

INSTITUTIONAL RESEARCH

Medical Devices UPDATE REPORT

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Arch Therapeutics (OTCqb: ARTH) -Neutral Rated

March 6, 2023

Getting Closer to Reimbursement – CMS Codes

We believe Arch is getting close to finalizing its CMS reimbursement for the company's lead product AC5. We know that the Centers for Medicare and Medicaid Services (CMS) made a preliminary recommendation to establish a dedicated Healthcare Common Procedure Coding System (HCPCS) Level II billing code specific to the AC5 Advanced Wound System. The preliminary recommendation was discussed at CMS' First Biannual 2022 HCPCS Public Meeting, (held on November 30, 2022).

CMS is Likely to Finalize its Reimbursement for AC5 Soon. The "public" commentary is concluded (Nov. 2022), typically we see finalization 60-90 days later. Finalization of the HCPCS code better enables providers to bill third-party payors for AC5 that is used in doctors' offices, supporting commercialization efforts.

What's Next? Capital. The company is capital constrained. Badly needed capital allows the company to begin generating sales and paves the way for an uplisting. Fundamentally we believe in AC5 and that hasn't changed. The stock remains at what we consider to be a deeply distressed valuation which we think corrects once the cash crunch is alleviated. We anticipate revising our rating, post-raise.

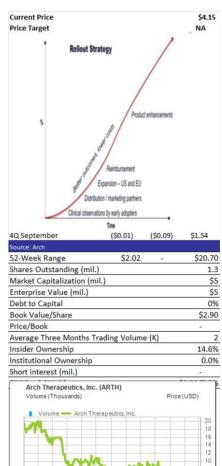
An Effective Barrier and Scaffold that Promotes Healing. The company's flagship product is based on its AC5 self-assembling peptide (SAP) technology platform. The platform includes AC5 Advanced Wound System and AC5 Topical Hemostat, which have received marketing authorization as medical devices in the United States and Europe, respectively, and which are intended for skin applications, such as the management of complicated chronic wounds or acute surgical wounds. The AC5 platform is a biocompatible peptide that is synthesized from proteogenic, naturally occurring L-amino acids. Unlike products that contain traditional peptide sequences, when applied to a wound, AC5-based products intercalate into the interstices of the connective tissue and self-assemble into a protective physical-mechanical nanoscale structure that can provide a barrier to leaking substances, such as blood, while also acting as a biodegradable scaffold that enables healing. Self-assembly is a central component of the mechanism of action.

Valuation: We have lowered our rating from Buy to Neutral and for the moment removed our price target. We have updated our revenue assumptions in our model. We assume a royalty model – 30% net to Arch. We apply a 30% risk rate in our Free Cash Flow to the Firm (FCFF), discounted EPS (dEPS), and Sum-of-the-Parts (SOP) models, which are then equal-weighted and averaged and rounded to the nearest whole number to derive our target valuation.

Risks to our thesis include: (1) commercial; (2) financial; (3) intellectual property; and (4) OEM and/or manufacturing. We review these risks in the Risks Analysis section of this report.

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Risk Analysis

Commercial risk. The focus of the company is on successfully developing its products and bringing them to the market. Competition may be intense from external players as well as customers who choose to "build it themselves".

Financial risk. The company may need to raise capital in the marketplace relatively soon. There can be no assurance that the company will be able to raise capital and do so on favorable terms successfully.

Intellectual property risk. The company may have to defend its patents and technical know-how, and there can be no assurances that the patents will not be infringed or will be held as valid if challenged, and the company may infringe on third parties' patents.

OEM and or manufacturing risk. Original Equipment Manufacturers (OEMs) may decide to make products themselves, and, as such, terminate production contracts before completion, creating revenue shortfalls. Manufacturing risks include the ability to produce and do so in a competitive, timely, and efficient way.



Exhibit 1. Income Statement

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Arch Therapeutics, Inc.: Income Statement (\$000)		****					****		****			2004
Arch Therapeutics, Inc.: YE September 30		2021A	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E
Product sales												
AC5 Revenues				5,000	10,739	21,704	32,898	44,324	55,988	67,891	80,038	92,433
		-	-									
				-								
				-								
Total Product Sales		12	_	5,000	137,998	221,950	328,879	44,324	55,988	67,891	80,038	92,433
Expenses				0,000	101,000	221,000	020,010	77,027	00,000	01,001	00,000	02,400
Cost of Goods Sold		26	_	500	13,800	22,195	32,888	4,432	5,599	6,789	8,004	9,243
000101 00000 0010	%COGS	10%	10%	10%	10%	10%	10%	10%	10%	10%	10%	10%
Research and Development	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	1,353	1,421	1,492	1,939	2,521	3,277	4,261	4,474	4,697	4,932	5,179
incesearch and Development	%R&D	1,000	1,121	1,102	1,000	2,021	0,211	1,201	1, 1, 1	1,007	1,002	0,170
General and Administrative	701142	5,009	5,260	5,523	5,302	5,090	4,886	5,033	5,184	5,443	5,715	6,001
Constant and Familional Ve	%SG&A	0,000	0,200	0,020	0,002	0,000	1,000	0,000	3,101	0,1.10	0,0	0,001
Total expenses		6,389	6,681	7,515	21,041	29,806	41,052	13,726	15,256	16,929	18,651	20,423
Operating Income (Loss)		(6,377)	(6,681)	(2,515)	116,957	192,144	287,828	30,599	40,731	50,961	61,387	72,010
Interest expense												
Fair value of derivative liabilities in excess of proceeds												
Gain on exercise of warrants												
Loss on warrant derivative modification												
Loss on issuance of warrants												
Adjustments of fair value of derivative												
Other income												
Culoi moomo												
Total other income		-	_	-	-	-	_	_	_	-	_	_
Pretax Income		(6,240)	(6,681)	(2,515)	116,957	192,144	287,828	30,599	40,731	50,961	61,387	72,010
Income Tax Benefit (Provision)			(133)	(201)	11,696	23,057	40,296	6,120	9,776	14,269	18,416	23,043
TaxRate		0%	5%	8%	10%	12%	14%	30%	34%	36%	38%	38%
GAAP Net Income (loss)		(6,240)	(6,548)	(2,313)	105,262	169,087	247,532	24,479	30,956	36,692	42,971	48,967
GAAP-EPS		(0.03)	(0.02)	(0.39)	14.47	23.15	33.76	3.33	4.19	4.94	5.77	6.55
GAAP EPS (dil)		(0.03)	(0.03)	(0.03)	14.47	8.73	12.73	1.25	1.58	1.86	2.17	2.47
Wgtd Avg Shrs (Bas) - '000s		220,001	250,453	69,309	7,273	7,302	7,332	7,361	7,391	7,420	7,450	7,480
Wgtd Avg Shrs (Dil) - '000s		220,001	250,453	69,309	7,273	19,369	19,446	19,524	19,602	19,681	19,760	19,839

Source: Dawson James estimates



Companies mentioned in this report:

Important Disclosures:

Price Chart:



Price target and ratings changes over the past three years:

Initiated – Buy – May 5, 2021 – Price Target \$3.00

Update Report – Buy – December 17, 2021 – Price Target \$3.00

Update Report – Buy – March 15, 2022 – Price Target \$3.00

Update Report – Buy – June 24, 2022 – Price Target \$3.00

Update Report – Buy – September 9, 2022 – Price Target \$3.00

Rating Change - Buy to Neutral - January 18, 2023 - Price Target NA

Update Report - Neutral - March 6, 2023 - Price Target NA

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- 1) **Buy**: The analyst believes the price of the stock will appreciate and produce a total return of at least 20% over the next 12-18 months.
- Neutral: The analyst believes the price of the stock is fairly valued for the next 12-18 months.
- 3) **Sell**: The analyst believes the price of the stock will decline by at least 20% over the next 12-18 months and should be sold.

The following chart reflects the range of current research report ratings for all companies, followed by the analysts of the Firm. The chart also reflects the research report ratings relating to those companies for which the Firm has performed investment banking services.

Current as of 3-Mar-23

	Company Coverage		Investment Banking	
				% of
Ratings Distribution	# of Companies	% of Total	# of Companies	Totals
Market Outperform (Buy)	24	69%	1	3%
Market Perform (Neutral)	11	31%	2	6%
Market Underperform (Sell)	0	0%	0	0%
Total	35	100%	3	9%

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