

ARCA biopharma, Inc.
Form 424B4
December 11, 2014

Prospectus Supplement No. 26

Filed pursuant to Rule 424(b)(4)

(to Prospectus dated May 30, 2013)

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), as supplemented by that certain Prospectus Supplement No. 1 dated July 17, 2013 (Supplement No. 1), by that certain Prospectus Supplement No. 2 dated July 19, 2013 (Supplement No. 2), by that certain Prospectus Supplement No. 3 dated July 24, 2013 (Supplement No. 3), by that certain Prospectus Supplement No. 4 dated July 30, 2013 (Supplement No. 4), by that certain Prospectus Supplement No. 5 dated August 6, 2013 (Supplement No. 5), by that certain Prospectus Supplement No. 6 dated September 4, 2013 (Supplement No. 6), by that certain Prospectus Supplement No. 7 dated September 23, 2013 (Supplement No. 7), by that certain Prospectus Supplement No. 8 dated October 29, 2013 (Supplement No. 8), by that certain Prospectus Supplement No. 9 dated November 6, 2013 (Supplement No. 9), by that certain Prospectus Supplement No. 10 dated November 13, 2013 (Supplement No. 10), by that certain Prospectus Supplement No. 11 dated November 21, 2013 (Supplement No. 11), by that certain Prospectus Supplement No. 12 dated December 5, 2013 (Supplement No. 12), by that certain Prospectus Supplement No. 13 dated January 8, 2014 (Supplement No. 13), by that certain Prospectus Supplement No. 14 dated February 10, 2014 (Supplement No. 14), by that certain Prospectus Supplement No. 15 dated February 12, 2014 (Supplement No. 15), by that certain Prospectus Supplement No. 16 dated February 18, 2014 (Supplement No. 16), by that certain Prospectus Supplement No. 17 dated March 3, 2014 (Supplement No. 17), by that certain Prospectus Supplement No. 18 dated March 20, 2014 (Supplement No. 18), by that certain Prospectus Supplement No. 19 dated May 13, 2014 (Supplement No. 19), by that certain Prospectus Supplement No. 20 dated June 9, 2014 (Supplement No. 20), by that certain Prospectus Supplement No. 21 dated August 13, 2014 (Supplement No. 21), by that certain Prospectus Supplement No. 22 dated August 18, 2014 (Supplement No. 22), by that certain Prospectus Supplement No. 23 dated November 12, 2014 (Supplement No. 23), by that certain Prospectus Supplement No. 24 dated December 1, 2014 (Supplement No. 24), and by that certain Prospectus Supplement No. 25 dated December 10, 2014 (Supplement No. 25), and together with Supplement No. 1, Supplement No. 2, Supplement No. 3, Supplement No. 4, Supplement No. 5, Supplement No. 6, Supplement No. 7, Supplement No. 8, Supplement No. 9, Supplement No. 10, Supplement No. 11, Supplement No. 12, Supplement No. 13, Supplement No. 14, Supplement No. 15, Supplement No. 16, Supplement No. 17, Supplement No. 18, Supplement No. 19, Supplement No. 20, Supplement No. 21, Supplement No. 22, Supplement No. 23, and Supplement No. 24, the Supplements), which form 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 and the Supplements with the information contained in our current report on Form 8-K, filed with the Securities and Exchange Commission (the Commission) on December 11, 2014 (the Current Report). Accordingly, we have attached the Current Report to this prospectus supplement.

The Prospectus, the Supplements 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 and the Supplements. This prospectus supplement updates and supplements the information in the Prospectus and the Supplements. If there is any inconsistency between the information in the Prospectus, the Supplements 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 December 11, 2014, the last reported sale price of our common stock was \$1.10 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 20 of our quarterly report on Form 10-Q for the period ended September 30, 2014 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 December 11, 2014

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 11, 2014 (December 11, 2014)

ARCA biopharma, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

000-22873
(Commission
File Number)

36-3855489
(I.R.S. Employer
Identification No.)

11080 CirclePoint Road, Suite 140, Westminster, CO 80020

(Address of Principal Executive Offices) (Zip Code)

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

(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 11, 2014, ARCA biopharma, Inc. (ARCA) announced the activation of the first GENETIC-AF clinical trial site in Canada. 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 Announces Activation of First Canadian GENETIC-AF Clinical Trial Site dated December 11, 2014.

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 11, 2014

ARCA biopharma, Inc.

(Registrant)

By: /s/ Christopher Ozeroff
Name: Christopher Ozeroff
Title: SVP and General Counsel

INDEX TO EXHIBITS

**Exhibit
Number**

Description

99.1	Press Release titled ARCA biopharma Announces Activation of First Canadian GENETIC-AF Clinical Trial Site dated December 11, 2014.
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**ARCA BIOPHARMA ANNOUNCES ACTIVATION OF FIRST CANADIAN
GENETIC-AF CLINICAL TRIAL SITE**

Clinical Trial is Evaluating Gencaro as a Potential Treatment for Atrial Fibrillation

Approximately 60 Trial Sites Planned in the United States and Canada

Westminster, CO, December 11, 2014 ARCA biopharma, Inc. (Nasdaq: ABIO), a biopharmaceutical company developing genetically-targeted therapies for cardiovascular diseases, today announced the activation of the first GENETIC-AF clinical trial site in Canada. The site activation follows on the August 2014 acceptance by Health Canada of the Company's Clinical Trial Application (CTA) for the GENETIC-AF clinical trial evaluating Gencaro™ as a potential treatment for atrial fibrillation (AF). This site brings the total current number of active trial sites to thirty-three. ARCA plans to activate a total of approximately 60 clinical trial sites in the United States and Canada for the Phase 2B portion of the trial.

ARCA is evaluating Gencaro, a pharmacologically unique beta-blocker and mild vasodilator, as a potential treatment for AF in the Phase 2B/3 GENETIC-AF clinical trial, which is now enrolling patients in the United States and Canada. ARCA has identified common genetic variations that it believes predict individual patient response to Gencaro, giving it potential to be the first genetically-targeted therapy for the prevention of atrial fibrillation.

Stuart Connolly, MD, Director of the Division of Cardiology at McMaster University in Hamilton, Ontario, Canada, and Co-Chairman of the GENETIC-AF Steering Committee, commented, "This trial is an innovative pharmacogenetic approach to evaluating the potential efficacy of bucindolol as a treatment for atrial fibrillation. Atrial fibrillation is a growing problem where current medical therapy does not provide adequate treatment, particularly in heart failure populations.

Jeff Healey, MD and Country Principal Investigator, commented further, "Canadian health care and its clinical trial culture is ideally suited for a trial such as GENETIC-AF, which investigates a potential advance in the unmet need areas of atrial fibrillation prevention and/or rate control in a heart failure population. I hope the Canadian GENETIC-AF trial sites will contribute a substantial number of patients to this program to help advance a potential new treatment for patients at high risk for developing, or living with, atrial fibrillation.

About Atrial Fibrillation (AF)

Atrial fibrillation, the most common sustained cardiac arrhythmia, is considered an epidemic cardiovascular disease and a major public health burden. The estimated number of individuals with AF globally in 2010 was 33.5 million. According to the 2014 American Heart Association report on Heart Disease and Stroke Statistics, the estimated number of individuals with AF in the U.S. in 2010 ranged from 2.7 million to 6.1 million people. Hospitalization rates for AF increased by 23% among US adults from 2000 to 2010 and hospitalizations account for the majority of the economic cost burden associated with AF.

AF 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 potentially resulting in stroke. AF increases the risk of mortality and morbidity due to stroke, congestive heart failure and impaired quality of life. The approved therapies for the treatment or prevention of AF have certain disadvantages in patients with heart failure and/or reduced left ventricular ejection fraction (HFREF) patients. These include toxic or cardiovascular adverse effects, and most of the approved drugs for AF are contra-indicated or have warnings in their prescribing information for such patients. The Company believes there is an unmet medical need for new AF treatments that have fewer side effects than currently available therapies and are more effective, particularly in HFREF patients.

GENETIC-AF Clinical Trial

GENETIC-AF is a Phase 2B/3, multi-center, randomized, double-blind clinical trial comparing the safety and efficacy of Gencaro to Toprol-XL for prevention of symptomatic AF/atrial flutter in HFREF patients. 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 initiated the trial as a Phase 2B trial in approximately 200 patients. The GENETIC-AF Data Safety Monitoring Board (DSMB) will analyze certain data from the Phase 2B portion of the trial and recommend, based on a comparison to the pre-trial statistical assumptions, whether the trial should proceed to Phase 3 and seek to enroll an additional 420 patients.

The AF indication for Gencaro was chosen based on clinical data from the previously conducted Phase 3 heart failure trial of 2,708 patients (the BEST trial). The Company believes data from the BEST trial indicate that Gencaro may have a genetically regulated effect in reducing or preventing AF, whereas the Company believes the therapeutic benefit of Toprol-XL does not appear to be enhanced in patients with this genotype. A retrospective analysis of data from the BEST trial shows that the entire cohort of patients in the BEST trial treated with Gencaro had a 41% reduction in the risk of new onset AF (time-to-event) compared to placebo ($p = 0.0004$). In the BEST DNA substudy, patients with the beta-1 389 arginine homozygous genotype experienced a 74% ($p = 0.0003$) reduction in risk of AF when receiving Gencaro, based on the same analysis.

About ARCA biopharma

ARCA biopharma is dedicated to developing genetically-targeted therapies for cardiovascular diseases. The Company's lead product candidate, GencarTM (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 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, 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, 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, 2013, and subsequent filings. The Company disclaims any intent or obligation to update these forward-looking statements.

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