ARCA biopharma, Inc.
Form 8-K
November 06, 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): November 6, 2013 (November 5, 2013)**

**ARCA biopharma, Inc.**

**(Exact Name of Registrant as Specified in Charter)**

| **Delaware** | **000-22873** | **36-3855489** |
|---|---|---|
| **(State or Other Jurisdiction of Incorporation)** | **(Commission File Number)** | **(I.R.S. Employer Identification No.)** |

**11080 CirclePoint Road, Suite 140, Westminster, CO 80020**

**(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))

**Item 1.01 Entry into a Material Definitive Agreement**

On November 5, 2013, ARCA biopharma, Inc. ( ARCA ) entered into a Clinical Research Agreement (the Agreement ) with Duke University s Duke Clinical Research Institute ( DCRI ), to serve as the coordinating center and principal investigator for GENETIC-AF (the Study ), a planned Phase 2B/3 genetically-targeted, comparative effectiveness clinical trial evaluating Gencaro™ (bucindolol hydrochloride) as a potential treatment for the prevention of atrial fibrillation in patients with heart failure.

Under the Agreement, the DCRI will coordinate GENETIC-AF with the approximately 50 clinical sites in the United States that are planned to participate in the Study (the Study Sites ) and the physician investigators at the Study Sites. The DCRI will enter into an agreement with each Study Site, and will provide all materials needed by the Study Sites to conduct the Study, including Gencaro and the comparator drug. All data generated from GENETIC-AF will be owned by ARCA, with the DCRI retaining the right to use the data for its internal, non-commercial purposes. All inventions directly related to Gencaro or arising from the protocol of the Study will be owned by ARCA, with ARCA having the option to license any other inventions arising from the Study. The publication of any peer-reviewed manuscripts will be reviewed and be subject to approval by a publications committee, which will be overseen by the steering committee of GENETIC-AF. The DCRI s obligation to conduct GENETIC-AF is subject to the approval of the DCRI Institutional Review Board.

The term of the Agreement will continue for the duration of the Study. ARCA may terminate the Agreement upon 90 days notice for any reason. In addition, the Agreement may be terminated immediately if the FDA withdraws approval for the Study, if animal, human or toxicological test results support termination of the Study, if adverse events related to the drugs administered in the Study emerge that support immediate termination, if the principal investigator at the DCRI cannot continue in that role and a successor acceptable to ARCA is not available, or if a material event occurs that affects ARCA s ability to finance the Study.

The foregoing summary is qualified in its entirety by reference to the Agreement, a copy of which will be filed with the Company s Annual Report on Form 10-K. Certain portions of the Agreement will be omitted and will be subject to a FOIA Confidential Treatment Request to the Securities and Exchange Commission pursuant to Rule 24b-2 under the Securities Exchange Act of 1934, as amended. The omitted material will be included in the request for confidential treatment.

A press release announcing the Agreement is also attached as Exhibit 99.1 hereto, the contents of which are incorporated herein by reference.

**Item 9.01 Financial Statements and Exhibits**

(d) Exhibits

| Exhibit No. | Description |
|---|---|
| 99.1 | Press Release titled ARCA biopharma Announces Clinical Trial Agreement for GENETIC-AF Trial, dated November 6, 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: November 6, 2013

**ARCA biopharma, Inc.**

(Registrant)

By: /s/ Christopher D. Ozeroff
Name: Christopher D. Ozeroff
Title: Senior Vice President and General Counsel

**EXHIBIT INDEX**

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