ARCA biopharma, Inc.
Form 8-K
February 26, 2018

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): February 26, 2018

ARCA biopharma, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware	000-22873	36-3855489
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)
11080 CirclePoint Road, Suite 140, Westminster, CO (Address of Principal Executive Offices)		80020 (Zip Code)

Registrant's Telephone Number, Including Area Code: (720) 940-2200

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 Instructions 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))
Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Section 2 — Financial Information

Item 2.02. Results of Operations and Financial Condition

On February 26, 2018, ARCA biopharma, Inc. ("ARCA") issued a press release which included updated cash, cash equivalents and marketable securities balance information.

The press release is attached hereto as Exhibit 99.1, which is furnished under Item 2.02 of this report and shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended (the "Securities Act"), or the Exchange Act, regardless of any general incorporation language in such filing.

Section 8 — Other Events

Item 8.01. Other Events.

On February 26, 2018, ARCA made the following announcements regarding clinical results from GENETIC-AF, ARCA's Phase 2B, double-blind, superiority clinical trial evaluating Gencaro™ (bucindolol hydrochloride) as a genetically-targeted treatment for atrial fibrillation ("AF") in patients with heart failure and reduced left ventricular ejection fraction ("HFrEF"). In all patients, Gencaro demonstrated a similar treatment benefit compared to the active control, metoprolol succinate (TOPROL-XL). In U.S. patients (127 of 267 total patients), a trend for potential superior benefit in favor of Gencaro (approximately 30% risk reduction over TOPROL-XL), was observed for the primary endpoint of time to recurrence of AF. Additionally, in U.S. patients, Gencaro demonstrated a trend for potential superior benefit in favor of Gencaro (approximately 51% risk reduction over TOPROL-XL) in a subset of patients who underwent continuous heart rhythm monitoring with Medtronic implanted devices. Safety data indicated that Gencaro was generally safe and well-tolerated in the AF/heart failure ("HF") population investigated with a safety profile similar to TOPROL-XL.

GENETIC-AF enrolled 267 patients from the United States, Canada and Europe. The primary analysis was conducted to evaluate the evidence of safety and superior efficacy of Gencaro versus an active control with demonstrated effectiveness and safety in this patient population TOPROL-XL. The primary endpoint of the trial was time to recurrent AF, atrial flutter ("AFL") or all-cause mortality ("ACM"). The trial was not powered to conventional significance for this endpoint and utilized Bayesian statistical modeling of predictive probability of success ("PPoS") of the primary endpoint to estimate outcome if the trial had enrolled 620 patients with 330 primary events.

In all patients, Gencaro demonstrated a similar treatment benefit compared to the active control, TOPROL-XL (143 total events, hazard ratio of 1.01 (95% confidence interval: 0.71, 1.42), which was associated with a PPoS of 14%. In the U.S. patient cohort of 127 patients (approximately 50% of all patients and events), a trend for potential superior benefit in favor of Gencaro over TOPROL-XL was observed (73 events, hazard ratio 0.70, [95% confidence interval: 0.41, 1.19]), with a PPoS of 61%, which was greater than the prespecified criteria set by the company to proceed to Phase 3 development. ARCA believes the difference in treatment effects between the overall and U.S. patient cohorts was primarily due to results in two non-U.S. countries exhibiting hazard ratios >1.0. The differences between patients enrolled at these sites versus the U.S. and other country cohorts are being investigated.

A subgroup of patients underwent continuous (24/7) heart rhythm monitoring via Medtronic implanted loop recorders or other Medtronic implanted therapeutic devices (e.g., ICDs, CRTs) to evaluate daily AF burden. AF burden is

defined as the amount of time per day a patient experiences AF. A prespecified time-to-first event analysis was conducted using a total AF burden of at least 6 hours per day to define an event of AF recurrence. In this analysis, hazard ratios of 0.75 (0.43, 1.32) and 0.49 (0.24, 1.04) were observed in the overall (n=69) and U.S. patient (n=42) cohorts, respectively.

Gencaro was generally safe and well-tolerated, with 84% of patients attaining their target dose compared to 72% of patients receiving TOPROL-XL. The most frequently reported adverse events were similar in both groups and consistent with the known safety profile of the beta-blocker class of drugs. Adverse events assessed as related to study drug by the investigator occurred in 23.8% of patients in the Gencaro group and in 30.1% of patients in the TOPROL-XL group. Of note, adverse events of bradycardia were less frequently reported in the Gencaro group (3.7%) compared to patients receiving TOPROL-XL (12.0%). During the 24-week efficacy follow-up period there were three deaths (ACM) in the TOPROL-XL group and none in the Gencaro group. Three patients died in the long-term treatment extension period after receiving Gencaro for more than a year.

ARCA anticipates meeting with the U.S. Food and Drug Administration in the second quarter of 2018 to review Gencaro Phase 2 data and potential Phase 3 development plan.

On February 26, 2018, ARCA made a presentation regarding the results described above, which is attached hereto as Exhibit 99.2 and the contents of which are incorporated herein by reference.

Caution Concerning Forward Looking Statements

This Current Report on Form 8-K may contain forward-looking statements made in reliance upon the safe harbor provisions of Section 27A of the Securities Act and Section 21 E of the Exchange Act. These statements include, but are not limited to, statements regarding potential Phase 3 development plans for Gencaro, the expected features and characteristics of Gencaro, including the potential for genetic variations to predict individual patient response to Gencaro, Gencaro's potential to treat AF, future treatment options for patients with AF, the potential for Gencaro to be the first genetically-targeted AF prevention treatment and the ability of ARCA's financial resources to support its operations through the end of 2018. 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: ARCA's financial resources and whether they will be sufficient to meet its business objectives and operational requirements; ARCA may not be able to raise sufficient capital on acceptable terms, or at all, to continue development of Gencaro or to otherwise continue operations in the future; results of earlier clinical trials may not be confirmed in future trials; the protection and market exclusivity provided by ARCA'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 Securities and Exchange Commission, including without limitation ARCA's annual report on Form 10-K for the year ended December 31, 2016, and subsequent filings. ARCA disclaims any intent or obligation to update these forward-looking statements.

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 Reports Topline Phase 2B Results for GENETIC-AF Clinical Trial" dated February 26, 2018.
99.2	Investor Presentation titled "ARCA biopharma Investment Community Webcast: Top-line Data from GENETIC-AF Phase 2B Clinical Trial" dated February 26, 2018.

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: February 26, 2018

ARCA biopharma, Inc.
(Registrant)

By: /s/ Brian L. Selby
Name: Brian L. Selby
Title: Vice President, Finance and Chief Accounting Officer