ARCA biopharma, Inc.
Form 8-K
April 22, 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): April 22, 2013 (April 18, 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.)**

8001 Arista Place, Suite 430, Broomfield, CO 80021

(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 April 18, 2013, ARCA biopharma, Inc. (ARCA) entered into a Clinical Trial Collaboration Agreement (the Agreement) with Medtronic, Inc. (Medtronic) to collaborate on ARCA s proposed clinical trial, known as GENETIC-AF, of its lead development drug, Gencaro (bucindolol hydrochloride). GENETIC-AF is planned as a Phase 2b/3 clinical trial comparing Gencaro to metoprolol CR/XL for prevention of atrial fibrillation (AF) in patients with heart failure and reduced left ventricular ejection fraction. Under the Agreement, ARCA plans, with the support of Medtronic, to conduct a substudy that will include continuous monitoring of the cardiac rhythms of all 200 patients enrolled during the Phase 2b portion of GENETIC-AF. Each patient will have heart rhythm monitoring via a Medtronic device, either a previously implanted cardiac resynchronization or defibrillation device, or a previously or newly inserted Reveal® loop recorder. The collaboration substudy will measure AF burden, defined as a patient s actual time in AF regardless of symptoms. In determining the presence of an efficacy signal in the Phase 2b portion of the trial, AF burden will be evaluated along with time to mortality or recurrent AF, which will also be the Phase 3 primary endpoint.

The collaboration will be administered by a joint ARCA-Medtronic committee. Medtronic will use its proprietary CareLink System to collect and analyze the cardiac rhythm data from the implanted Medtronic devices and provide the data to ARCA at the close of Phase 2b portion of the trial. The parties will negotiate in good faith to agree on the substudy protocol, specifying the elements of the substudy and of the cardiac rhythm data collection and analysis to be provided for the substudy by Medtronic by August 15, 2013. Medtronic will support the reimbursement process for patients enrolled in the Phase 2b portion, and will provide financial support of unreimbursed costs for a certain number of patients in the Phase 2B portion, and up to a certain maximum amount per patient. If GENETIC-AF proceeds to Phase 3, ARCA will seek to enroll an additional 100 patients in the substudy, and Medtronic will provide the agreed-on CareLink System cardiac rhythm data collection and analysis for the Phase 3 portion of the substudy, and support the reimbursement process.

The Agreement may be terminated by Medtronic for various reasons including uncured material breach, an ARCA bankruptcy, if, after FDA communication, it is reasonably concluded that the FDA will not allow GENETIC-AF to enroll or proceed, if the trial has not begun by December 1, 2014, if the substudy protocol is not agreed-to by August 15, 2013, or if Medtronic s obligations are unilaterally expanded. ARCA may terminate the Agreement for various reasons, including uncured material breach, a Medtronic bankruptcy, if a claim is made that Medtronic s performance infringes third party rights, if ARCA determines it cannot enroll or continue GENETIC-AF, or if the substudy protocol is not agreed to by August 15, 2013.

The foregoing summary is qualified in its entirety by reference to the Agreement, a copy of which is filed as Exhibit 10.1 to this Current Report on Form 8-K, and which is incorporated herein by this reference. Certain portions of the Agreement have been omitted and are 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, which has been submitted on the date hereof. 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
10.1*	Clinical Trial Collaboration Agreement between ARCA biopharma, Inc. and Medtronic, Inc. dated as of April 18, 2013.
99.1	Press Release titled ARCA Biopharma And Medtronic To Collaborate On Atrial Fibrillation Clinical Trial for Gencaro , dated April 22, 2013.

* Confidential treatment has been requested with respect to certain portions of this exhibit. This exhibit omits the information subject to this confidentiality request. Omitted portions have been filed separately 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.

Dated: April 22, 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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