

September 23, 2022



Arch Therapeutics Announces First Shipments of AC5® Advanced Wound System Under New Reimbursement Support Program

Significant Milestone in Commercialization Plan Expected to Drive Sales Momentum

FRAMINGHAM, Mass., Sept. 23, 2022 (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 confirmed the first shipments of AC5® Advanced Wound System (“AC5”) under the Company’s new reimbursement support program (the “Program”). This development represents a significant milestone in the Company’s overall commercialization effort, which management believes will support the accelerated growth and utilization of AC5 in doctor’s offices and wound care clinics.

AC5 is a synthetic self-assembling wound care product that provides clinicians with multi-modal support and utility across all phases of wound healing. AC5 was cleared by the Food and Drug Administration (“FDA”) for the management of partial and full-thickness wounds, such as pressure sores, leg ulcers, diabetic ulcers, and surgical wounds. The Program seeks to leverage recently announced policy changes from the Centers for Medicare and Medicaid Services (“CMS”) for synthetic skin substitutes while the Company is awaiting a response on its HCPCS application for a unique code for AC5. The Program is also intended to facilitate the Company’s engagement with payors to advocate for clinically appropriate AC5 coverage and payment policies.

“This is an exciting time for Arch and the launch of the reimbursement support program represents a huge step forward. Not only do CMS’s policy changes provide doctors with greater clarity regarding the potential billing and reimbursement pathway for their use of AC5 to treat patients, but the Program also supports our ability to work with payors to develop specific, appropriate AC5 reimbursement policies. Taken together, we expect they will further promote enhanced customer confidence in AC5. In September alone, we expect to invoice more than twice the total number of commercial units shipped year to date. While the total number of units remains relatively modest, we believe the foundation provided by the Program will drive the acceleration of near and long-term revenue growth opportunities for the Company,” stated Dan Yrigoyen, Vice President of Sales of Arch Therapeutics.

About Arch Therapeutics, Inc.

Arch Therapeutics, Inc. is a biotechnology company with a novel approach to stop bleeding (hemostasis), control leaking (sealant) and manage wounds during surgery, trauma, and

interventional care. Arch is developing wound care and biosurgical products based on an innovative self-assembling peptide technology platform with the goal of improving healing outcomes for patients. Arch has received regulatory clearance to market AC5[®] Advanced Wound System in the United States and AC5[®] Topical Hemostat in Europe. Arch's development stage product pipeline includes AC5-G[™] for endoscopic resection of gastrointestinal tumors, AC5-V[®] for hemostasis during vascular surgery and AC5 Surgical Hemostat for general surgical hemostasis, 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 ability to recruit additional field sales representatives and their effectiveness, 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 obtain the inclusion of our AC5[®] Advanced Wound System on targeted federal supply schedules, 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.

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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.