

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 25, 2017**

ARCH THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Nevada
(State or other jurisdiction
of incorporation)

000-54986
(Commission
File Number)

46-0524102
(I.R.S. Employer
Identification No.)

235 Walnut Street, Suite 6
Framingham, Massachusetts
(Address of principal executive offices)

01702
(Zip Code)

Registrant's telephone number, including area code: **(617) 431-2313**

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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2). 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 7.01 Regulation FD Disclosure.

On July 25, 2017, Arch Therapeutics, Inc. (the “**Company**”) issued a press release announcing the filing of its 510(k) submission to the U.S. Food and Drug Administration (FDA) for its AC5™ Topical Gel. The text of the press release is attached hereto as Exhibit 99.1 and is incorporated by reference herein.

Item 8.01 Other Events.

The disclosure under Item 7.01 (Regulation FD Disclosure) is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibit

(d) Exhibits

Exhibit	Description
99.1	Press Release issued by Arch Therapeutics, Inc. on July 25, 2017

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.

ARCH THERAPEUTICS, INC.

Dated: July 25, 2017

By: /s/ Terrence W. Norchi, M.D.
Name: Terrence W. Norchi, M.D.
Title: President, Chief Executive Officer

Exhibit List

Exhibit	Description
99.1	Press Release issued by Arch Therapeutics, Inc. on July 25, 2017

Arch Therapeutics Announces 510(k) Submission to the U.S. FDA for AC5™ Topical Gel

Company achieves milestone of its first U.S. regulatory filing for a medical device

FRAMINGHAM, MA – July 25, 2017 -- Arch Therapeutics, Inc. (OTCQB: ARTH) (“Arch” or the “Company”), developer of novel liquid, gel and solid hemostatic and wound care devices, today announced that the Company made a 510(k) submission to the U.S. Food and Drug Administration (FDA) for its AC5™ Topical Gel on July 17, 2017.

If the Company’s 510(k) application is cleared by the FDA, it is expected that the AC5™ Topical Gel will be used for external wounds . “This is an important milestone for Arch,” said Terrence W. Norchi, President and CEO of Arch Therapeutics, Inc. “As previously shared, we planned to request 510(k) clearance in the middle of 2017 for the external use AC5™, which is a significant acceleration from original expectations of seeking U.S. regulatory approval through the PMA process, and we have met that goal. This achievement illustrates the ability of our team to execute on our development and regulatory strategies.”

As previously disclosed, the Company still plans to seek regulatory approval to market other AC5™ products for internal use through the PMA process. Arch will continue to concentrate resources on the rest of its development and regulatory objectives. The Company is also working to scale up production and at the present time expects to have commercial product available in the second half of 2018. In the interim, Arch will continue to evaluate its commercialization options and it will provide further guidance as appropriate.

Dr. Norchi added, “This 510(k) submission, which incorporates recommendations provided by the FDA during pre-submission communications, is the culmination of the collective effort and success of our team in completing important biocompatibility, toxicology, preclinical, and clinical studies. Simultaneously, we continue to make progress on our preclinical pipeline, including several product applications with high unmet medical needs.”

About Arch Therapeutics, Inc.

Arch Therapeutics, Inc. is a biotechnology company developing a novel approach to stop bleeding (hemostasis), control leaking (sealant) and manage wounds during surgery, trauma and interventional care. Arch is developing products based on an innovative self-assembling barrier technology platform with the goal of making care faster and safer for patients. Arch's development stage product candidates include the AC5™ Topical Gel and the AC5™ Surgical Hemostatic Device.

Notice Regarding Forward-Looking Statements

This news release contains "forward-looking statements" as that term is defined in Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Statements in this press release that are not purely historical are forward-looking statements and include any statements regarding beliefs, plans, expectations or intentions regarding the future. Such forward-looking statements include, among other things, references to novel technologies and methods, our business and product development plans and projections, or market information. Actual results could differ from those projected in any forward-looking statements due to numerous factors. Such factors include, among others, the inherent uncertainties associated with developing new products or technologies and operating as a development stage company, our ability to retain important members of our management team and attract other qualified personnel, our ability to raise the additional funding we will need to continue to pursue our business and product development plans, our ability to obtain required regulatory approvals, our ability to produce commercial quantities of our products within projected timeframes, our ability to develop and commercialize products based on our technology platform, and market conditions. These forward-looking statements are made as of the date of this news release, and we assume no obligation to update the forward-looking statements, or to update the reasons why actual results could differ from those projected in the forward-looking statements. Although we believe that any beliefs, plans, expectations and intentions contained in this press release are reasonable, there can be no assurance that any such beliefs, plans, expectations or intentions will prove to be accurate. Investors should consult all of the information set forth herein and should also refer to the risk factors disclosure outlined in the reports and other documents we file with the SEC, available at www.sec.gov.

Terrence W. Norchi, MD
Arch Therapeutics, Inc.

Source: Arch Therapeutics, Inc.

Contact

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