, *trabodenoson* 6%/*latanaprost* 0.0025%; *latanaprost* 0.005%; and *latanaprost* 0.0025%. Trabodenoson doses were selected to optimize intraocular pressure lowering, while maintaining the excellent tolerability and safety profile observed to date. Latanaprost doses were selected based on efficacy and safety profiles which vary based on dose.

The trial will enroll approximately 165 patients with an IOP greater than or equal to 25 mmHg and less than or equal to 34 mmHg; which represents the patients most likely to receive treatment for glaucoma or ocular hypertension. Following a placebo run-in period, treatment will be administered to both eyes for a total of eight weeks. Each subject will be assigned four weeks of morning and four weeks of evening dosing in a masked manner. Morning versus evening dosing is masked using placebo in addition to the active drug product.

For more information, please visit www.clinicaltrials.gov/ct2/show/NCT02829996.

### **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, *trabodenoson*, is a first-in-class, highly selective adenosine mimetic currently in Phase 3 development. *Trabodenoson* was developed in Inotek's laboratories and is designed to restore the eye's natural pressure control mechanism by targeting the adenosine A<sub>1</sub> subreceptor. 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 <a href="https://www.inotekpharma.com">www.inotekpharma.com</a>.

### Forward-Looking Statements

This press release contains forward-looking statements, which are subject to substantial risks, uncertainties and assumptions. These forward-looking statements often include words such as "believe," "expect," "anticipate," "intend," "plan," "estimate," "seek," "will," "may" or similar expressions. 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.

Source: Inotek Pharmaceuticals

#### **Inotek Contact:**

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