

ARCA biopharma, Inc.
Form 8-K
December 05, 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): December 5, 2013 (December 4, 2013)

ARCA biopharma, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction

000-22873
(Commission

36-3855489
(I.R.S. Employer

of Incorporation)

File Number)

Identification No.)

11080 CirclePoint Road, Suite 140, Westminster, CO 80020

Edgar Filing: ARCA biopharma, Inc. - Form 8-K
(Address of Principal Executive Offices) (Zip Code)

(720) 940-2200

(Registrant's telephone number, including area code)

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 (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))

Section 8 Other Events

Item 8.01. Other Events.

On December 4, 2013, ARCA biopharma, Inc. (ARCA) announced that its Investigational New Drug application for Gencaro™, a pharmacologically unique beta-blocker and mild vasodilator being developed for atrial fibrillation, has been accepted by the U.S. Food and Drug Administration and is now active. The press release is furnished as Exhibit 99.1 hereto, the contents of which are incorporated herein by reference.

Additionally, on December 5, 2013, ARCA announced that Laboratory Corporation of America (LabCorp®) has submitted an Investigational Device Exemption application to the U.S. Food and Drug Administration for the planned companion diagnostic test for Gencaro. The press release is furnished as Exhibit 99.2 hereto, the contents of which are incorporated herein by reference.

Section 9 Financial Statements and Exhibits

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

| Exhibit Number | Description |
|-----------------------|---|
| 99.1 | Press Release titled ARCA biopharma Announces U.S. FDA Acceptance of Gencaro IND Application for the Treatment of Atrial Fibrillation dated December 4, 2013. |
| 99.2 | Press Release titled ARCA biopharma Announces IDE Submission to U.S. FDA for Gencaro Companion Diagnostic Test dated December 5, 2013. |

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.

Dated: December 5, 2013

ARCA biopharma, Inc.

(Registrant)

By: /s/ Christopher D. Ozeroff
Name: Christopher D. Ozeroff

Title: SVP and General Counsel

INDEX TO EXHIBITS

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