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): **September 13, 2023**

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 September 13, 2023, Arch Therapeutics, Inc. (the "**Company**") issued a press release providing a commercialization update on the Company's first product, AC5® Advanced Wound System (" **AC5**"). AC5 is cleared by the Food and Drug Administration for the management of partial and full-thickness wounds, such as pressure sores, leg ulcers, diabetic ulcers, and surgical wounds. AC5 is a synthetic self-assembling wound care product that provides clinicians with multi-modal support and utility across all phases of wound healing.

Since the Centers for Medicare and Medicaid Services ("**CMS**") established A2020, a Level II Healthcare Common Procedure Coding System ("**HCPCS**") code dedicated to AC5, both orders and payments for submitted claims have accelerated.

Since the April 1, 2023, effective date of A2020, average monthly order volume for AC5 has grown significantly, increasing over four-fold when compared to average monthly order volume from the first calendar quarter. The Company can already confirm reimbursement through paid claims in various regions of the country and continues to make progress on its efforts to expand coverage and optimize payment policies with both commercial payors and contracting administrators for CMS.

While coverage and payment decisions by payor can vary, and total revenue remains modest relative to our long-term expectations, the increase in order volume, reimbursement trends, and the number of providers using AC5 in their respective practice settings exceeds management's internal targets for this point in the process.

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 No.	**Description**
99.1	Press Release issued by Arch Therapeutics, Inc., datedSeptember 13, 2023.
104	Cover Page Interactive Data File (embedded within the Inline XBRL Document)

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: September 13, 2023

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

Exhibit 99.1

Arch Therapeutics Provides AC5® Commercialization Update

Orders and Paid Claims Increasing Since Rollout of Reimbursement Code

FRAMINGHAM, MA – **September 13, 2023** – Arch Therapeutics, Inc. (OTCQB: ARTH) ("Arch" or the "Company"), a marketer and developer of novel self-assembling wound care and biosurgical products, today provided a commercialization update on the Company's first product, AC5® Advanced Wound System. Since the Centers for Medicare and Medicaid Services ("CMS") established A2020, a Level II Healthcare Common Procedure Coding System ("HCPCS") code dedicated to AC5, both orders and payments for submitted claims have accelerated.

Since the April 1, 2023 effective date of A2020, average monthly order volume for AC5 has grown significantly, increasing over four-fold when compared to average monthly order volume from the first calendar quarter. The Company can already confirm reimbursement through paid claims in various regions of the country and continues to make progress on its efforts to expand coverage and optimize payment policies with both commercial payors and contracting administrators for CMS.

While coverage and payment decisions by payor can vary, and total revenue remains modest relative to our long-term expectations, the increase in order volume, reimbursement trends, and the number of providers using AC5® in their respective practice settings exceeds management's internal targets for this point in the process.

"The establishment of coverage and payment decisions from commercial payors and CMS contractors is an important element of our growth strategy for AC5. We expect to build on our recent sales momentum throughout 2023 and 2024," stated Terrence Norchi, MD, President and CEO of Arch. "At any given time, there are more than 7 million challenging wounds in the U.S., with approximately 4 million new wounds emerging each year. Mitigating suffering, reducing the risk of amputation and death among patients living with these wounds, and potentially lowering the overall cost to the healthcare system related to treating these wounds, remain a driving force for the Company," concluded Dr. Norchi.

AC5 is cleared by the Food and Drug Administration for the management of partial and full-thickness wounds, such as pressure sores, leg ulcers, diabetic ulcers, and surgical wounds. AC5 is a synthetic self-assembling wound care product that provides clinicians with multi-modal support and utility across all phases of wound healing. Additional information may be found here:
https://www.archtherapeutics.com/technology/clinical-data.

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 has received regulatory authorization to market AC5® Advanced Wound System and AC5® Topical Hemostat as medical devices in the United States and Europe, respectively. Arch's development stage product candidates include AC5-G™, AC5-V® and AC5® Surgical Hemostat, among others.

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, and our ability to establish additional commercialization partnerships and build a critical mass of field sales representatives. 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.

Contact:
ARTH Investor Relations
Toll Free: +1-855-340-ARTH (2784) (US and Canada)
Email: investors@archtherapeutics.com
Website: www.archtherapeutics.com

or

Michael Abrams
Chief Financial Officer
Arch Therapeutics, Inc.
Phone: 617-680-7841
Email: mabrams@archtherapeutics.com
Website: www.archtherapeutics.com

---

[1] AC5-G, AC5-V, and AC5 Surgical Hemostat are currently investigational devices limited by law to investigational use.

[2] AC5, AC5-G, AC5-V and associated logos are trademarks and/or registered trademarks of Arch Therapeutics, Inc. and/or its subsidiaries.