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): **November 28, 2018**

ARCH THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Nevada	**000-54986**	**46-0524102**
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

235 Walnut Street, Suite 6 **Framingham, Massachusetts**	**01702**
(Address of principal executive offices)	(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 November 28, 2018, Arch Therapeutics, Inc. (the "**Company**") issued a press release to announce the the submission of the required CE Mark documents for its AC5™ Topical Hemostat (AC5) product. 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 Exhibits

(d) The following exhibits are being filed herewith:

Exhibit	Description
99.1	Press Release issued by Arch Therapeutics, Inc. on November 28, 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.

ARCH THERAPEUTICS, INC.

Dated: November 28, 2018

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

Exhibit 99.1

Arch Therapeutics Announces Submission of CE Mark File for AC5™ Topical Hemostat in Europe

Company anticipates review process could take up to six months

FRAMINGHAM, MA – November 28, 2018 -- 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 has submitted the required documents for AC5ä Topical Hemostat (AC5)[1] to its Notified Body as it seeks a CE mark, which is a next step on the path to commercialization in countries governed by the European Medical Devices Directive (MDD). This first such submission by Arch to a European regulatory body follows the recent submission of a 510(k) premarket notification to the US Food and Drug Administration.

Receipt of a CE mark would allow AC5 to be commercialized for use on external wounds, and in particular, for controlling bleeding by mechanically sealing areas of leakage and managing wounds in skin. The CE mark represents a company's claim that a product meets the essential requirements of relevant European directives, and it is a legal prerequisite in order to place a device on the market in the European Union. AC5 will be assessed as a Class IIb device. We expect that the review process could take up to 6 months.

A Notified Body is an independent third-party selected by a Competent Authority to assess a medical device manufacturer's compliance by conducting a conformity assessment under the MDD. Each country has one Competent Authority, which is a local government body responsible for, among other things, ensuring that the MDD requirements are placed into National Law.

Terrence W. Norchi, MD, President and CEO of Arch, said, "This is an important step in a busy quarter for Arch. Having filed the 510(k) notification in the third calendar quarter, we are happy to have also completed the work necessary to file this submission."

As previously disclosed, Arch is seeking regulatory clearance in the U.S. and, following this initial clearance, potential clearance or approval for expanded indications. The company is also pursuing commercial opportunities for other AC5-related products, including use in open and laparoscopic surgical procedures. Arch continues to evaluate commercialization options and will provide updates when appropriate.

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 AC5™ Topical Gel[1], AC5™ Topical Hemostat[1] and AC5™ Surgical Hemostat[1].

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.

Source: Arch Therapeutics, Inc.

Contact

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1. AC5 is currently an investigational device and is limited by federal law to investigational use.