

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): **August 5, 2019**

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))

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 August 5, 2019, Arch Therapeutics, Inc. (the “**Company**”) issued a press release that announced the results of two studies conducted to assess the antimicrobial properties of the Company’s AC5™ self-assembling peptide technology platform (AC5), and provided an update on the status of the Company’s application for a CE Mark for its AC5 Topical Hemostat 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
<u>99.1</u>	<u>Press Release issued by Arch Therapeutics, Inc. on August 5, 2019</u>

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: August 5, 2019

By: /s/ Terrence W. Norchi, M.D.

Name: Terrence W. Norchi, M.D.

Title: President, Chief Executive Officer

Arch Therapeutics Announces AC5 Self-Assembling Peptide Technology Platform Demonstrates Antimicrobial Activity in Two Studies and Provides CE Marking Status Update for AC5™ Topical Hemostat

Studies highlight antimicrobial activity for AC5 technology platform; AC5™ Topical Hemostat¹ under Review by Notified Body

FRAMINGHAM, Mass., August 5, 2019 (GLOBE NEWSWIRE) -- Arch Therapeutics, Inc. (OTCQB: ARTH) ("Arch" or the "Company"), developer of novel liquid, gel and solid hemostatic and wound care devices, announced today the results of two studies supporting the underlying antimicrobial properties of the Company's AC5™ self-assembling peptide technology platform (AC5). Arch also provided an update on the status of the CE Marking process for AC5™ Topical Hemostat in the European Union.

The first study used an *in vitro* bioburden model in which AC5 and control media were exposed to the same levels of three common and potentially pathogenic wound bacteria: Staphylococcus epidermidis (SE), methicillin-susceptible Staphylococcus aureus (MSSA), and methicillin-resistant Staphylococcus aureus (MRSA). AC5 media demonstrated lower bacterial counts for each organism when compared to a control, which is consistent with inhibition of bacterial growth. The results were statistically significant for both SE and MSSA ($p < 0.05$).

In the second study, porcine burn wounds were treated with either AC5, or a standard control dressing or a well-established silver-based antimicrobial dressing. AC5 and the silver-based antimicrobial dressing demonstrated lower total bacterial counts compared to the standard control dressing, and the results were statistically significant for both ($p < 0.05$). Furthermore, the total bacterial count attributed to AC5 was not statistically different from that of the silver-based antimicrobial dressing.

Bioburden refers to the number of micro-organism that are present in, or colonize, a wound. As bioburden level rises, so does the probability of infection. Infection leads to worse outcomes, including delayed healing and compromised tissue repair. Commercial wound dressings are commonly offered in an antimicrobial version formulated with additional antimicrobial components, such as silver, iodine, chlorhexidine and other chemicals, in an effort to manage bioburden.

Terrence W. Norchi, MD, CEO of Arch Therapeutics commented, "Managing and controlling bioburden is inherently important for optimal wound healing, and these highlight that AC5 technology may play a role in achieving a lower bioburden without requiring additional antimicrobial ingredients, which are often toxic to healing cells and tissue. The findings are significant as we continue to establish the position of our products in wound care, and we intend to continue to develop and highlight the features that we believe will make the AC5 platform valuable and successful."

Considering the importance of managing bioburden, the Company anticipates collecting additional data for potential regulatory submissions related to antimicrobial claims in the future for products emanating from the AC5 platform. To date, antimicrobial claims have not been sought for Arch products in any jurisdiction, and none are being marketed for such claims.

The Company also provided an update on the status of its application for a CE Mark for AC5 Topical Hemostat. Arch submitted its CE Mark technical file to BSI, the Company's Notified Body, on November 28, 2018 and expected a response within approximately 6 months. During the review period, Arch has received and responded to written and verbal questions related to the technical file, which is customary during the review process, and has not been required to generate any additional data. BSI has recently indicated that the responses provided and assessed during the review period so far are acceptable, and we are confident that we can address additional questions should any arise as they complete their review of the file and this process moves forward to completion.

Norchi said, "Our interactions with the Notified Body have been positive and, except for the lengthy timeline, in line with standard protocol. We are pleased that no additional data has been required to address any questions received. While we wish to have received our CE Mark by now, we believe that the delay in completing the CE Mark technical file review is due to a backlog of work for EU notified bodies related to both Brexit and the implementation of the new EU Medical Devices Regulation. As a result, we currently expect the review process to be completed this fall, and we anticipate our next update to coincide with a definitive and material announcement."

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 Hemostat¹ 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 Topical Hemostat and AC5 Surgical Hemostat are currently investigational devices limited by law to investigational use.
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