

ARCA biopharma, Inc.

Form 424B4

July 18, 2013

Prospects Supplement No. 1

(to Prospectus dated May 30, 2013)

Filed Pursuant to Rule 424(b)(4)

Registration No. 333-187508

125,000 Shares of Series A Convertible Preferred Stock

12,500,000 Shares of Common Stock Underlying the Preferred Stock

Warrants to Purchase up to 6,250,000 Shares of Common Stock and

6,250,000 Shares of Common Stock Underlying the Warrants

ARCA biopharma, Inc.

This prospectus supplement supplements the prospectus dated May 30, 2013 (the "Prospectus"), which forms a part of our Registration Statement on Form S-1 (Registration No. 333-187508). This prospectus supplement is being filed to update and supplement the information in the Prospectus with the information contained in our current report on Form 8-K, filed with the Securities and Exchange Commission (the "Commission") on July 17, 2013 (the "Current Report"). Accordingly, we have attached the Current Report to this prospectus supplement.

The Prospectus and this prospectus supplement relate to the offer and sale of up to 125,000 shares of Series A Convertible Preferred Stock ("Preferred Stock") which are convertible into 12,500,000 shares of Common Stock, warrants to purchase up to 6,250,000 shares of our Common Stock and 6,250,000 shares of Common Stock underlying the warrants.

This prospectus supplement should be read in conjunction with the Prospectus. This prospectus supplement updates and supplements the information in the Prospectus. If there is any inconsistency between the information in the Prospectus and this prospectus supplement, you should rely on the information in this prospectus supplement.

Our common stock is traded on the Nasdaq Global Market under the trading symbol ABIO. On July 17, 2013, the last reported sale price of our common stock was \$1.40 per share.

Investing in our securities involves a high degree of risk. You should review carefully the risks and uncertainties described under the heading "Risk Factors" beginning on page 5 of the Prospectus and beginning on page 23 of our quarterly report on Form 10-Q for the quarterly period ended March 31, 2013 before you decide whether to invest in shares of our common stock.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if the Prospectus or this prospectus supplement is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus supplement is July 17, 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): July 17, 2013 (July 17, 2013)

ARCA biopharma, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction

of Incorporation)

000-22873
(Commission

File Number)

8001 Arista Place, Suite 430, Broomfield, CO 80021

36-3855489
(I.R.S. Employer

Identification No.)

Edgar Filing: ARCA biopharma, Inc. - Form 424B4

(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 July 17, 2013, ARCA biopharma, Inc. provided a general business update and clinical development guidance. The press release is furnished as Exhibit 99.1 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 Provides Business Update; GENETIC-AF Trial Evaluating Gencaro as Potential Treatment for Atrial Fibrillation Planned to Begin Patient Enrollment in Q1 2014; ARCA and Medtronic, Inc. Are Collaborating on Phase 2B Portion of GENETIC-AF .
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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: July 17, 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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ARCA BIOPHARMA PROVIDES BUSINESS UPDATE

GENETIC-AF Trial Evaluating Gencaro as Potential Treatment for Atrial Fibrillation Planned to Begin Patient Enrollment in Q1 2014

ARCA and Medtronic, Inc. are Collaborating on Phase 2B Portion of GENETIC-AF

Broomfield, CO, July 17, 2013 ARCA biopharma, Inc. (Nasdaq: ABIO), a biopharmaceutical company developing genetically-targeted therapies for cardiovascular diseases, today provided a general business update and clinical development guidance.

ARCA was founded on the belief that a personalized medicine approach to drug development, tailoring medical treatment to the individual genetic characteristics of each patient, can enable more effective therapies, improve patient outcomes and reduce healthcare costs. ARCA's lead development program is intended to be a direct implementation of those ideas. Gencaro (bucindolol hydrochloride) is being developed as a potential treatment for atrial fibrillation (AF). ARCA has identified common genetic variations that it believes may predict individual patient response to Gencaro, giving it the potential to be the first genetically-targeted AF prevention treatment. AF is considered an epidemic cardiovascular disease with an estimated prevalence of at least 2.7 million Americans in 2010.

We believe we have a significant opportunity to improve the treatment options for patients living with atrial fibrillation, said Dr. Michael R. Bristow, President and Chief Executive Officer of ARCA. With the completion of our recent capital raise, and the support of Medtronic, we now have the resources to advance Gencaro into Phase 2B clinical evaluation. We believe there is an unmet medical need for new atrial fibrillation treatments that have fewer side effects than currently available therapies.

In June, the Company completed an equity offering, raising net proceeds of approximately \$18 million. As of June 30, 2013, the Company had approximately \$20.4 million in cash and cash equivalents.

ARCA and Medtronic, Inc. (NYSE:MDT), a leader in medical technologies to improve the treatment of chronic diseases, including cardiac rhythm disorders, have entered into a collaboration agreement for the Phase 2B portion of GENETIC-AF, the Company's Phase 2B/3 trial evaluating Gencaro as a potential treatment for AF.

GENETIC-AF Clinical Trial

GENETIC-AF is planned as a Phase 2B/3, multi-center, randomized, double-blind clinical trial comparing Gencaro to metoprolol CR/XL for prevention of AF in patients with heart failure and reduced left ventricular ejection fraction (HFREF). ARCA plans to enroll only patients with the genetic variant of the beta-1 cardiac receptor which the Company believes responds most favorably to Gencaro. GENETIC-AF has an adaptive design, under which the Company plans to initiate it as a Phase 2B study in approximately 200 patients and then, depending on the results of an interim analysis by the trial Data Safety Monitoring Board (DSMB), expand the trial to a Phase 3 study by enrolling an estimated additional 420 patients. The Company now anticipates that patient enrollment in GENETIC-AF will begin in the first quarter of 2014.

Under the collaboration with Medtronic, ARCA plans 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. For the DSMB interim analysis, AF burden and the primary endpoint of the study, time to recurrence of symptomatic AF after electrical cardioversion, or death, will be reviewed by the DSMB to determine if there is sufficient potential for a statistically significant efficacy signal to be determined for all patients enrolled in the Phase 2B/3 study.

Upcoming GENETIC-AF Trial Implementation Milestones

- | | |
|--|------------|
| - GENETIC-AF Implementation Team Additions | July 2013 |
| - GENETIC-AF Steering Committee Formalization | July 2013 |
| - GENETIC-AF Data Safety Monitoring Board Formalization | Aug 2013 |
| - Gencaro AF Investigational New Drug (IND) Application Submission | Q3 2013 |
| - GENETIC-AF Clinical Research Organization Selection | Q3/Q4 2013 |
| - GENETIC-AF Patient Enrollment Initiation | Q1 2014 |

Our forecast of the time periods to achieve these milestones is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors, including the factors discussed in [Risk Factors](#) in our periodic filings.

Atrial Fibrillation (AF)

Atrial fibrillation is a disorder in which the normally regular and coordinated contraction pattern of the heart's two small upper chambers (the atria) becomes irregular and uncoordinated. The irregular contraction pattern associated with AF causes blood to pool in the atria, predisposing the formation of clots. These clots may travel from the heart and become lodged in the arteries leading to the brain and other organs, thereby blocking necessary blood flow and potentially resulting in stroke. In addition, in patients with HFREF, new onset AF may also contribute to worsening heart failure and increased risk of death.

Gencaro Data in Atrial Fibrillation

Clinical data analysis from a post-hoc review of patient forms from the BEST trial, a Phase 3 trial in 2,708 patients with advanced heart failure, indicate that Gencaro may have a potentially enhanced and pharmacogenetically-influenced effect in reducing and preventing AF. In that trial, patients in the Gencaro arm had a reduction in the risk of new onset AF time to event compared to patients in the placebo arm of 41% (AF measured as an adverse event/serious adverse event or as detected on surveillance ECGs, time to event analysis, $p = 0.0004$). In a 1,040 patient DNA substudy of BEST, Gencaro exhibited potential pharmacogenetic enhancement and differentiation for AF prevention in patients with a specific genotype (beta₁389 arginine homozygous (Arg/Arg) adrenergic receptor (AR); approximately 47% of the patients). These patients experienced a 74% ($p = 0.0003$) reduction in risk of AF versus no detectable reduction in patients who had alternative genotypes (beta₁389 Gly carriers; 53% of the patients) who had received placebo. The Company believes this data supports the potential ability of Gencaro to prevent AF in patients who have the genotype the Company believes responds most favorably to Gencaro.

In prior placebo controlled trials of beta blockers in chronic HFREF, most studies comparing beta-blockers to placebo have detected a positive signal for prevention of AF, with an event rate reduction averaging approximately 27%, although AF had not been a pre-specified primary or secondary endpoint in these studies. Currently, no beta-blocker has been approved by the U.S. Food and Drug Administration for the prevention of AF in heart failure patients.

About ARCA biopharma

ARCA biopharma is dedicated to developing genetically-targeted therapies for cardiovascular diseases. The Company's lead product candidate, Gencaro™ (bucindolol hydrochloride), is an investigational, pharmacologically unique beta-blocker and mild vasodilator being developed for atrial fibrillation. ARCA has identified common genetic variations that it believes predict individual patient response to Gencaro, giving it the potential to be the first genetically-targeted atrial fibrillation prevention treatment. ARCA has a collaboration with Medtronic, Inc. for support of the Phase 2B portion of the GENETIC-AF trial. For more information please visit www.arcabiopharma.com.

Safe Harbor Statement

This press release contains forward-looking statements for purposes of the safe harbor provided by the Private Securities Litigation Reform Act of 1995. These statements include, but are not limited to, statements regarding upcoming GENETIC-AF trial implementation milestones, potential timing for patient enrollment in the GENETIC-AF trial, the sufficiency of the Company's capital to support its operations, the potential for genetic variations to predict individual patient response to Gencaro, Gencaro's potential to treat atrial fibrillation, future treatment options for patients with atrial fibrillation, the role of AF burden in diagnosis and treatment of atrial fibrillation and the potential for Gencaro to be the first genetically-targeted atrial fibrillation prevention treatment. Such statements are based on management's current expectations and involve risks and uncertainties. Actual results and performance could differ materially from those projected in the forward-looking statements as a result of many factors, including, without limitation, the risks and uncertainties associated with: the Company's financial resources and whether they will be sufficient to meet the Company's business objectives and operational requirements; results of earlier clinical trials may not be confirmed in future trials, the protection and market exclusivity provided by the Company's intellectual property; risks related to the drug discovery and the regulatory approval process; and, the impact of competitive products and technological changes. These and other factors are identified and described in more detail in ARCA's filings with the SEC, including without limitation the Company's annual report on Form 10-K for the year ended December 31, 2012, and subsequent filings. The Company disclaims any intent or obligation to update these forward-looking statements.

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