

November 9, 2023



Arch Therapeutics Provides Year End Operational Update

Continued Strong Trends in Orders and Paid Claims

FRAMINGHAM, Mass., Nov. 09, 2023 (GLOBE NEWSWIRE) -- 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 year-end operational update, including key performance metrics related to the ongoing commercialization activities for the Company's first product, AC5[®] Advanced Wound System ("AC5"). During its fourth fiscal quarter, the Company experienced a significant increase in AC5 orders, posting record monthly order volumes during both August and September. Taken together, orders from August and September represented more than half of total fiscal year volume, and September orders more than doubled August orders. The Company also observed favorable coverage and reimbursement decisions from multiple payors in different regions of the country with a commensurate increase in paid claims. A more detailed summary of key milestones and achievements from the fiscal year ended September 30, 2023 is provided below.

First Fiscal Quarter Ended December 31, 2022

- The Company received notification that the Centers for Medicare and Medicaid Services ("CMS") had made a preliminary recommendation to establish a Level II Healthcare Common Procedure Coding System ("HCPCS") code dedicated to AC5.
- At the Symposium on Advanced Wound Care ("SAWC") Fall 2022 meeting, the Company was featured in the live new technology session, *Innovation Spotlight: Shining a Light on Bold Ideas in Wound Care*, in which a Key Opinion Leader discussed his AC5 experience in a presentation entitled, "Changing the Healing Experience – Improving Lives with Self-Assembly".
- Also at SAWC Fall 2022, AC5 was featured in two poster presentations, one of which received a first place award for the "Highest Scoring Poster Abstract; Case Series/Study." Judgment criteria for the award included assessments of data reproducibility, patient complexity, wound uniqueness, and treatment duration.

Second Fiscal Quarter Ended March 31, 2023

- In line with its prior preliminary recommendation, CMS announced that it established a HCPCS code, A2020, dedicated exclusively to AC5 and which would become effective on April 1, 2023.
- The Company announced the creation of a Medical Advisory Board dedicated to advancing AC5 commercialization and comprising respected doctors from multiple specialties, including vascular surgery, podiatric medicine, and foot and ankle surgery.

- The Company expanded proprietary programs designed to increase provider engagement and drive AC5 adoption and usage upon the effectiveness of A2020.

Third Fiscal Quarter Ended June 30, 2023

- The HCPCS code for AC5, A2020, went effective, marking a central milestone in the Company's strategic commercialization plan.
- At SAWC Spring 2023, Arch introduced the theme "Experience the Difference" to highlight AC5's technology, application, wound coverage, and efficacy. This represented the first time that Arch could simultaneously present the features and benefits of AC5 and the new A2020 HCPCS reimbursement code to a clinical audience.
- Also at SAWC Spring 2023, AC5 was featured in two additional poster presentations that demonstrated the clinical efficacy of AC5 in challenging wounds.
- Providers submitted the first set of coverage and reimbursement requests to CMS and commercial insurer payer networks using A2020 in connection with the application of AC5 to treat wounds.

Fourth Quarter Ended September 30, 2023

- As noted above, the Company experienced a significant increase in AC5 orders, posting record monthly order volumes during both August and September. Taken together, orders from August and September represented more than half of total fiscal year volume, and September orders more than doubled August orders.
- The Company observed favorable coverage and reimbursement decisions from multiple payors in different regions of the country.
- Early in the fourth fiscal quarter, the Company received its first payment from a provider as a result of a paid claim for reimbursement of AC5 using A2020, and the number of paid claims across different payor networks increased throughout the quarter. The trend has continued into the current fiscal quarter.

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 on our website at <https://www.archtherapeutics.com>.

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.^{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, our sales trends, 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.



Source: Arch Therapeutics, Inc.