Ampio Pharmaceuticals, Inc.
Form 8-K
March 01, 2013

# 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): February 25, 2013**

# AMPIO PHARMACEUTICALS, INC.

**(Exact name of registrant as specified in Charter)**

| **Delaware** | **001-35182** | **26-0179592** |
|---|---|---|
| **(State or other jurisdiction of incorporation or organization)** | **(Commission File No.)** | **(IRS Employee Identification No.)** |

**5445 DTC Parkway, Suite 925**

**Greenwood Village, Colorado 80111**

**(Address of principal executive offices, including zip code)**

**(720) 437-6500**

**(Registrant s telephone number, including area code)**

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 8.01 Other Events.**

On February 25, 2013, Ampio Pharmaceuticals, Inc. ( Ampio or the Company ) issued a press release announcing that it s Phase III clinical study of Ampion for the treatment for osteoarthritis of the knee will include a dose-escalation run-in study as recommended by the FDA. Our prior IND submission and FDA guidance suggested we would complete two Phase III studies (AP-003 and AP-004) with respect to Ampion , each having approximately 800 patients. However, the formal guidance the Company received from the FDA indicated that the Company should conduct a dose ranging study as a Phase II dose-escalation study or as a run-in study for one of the Phase III studies. Now, as currently proposed in our revised IND, one of our Phase III studies (AP-004) will be conducted as a run-in study following the first study (AP-003A) with 320 patients. The size of the AP-004 study will be determined by statistical power based on the AP-003A study. The run-in allowance that the FDA has provided Ampio means that data can be presented anytime enough data is collected to support the hypothesis, which will allow for a rapid turn-around. A copy of the press release is furnished as Exhibit 99.1 to this report.

Ampio and the previously engaged clinical research organization (the Ampion CRO ) agreed to modify the scope of work which was entered into on January 21, 2013, in connection with the Company s clinical trial of Ampion™. Ampio and the Ampion CRO are working to finalize a new scope of work reflecting the reduction in patient scope, pursuant to which the fees due thereunder are not expected to exceed $3 million in the aggregate, which reflects a significant reduction from the previously announced $6.8 million aggregate consideration.

The Company expects to finalize the scope of work after FDA approval of the revised IND, and expects to file the Master Service Agreement and Scope of Work between the Company and the Ampion CRO (the Ampion Agreement ) as an exhibit to its Quarterly Report on Form 10-Q for the period ending March 31, 2013. In addition, the Company intends to seek confidential treatment for certain terms and provisions of the Ampion Agreement. The foregoing description is qualified in its entirety by reference to the text of the Ampion Agreement when filed.

On February 27, 2013, Ampio issued a press release announcing the oral dosing of the first patient in a 505(b)(2) clinical trial of the investigational drug Optina in diabetic macular edema, a copy of which press release is furnished as Exhibit 99.2 to this report.

The information contained in this Item 8.01 and Exhibit 99.1 to this report shall not be deemed to be filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liability of that section, and shall not be incorporated by reference into any filings made by Ampio under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, except as may be expressly set forth by specific reference in such filing.

**Item 9.01 Financial Statements and Exhibits.**
**(d) Exhibits.**

The following exhibit is furnished with this report:

99.1 Press Release dated February 25, 2013
99.2 Press Release dated February 27, 2013

*This Current Report on Form 8-K and Exhibit 99.1 contain 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 and in Exhibit 99.1 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 9, 2012, and its Form 10-Qs on file with the SEC.*

**SIGNATURE**

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.**

By: /s/ Mark D. McGregor
Mark D. McGregor
*Chief Financial Officer*

Dated: March 1, 2013

**AMPIO PHARMACEUTICALS, INC.**

**FORM 8-K**

**Exhibit Index**

| Exhibit No. | Description | Method of Filing |
|---|---|---|
| 99.1 | Press Release issued by Ampio Pharmaceuticals, Inc. on February 25, 2013 | Furnished |
| 99.2 | Press Release issued by Ampio Pharmaceuticals, Inc. on February 27, 2013 | Furnished |