Edgar Filing: Ampio Pharmaceuticals, Inc. - Form 8-K

Ampio Pharmaceuticals, Inc. Form 8-K February 18, 2011

# 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): February 14, 2011

# AMPIO PHARMACEUTICALS, INC.

(Exact name of registrant as specified in Charter)

Delaware (State or other jurisdiction of

333-146542 (Commission 26-0179592 (IRS Employee

incorporation or organization)

File No.) 5445 DTC Parkway, P4 Identification No.)

Greenwood Village, Colorado 80111

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(Address of Principal Executive Offices)

(303) 418-1000

(Issuer Telephone number)

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 (see General Instruction A.2. below):

- " 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 7.01 Regulation FD Disclosure

On February 14, 2011, Ampio Pharmaceuticals, Inc. (the Company) was advised by St. Michaels Hospital, Toronto, Canada, that the first patient had been enrolled and was orally administered the first dose in the clinical trial of Optina, the Company sproduct candidate designed to treat diabetic macular edema, or DME. The trial being conducted on the Company sbehalf by St. Michaels is a Phase II randomized, placebo-controlled, parallel treatment group, double-masked study to evaluate the efficacy and safety of Optina in adult subjects with DME. It is estimated that 68 patients will be enrolled for this trial.

#### **About Diabetes and DME**

The American Diabetes Association reports that 20.8 million people in the U.S. have diabetes and another 54 million are pre-diabetic with 20% of type-2 diabetic patients having retinopathy when diagnosed. Over 360 million people worldwide are projected to have diabetes and its complications by 2030 with almost all patients with type-1 diabetes and more than 60% of patients with type-2 diabetes developing retinopathy. The International Diabetes Federation estimates that 285 million people around the world have diabetes and approximately 14% of people with diabetes have DME. According to the American Academy of Ophthalmology, the prevalence of DME increases to 29% for people with diabetes who use insulin for more than 20 years. By 2030, the incidence of diabetes is expected to rise to 438 million people worldwide, and the incidence of diabetes-related conditions like DME are expected to continue to increase proportionately.

This Current Report on Form 8-K contains forward-looking statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements typically are identified by use of terms such as may, project, should, plan, expect, anticipate, believe, estimate and similar words, although some forward-looking statements are expressed differently. Forward-looking statements represent our management s judgment regarding future events. Although the Company believes that the expectations reflected in such forward-looking statements are reasonable, the Company can give no assurance that such expectations will prove to be correct. All statements other than statements of historical fact included in this Current Report on Form 8-K are forward-looking statements. Except as required by applicable law, the Company undertakes no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise. The Company cannot guarantee the accuracy of the forward-looking statements, and you should be aware that the Company s actual results could differ materially from those contained in forward-looking statements due to a number of factors, including the statements under Risk Factors found in the Company s Annual Report on Form 10-K filed with the Securities and Exchange Commission on February 16, 2011 and any subsequent filings made by the Company with the SEC.

#### **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.

## AMPIO PHARMACEUTICALS, INC.

Dated: February 18, 2011 By: /s/ Donald B. Wingerter, Jr.

Name: Donald B. Wingerter, Jr. Title: Chief Executive Officer