ARCA biopharma, Inc.
Form 8-K
January 25, 2019

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): January 25, 2019

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.

Item 1.01 Entry Into a Material Definitive Agreement.

On January 25, 2019, ARCA biopharma, Inc. (the "Company") entered into Amendment No. 2 (the "Amendment") to its Capital on Demand™ Sales Agreement, dated as of January 11, 2017, as amended by the Amendment No. 1, dated as of August 21, 2017, (together, the "Sales Agreement" and, as amended by the Amendment, the "Amended Sales Agreement"), with JonesTrading Institutional Services LLC, as agent ("Agent"). The Amendment, among other things, increased the maximum aggregate offering value of shares of the Company's common stock (the "Additional Shares") which the Company may issue and sell from time to time under the Amended Sales Agreement (the "Offering") by approximately $2.5 million, from $10,242,863 to $12,742,739. As of January 25, 2019, the Company had sold 4,811,353 shares of its common stock under the Sales Agreement for an aggregate offering price of $10,083,445, before deducting sales and commissions and offering expenses. The Company will file a prospectus supplement with the Securities and Exchange Commission (the "SEC") in connection with the Offering (the "Prospectus Supplement") under its existing Registration Statement on Form S-3 (File No 333-217459), which became effective on May 12, 2017 (the "Registration Statement").

Under the Amended Sales Agreement, Agent may sell the Additional Shares by any method permitted by law and deemed to be an "at the market offering" as defined in Rule 415 promulgated under the Securities Act of 1933, as amended. The Company may instruct Agent not to sell Additional Shares if the sales cannot be effected at or above the price designated by the Company from time to time.

The Company is not obligated to make any sales of the Additional Shares under the Amended Sales Agreement. The Offering will terminate upon the earlier of (a) the sale of all of the Additional Shares subject to the Amended Sales Agreement or (b) the termination of the Amended Sales Agreement by Agent or the Company, as permitted therein.

The Company will pay Agent a commission rate equal to 3.0% of the aggregate gross proceeds from each sale of Additional Shares and has agreed to provide Agent with customary indemnification and contribution rights. The Company will also reimburse Agent for certain specified expenses in connection with entering into the Amended Sales Agreement.

The foregoing description of the Amended Sales Agreement is not complete and is qualified in its entirety by reference to the full text of such agreement, a copy of which is filed herewith as Exhibit 10.1 to this Current Report on Form 8-K and is incorporated herein by reference. The Company previously filed the Sales Agreement as Exhibit 10.1 to its Current Report on Form 8-K filed with the SEC on January 11, 2017 and the Amendment No.1 as Exhibit 10.1 to its Current Report on Form 8-K filed with the SEC on August 21, 2017.

Cooley LLP, counsel to the Company, has issued a legal opinion relating to the Additional Shares. A copy of such legal opinion, including the consent included therein, is attached as Exhibit 5.1 hereto.

The Additional Shares will be sold pursuant to the Registration Statement, and offerings of the Additional Shares will be made only by means of the Prospectus Supplement and any accompanying prospectus. This Current Report on Form 8-K shall not constitute an offer to sell or solicitation of an offer to buy these securities, nor shall there be any sale of these securities in any state in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities law of such state or jurisdiction.

Section 8 — Other Events

Item 8.01. Other Events.

The Company is seeking a Special Protocol Assessment ("SPA") agreement with the U.S. Food and Drug Administration (the "FDA"). The FDA's SPA process is designed to facilitate the FDA's review and approval of drugs by allowing FDA to evaluate the proposed design and size of certain clinical trials that are intended to form the primary basis for determining a drug product's efficacy and safety. Upon specific request by a clinical trial sponsor, the FDA will evaluate the protocol and respond to a sponsor's questions regarding, among other things, primary efficacy endpoints, trial conduct and data analysis, within 45 days of receipt of the request. The FDA ultimately assesses whether the protocol design and planned analysis of the trial are acceptable to support regulatory approval of the product candidate for the indication studied. An SPA agreement can potentially reduce the regulatory risk of bringing a drug to market.

The Company submitted an SPA request to the FDA in September 2018. In late October 2018, the Company received a No Agreement letter from the FDA on its SPA request. After further correspondence and following provision of information regarding the SPA, the Company met with the FDA in December 2018 and the FDA agreed to reconsider the Company's SPA request. In December 2018, the Company submitted an amendment to the original SPA request that addressed the feedback and guidance from the FDA on the target population for the Company's planned Phase 3 clinical trial. In January 2019, the Company received a No Agreement letter in response to the SPA amendment. In January 2019, addressing the FDA's new guidance, the Company refined the design and statistical power for the Company's planned Phase 3 clinical trial and resubmitted its SPA request to the FDA.

The Company's SPA request, as resubmitted, details a single adequate and well-controlled Phase 3 clinical trial (PRECISION-AF) designed as a double-blind, active-controlled, multicenter, international, study comparing Gencaro with TOPROL-XL (metoprolol succinate) for the prevention of recurrent atrial fibrillation ("AF") or all-cause mortality ("ACM"), in patients with chronic heart failure and a mid-range left ventricular ejection fraction (LVEF) ≥ 0.40 and < 0.50 ("HFmrEF"). Eligible patients will have HFmrEF, a recent AF event and the genotype which responds most favorably to Gencaro. The primary endpoint of the submitted trial will be time to first event of atrial fibrillation/atrial flutter or ACM during a 26-week follow-up period. Subject to the FDA's approval of the Company's SPA request and securing significant additional financing, the Company anticipates initiating PRECISION-AF in the fourth quarter of 2019. The Company expects to receive the FDA's response to the Company's SPA request in February 2019.

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 timing and results of any clinical trials, including PRECISION-AF, any potential future PRECISION-AF trials, the Company's requested SPA from the FDA relating to the Company's planned Phase 3 program 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 first quarter of 2019. 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, 2017, 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
5.1	Opinion of Cooley LLP.
10.1	Amendment No. 2 to Capital on Demand™ Sales Agreement, dated January 25, 2019, by and between ARCA biopharma, Inc. and JonesTrading Institutional Services LLC.
23.1	Consent of Cooley LLP (included in Exhibit 5.1).

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: January 25, 2019

ARCA biopharma, Inc.
(Registrant)

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