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): **April 13, 2020**

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** (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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
N|A	N|A	N|A

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 April 13, 2020, Arch Therapeutics, Inc. (the "**Company**") issued a press release announcing the Company's receipt of a CE (Conformité Européenne) mark for its first-in-class wound care product, AC5™ Topical Hemostat ("**AC5**").

Under applicable European Union ("**EU**") medical device directives, a CE mark is a symbol placed on a product that declares that the product is compliant with the essential requirements of applicable EU health, safety and environmental protection legislation. In order to receive a CE mark for a product candidate, the company producing the product candidate must select a country in which to apply. Each country in the EU has one competent authority ("**CA**") that implements the national regulations by interpreting the EU directives. CAs also designate and regulate Notified Bodies. An assessment by a Notified Body in the selected country within the EU is required in order to commercially distribute the device. In addition, compliance with ISO 13485 issued by the International Organization for Standardization, among other standards, establishes the presumption of conformity with the essential requirements for CE marking. Certification to the ISO 13485 standard demonstrates the presence of a quality management system that can be used by a manufacturer for design and development, production, installation and servicing of medical devices and the design, development and provision of related services.

Devices that comply with the requirements of the laws of the selected member state applying the applicable EU directive are entitled to bear a CE mark and can be distributed throughout the member states of the EU, as well as in other countries that have mutual recognition agreements with the EU or have adopted the EU's regulatory standards.

The CE mark provides authorization to commercialize AC5 in Europe as a dressing and to control bleeding in external skin wounds in both out- and in-patient settings.

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 April 13, 2020

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: April 13, 2020

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

Exhibit 99.1

Arch Therapeutics Receives CE Mark Approval for AC5™ Topical Hemostat in Europe

Novel hemostatic wound dressing provides distinctive features

FRAMINGHAM, Mass., April 13, 2020 (GLOBENEWSWIRE) -- Arch Therapeutics, Inc. (OTCQB: ARTH) ("Arch" or the "Company"), developer of novel liquid, gel and solid hemostatic and wound care devices, today announced receipt of the CE (Conformité Européenne) mark for its first-in-class wound care product, AC5™ Topical Hemostat ("AC5").

The CE mark provides authorization to commercialize AC5 in Europe as a dressing and to control bleeding in skin wounds in both out- and in-patient settings.

Chief Executive Officer, Terrence W. Norchi, MD, said, "Experts continue to describe their desire for a hemostatic wound dressing with the broad array of features and benefits that AC5 offers. We expect earliest adoption to be in complicated acute surgical wounds as well as wounds that require better sharp debridement and wound bed preparation."

AC5 is a clear, conformable therapy that can uniquely support chronic and complicated wounds across all phases of the healing continuum. AC5 contains a proprietary synthetic peptide that self-assembles into a contiguous physical-mechanical seal on tissue, where it becomes a nanofiber scaffold similar to the body's native extracellular matrix.

Additional AC5 features include that it:

- is hemostatic in the presence of anti-thrombotic therapy,
- conforms to irregular wound geometry and provides a protective barrier,
- has utility across all phases of wound healing,
- contains no human or other animal sourced materials, and
- it is naturally resorbed from the wound bed.

Norchi added, "Arch appreciates approval of the CE mark, especially considering the ongoing regulatory backlog in Europe due to changes in statutes and the current Covid-19-related encumbrances."

In addition to the broad benefits described above, AC5 may allow clinicians to better treat wounds at the bedside and temporize wounds in patients who cannot access an operating room by providing critical protection and optimize the microenvironment for healing.

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, AC5 Topical Hemostat and AC5 Surgical Hemostat.[1, 2]

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.

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or

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1. AC5 Surgical Hemostat is currently an investigational device limited by law to investigational use.
2. AC5 and associated logos are trademarks and/or registered trademarks of Arch Therapeutics, Inc. and/or its subsidiaries.