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Arch Therapeutics (OTCqb: ARTH)

May 5, 2021

BUY: AC5 Topical (clear) Hemostat – Approved, Launch Begins

Arch is developing an innovative platform of peptides that act as a barrier to seal and protect against infection as well as control bleeding, leaking, and injured tissues in a range of procedures. The initial product is based on the AC5, a self-assembling peptide technology platform, which rapidly generates nanofiber networks that control the movement of fluids and substances while enabling healing. The product is now approved in the U.S., and commercialization has begun. The E.U. is next. As resources allow, we expect to see indications expand and new products emerge from the pipeline.

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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 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.

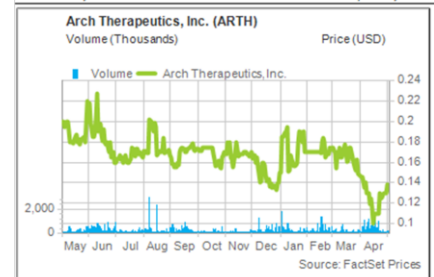
Commercializing Begins. We expect the launch is likely to be gradual, building slowly over time. The company's strategy is to drive use with key opinion leaders and early adopters. The company is prioritizing its focus on private and government facilities. Hospitals in the Veterans Health Administration tend to have many patients whose needs may be applicable to AC5. The company has also engaged with third parties in the United States, from distributors to contract organizations, consultants, advisors, scientists, clinicians, and/or other collaborators.

Modest Expectations: We assume a very slow and gradual market share build in the U.S. and E.U. Initially, the focus is likely to be on the dermatological sciences area, which we think of as outside the body versus Biosurgery (inside the body). We assume pricing in-line with the competitive market place \$2500-\$3,000 for a 2x2 area (4 cm sq area) versus AC5 as a liquid application.

Valuation: We project detailed revenue assumptions in our model out to 2031. We assume a royalty model – 30% net to Arch in our product models. 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 12-month projected price target of \$3.00.

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.

Current Price				\$0.13
Price Target				\$3.00
Estimates	2022E	2023E	2024E	
Expenses (\$000s)	\$5,979	\$7,458	\$50,412	
1Q December	\$1,487	\$1,832	\$11,718	
2Q March	\$1,550	\$1,923	\$12,664	
3Q June	\$1,491	\$1,848	\$12,160	
4Q September	\$1,451	\$1,854	\$13,870	
Estimates	2022E	2023E	2024E	
Revenues (\$000s)	\$4,000	\$16,000	\$442,662	
1Q December	\$920	\$3,680	\$101,812	
2Q March	\$1,000	\$4,000	\$110,666	
3Q June	\$960	\$3,840	\$106,239	
4Q September	\$1,120	\$4,480	\$123,945	
Estimates	2022E	2023E	2024E	
EPS (diluted)	(\$0.01)	\$0.03	\$1.48	
1Q December	(\$0.00)	\$0.01	\$0.34	
2Q March	(\$0.00)	\$0.01	\$0.37	
3Q June	(\$0.00)	\$0.01	\$0.36	
4Q September	(\$0.00)	\$0.01	\$0.42	
Stock Data				
52-Week Range	\$0.10	-	\$0.23	
Shares Outstanding (mil.)				236.7
Market Capitalization (mil.)				\$31
Enterprise Value (mil.)				\$31
Debt to Capital				0%
Book Value/Share				\$0.01
Price/Book				-
Average Three Months Trading Volume (K)				141
Insider Ownership				13.3%
Institutional Ownership				0.0%
Short interest (mil.)				-
Dividend / Yield				\$0.00/0.0%



Company Background. Arch Therapeutics is a medical device company that is focused on developing innovative products for the rapid cessation of bleeding (hemostasis) and control of fluid leakage (sealant) during surgery and trauma care. The technology underlying the “stasis and barrier application” platform has been exclusively licensed to Arch Therapeutics from the Massachusetts Institute of Technology (M.I.T.). The platform is based on a system of “smart materials,” such as synthetic peptides that form intricate networks of fibers, which stop bleeding and seal wounds to allow the body to heal following wound closure. The company’s lead product, the AC5 Surgical Hemostatic Device, is a solution of synthetic peptides and water that, when placed in a charged environment (i.e., human body fluids and tissues), self-assemble into a peptide nanofiber scaffold that stops bleeding and leakage in seconds.

Hemostasis occurs when blood is present outside of the body’s blood vessels, a situation that is common in plastic and general surgery (laparoscopic and open procedures). Bleeding can also significantly impair the visual field of the surgeon, thus increasing error risk. The instinctive response of the body is to stop the bleeding by activating platelets and clotting factors that form a platelet-fibrin clot. Good surgical technique requires that a surgeon minimize blood loss, and surgeons often depend on hemostatic agents to manage bleeding both during the procedure and during the postoperative period.

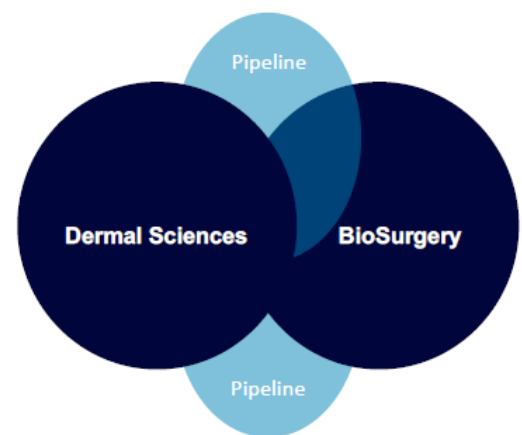
AC5 is differentiated from other hemostatic agents on the market today and may be the first universal product with applications ranging from plastic and general surgery to wound care. AC5 induces hemostasis rapidly by forming a natural peptide barrier that fills irregular-shaped wounds to allow healing of the area. In animal studies, AC5 has been shown to stop bleeding within seconds in the presence of anticoagulants. Anticoagulants, such as warfarin-sodium (31 million prescriptions in 2014), are used to prevent clots for multiple thrombotic disorders, including pulmonary embolism, ischemic stroke, and myocardial infarction. Patients receiving anticoagulant therapy are at risk for bleeding, which limits surgical procedures and also subjects them to bleeding complications that are often fatal.

Senior Management

Terrence Norchi, MD, Chief Executive Officer. Dr. Norchi is a co-founder, President, and C.E.O. of Arch Therapeutics. Dr. Norchi co-founded A.B.S., Arch Therapeutics’s predecessor company, in 2006. Prior to A.B.S., Dr. Norchi was Portfolio Manager of one of the world’s largest healthcare mutual funds and Pharmaceutical Analyst at Putnam Investments. Prior to that, he served as the Senior Global Biotech and International Pharmaceutical Equity Analyst at Citigroup Asset Management and as a Sell-Side Analyst covering non-US pharmaceutical equities at Sanford C. Bernstein in New York City. Dr. Norchi earned an M.B.A. from the Massachusetts Institute of Technology, Sloan School of Management, in 1996. He earned an M.D. degree in 1990 from Northeast Ohio Medical University and completed his internal medicine residency in 1994 at Baystate Medical Center, Tufts University School of Medicine, where he was selected to serve as the Chief Medical Resident.

Exhibit 1. AC5: Focus on Outside (Dermal) and Inside (Biosurgery) Markets in the U.S. and Europe

MARKETING AUTHORIZATION GRANTED	
Dermal Sciences	AC5 Advanced Wound System (USA) AC5 Topical Hemostat (EU)
RESEARCH & DEVELOPMENT	
BioSurgery	AC5-G: Hemostatic lift agent for Endoscopic Mucosal Resection (EMR) & Submucosal Dissection (ESD) AC5-V: Hemostatic agent for vascular reconstruction New compositions Ophthalmology applications Form factors Combination products



Source: Arch Therapeutics

Exhibit 2. AC5 Technology is Unique

Designed to self-assemble in diverse situations to provide greater utility to clinicians and enable better outcomes for patients.



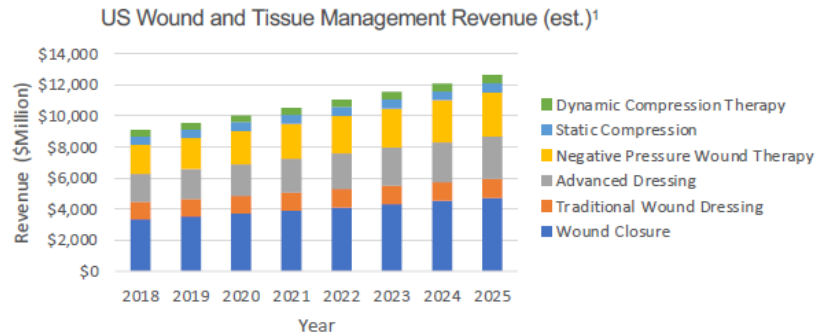
- Composed of naturally occurring proteogenic amino acids; biocompatible and biodegradable
- Forms physical barrier responsible for hemostatic and sealant properties
- Architecture resembles collagen I; provides ECM-like scaffold
- Enables cell migration/proliferation and repair of damaged tissue
- Entanglement with ECM components may provide additional mechanical strength at AC5-wound interface
- Nanofibril non-covalent interactions allow for dynamic reassembly, or self-repairing

Source: Arch Therapeutics

Exhibit 3. AC5 – Initial Focus on the large Derm market

Medicare spending estimates for all wounds: \$28 - \$96 billion²

- Surgical wounds ~\$12-38B
- Diabetic foot ulcers ~\$6-19B



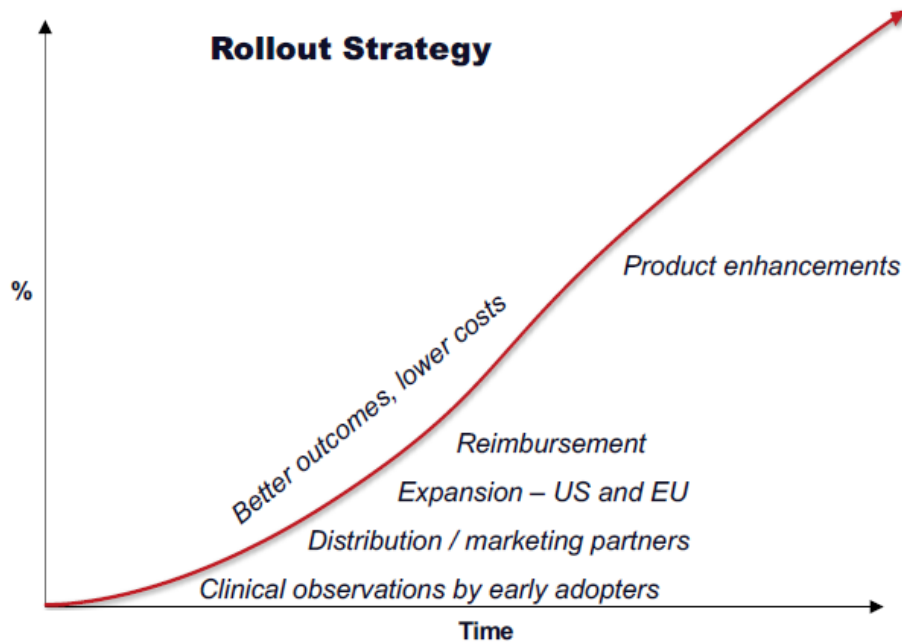
Commercially Available Wound Dressings¹

Wound Dressings	2018 Sales (\$Million)	2020 Est. Sales (\$Million)	2025 Est. Sales (\$Million)	Advanced Wound Dressings	2018 Sales (\$Million)	2020 Est. Sales (\$Million)	2025 Est. Sales (\$Million)	2018 Ave. Selling Price (\$)
Advanced*	\$1,802	\$2,045	\$2,744	Low-cost Skin Substitutes	\$93	\$105	\$133	\$320
Traditional	\$1,116	\$1,144	\$1,211	High-cost Skin Substitutes	\$733	\$866	\$1,254	\$1,537

*Moist, antimicrobial, interactive dressings and non-adherent contact layer dressings

Source: Arch Therapeutics

Exhibit 4. Commercialization Strategy



Source: Arch Therapeutics

Exhibit 5. 2021 Goals

Dermal Sciences commercialization

- Enhance sales management team
- Integrate new VA/government sector distributor partnership
- Engage independent sales reps in targeted territories
- Generate commercial revenues with initial VA focus
- Deploy resources (re-engage potential EU partners) to support AC5 Topical Hemostat commercialization efforts

R&D

- Biosurgery: advance selected program into next stage of development
- Dermal Sciences: submit regulatory application to support new indication

Raise capital to support R&D programs and commercialization infrastructure

File patent(s) to protect assets in development

Source: Arch Therapeutics

VALUATION

Our current assumption is that the AC5 launch in Europe follows the current launch in the U.S. The hemostat market is fragmented. We assume the initial indications will likely be “derm” markets, with Biosurgery to follow. Our models assume that Arch will receive a double-digit royalty from its partner(s) and or distributors. We discount back 30% in our free-cash-flow, discounted-EPS, and sum-of-the-parts models to arrive at a \$3.00 price target. Our estimates are based on a projected out-year (diluted) share count.

Exhibit 6. Discounted free-cash-flow model

Average	\$	3
Price Target	\$	4
Year		2021

DCF Valuation Using FCF (mln):

units ('000)	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E
EBIT	(18,375)	(3,333)	(5,579)	(5,858)	392,250	808,870	644,927	733,835	836,873	226,772	933,791	558,623
Tax Rate	0%	0%	5%	8%	10%	14%	20%	24%	28%	14%	30%	32%
EBIT(1-t)	(18,375)	(3,333)	(5,300)	(5,389)	353,025	695,628	515,941	557,715	602,548	195,024	653,653	379,863
FCF	(18,375)	(3,333)	(5,300)	(5,389)	353,025	695,628	515,941	557,715	602,548	195,024	653,653	379,863
PV of FCF	(18,375)	(3,333)	(4,077)	(3,189)	160,685	243,559	138,958	115,545	96,026	23,908	61,639	27,555
Discount Rate	30%											
Long Term Growth Rate	1%											
Terminal Cash Flow	1,322,973											
Terminal Value YE2025	95,966											
NPV	953,242											
NPV-Debt	2,207											
Shares out (thousands)	245,014											2031E
NPV Per Share	\$ 3.9											

Source: Dawson James estimates

Exhibit 7. Discounted-EPS model

Current Year	2021
Year of EPS	2031
Earnings Multiple	15
Discount Factor	30%
Selected Year EPS	\$ 1.55
NPV	\$ 1.7

Source: Dawson James estimates

		Discount Rate and Earnings Multiple Varies, Year is Constant					
		2031 EPS					
Earnings Multiple	1.7	5%	10%	15%	20%	25%	30%
		0	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00
5	\$3.87	\$2.43	\$1.56	\$1.02	\$0.68	\$ 0.46	
10	\$7.74	\$4.86	\$3.12	\$2.04	\$1.35	\$ 0.91	
15	\$11.61	\$7.29	\$4.68	\$3.05	\$2.03	\$ 1.37	
20	\$15.48	\$9.72	\$6.23	\$4.07	\$2.71	\$ 1.83	
25	\$19.35	\$12.15	\$7.79	\$5.09	\$3.39	\$ 2.29	
30	\$23.22	\$14.59	\$9.35	\$6.11	\$4.06	\$ 2.74	
35	\$27.10	\$17.02	\$10.91	\$7.13	\$4.74	\$ 3.20	

Exhibit 8. Sum-of-the-parts model

Arch Therapeutics	LT Gr	Discount Rate	Yrs. to Mkt	% Success	Peak Sales MMs	Term Val
AC5 (Surgery; US)	1%	30%	1	10%	\$1,849	\$6,375
NPV						\$1.40
AC5 (Surgery; EU)	1%	30%	2	10%	\$1,433	\$4,943
NPV						\$0.84
AC5 (Wound Sealant; US)	1%	30%	4	10%	\$1,219	\$4,203
NPV						\$0.42
AC5 (Wound Sealant; EU)	1%	30%	5	10%	\$1,817	\$6,266
NPV						\$0.48
Pipeline	1%	30%	5	10%	\$100	\$345
						\$0.03
Net Margin						70%
MM Shrs OS (2031E)						245
Total						\$3.2

Source: Dawson James estimates

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 9. Income Statement

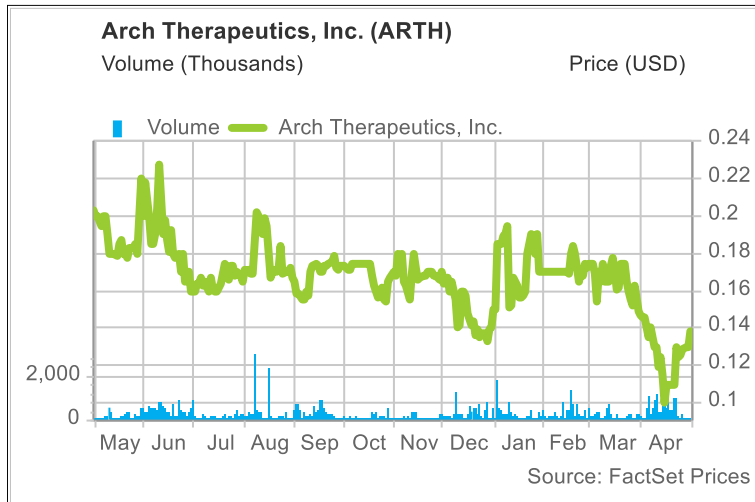
Arch Therapeutics, Inc.: Income Statement (\$000)	Oct-Dec	Jan-Mar	Apr-Jun	Jul-Sep		Oct-Dec	Jan-Mar	Apr-Jun	Jul-Sep											
Arch Therapeutics, Inc.: YE September 30	1Q21A	2Q21E	3Q21E	4Q21E	2021E	1Q22E	2Q22E	3Q22E	4Q22E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	
Product sales																				
AC5 (US) Dermatologic Science			1,000	1,200	2,200	920	1,000	960	1,120	4,000	12,000	21,478	43,408	65,795	88,649	111,975	135,782	160,076	184,866	
AC5 (EU) " "	-	-	-	-	-	-	-	-	-	-	4,000	29,608	44,878	60,466	76,376	92,614	109,185	126,094	143,346	
AC5 (US) BioSurgery						178,345	288,532	339,996			-	178,345	288,532	339,996	404,585	454,604	527,452	582,152	621,898	
AC5 (EU) " "											-	85,972	143,002	144,504	156,226	165,805	167,547	179,836	181,725	
Total Product Sales	-	-	1,000	1,200	2,200	920	1,000	960	1,120	4,000	16,000	442,662	720,066	906,743	725,836	824,999	939,966	1,048,158	631,835	
Expenses																				
Cost of Goods Sold			100	120	220	92	100	96	112	400	1,600	44,266	72,007	90,674	72,584	82,500	93,997	104,816	63,184	
%COGS	10%	10%	10%	10%	10%	10%	10%	10%	10%	10%	10%	10%	10%	10%	10%	10%	10%	10%	10%	
Research and Development	344	350	350	350	1,394	366	380	366	351	1,463	1,536	1,997	2,597	3,376	4,388	4,608	4,838	5,080	5,334	
%R&D																				
General and Administrative	919	1,000	1,000	1,000	3,919	1,029	1,070	1,029	988	4,115	4,321	4,148	3,982	3,823	3,938	4,056	4,259	4,472	4,695	
%SG&A																				
Total expenses	1,263	1,350	1,450	1,470	5,533	1,487	1,550	1,491	1,451	5,979	7,458	50,412	78,586	97,873	80,910	91,163	103,093	114,367	73,213	
Operating Income (Loss)	(1,263)	(1,350)	(450)	(270)	(3,333)	(567)	(550)	(531)	(331)	(1,979)	8,542	392,250	641,480	808,870	644,927	733,835	836,873	933,791	558,623	
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																				
Total other income	109	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
Pretax Income	(1,263)	(1,350)	(450)	(270)	(3,333)	(567)	(550)	(531)	(331)	(1,979)	8,542	392,250	641,480	808,870	644,927	733,835	836,873	933,791	558,623	
Income Tax Benefit (Provision)	-	-	-	-	-	(28)	(28)	(27)	(17)	(99)	683	39,225	76,978	113,242	128,985	176,120	234,324	280,137	178,759	
Tax Rate	0%	0%	0%	0%	0%	5%	5%	5%	5%	5%	8%	10%	12%	14%	20%	24%	28%	30%	32%	
GAAP Net Income (loss)	(1,154)	(1,350)	(450)	(270)	(3,333)	(538)	(523)	(504)	(314)	(1,880)	7,859	353,025	564,503	695,628	515,941	557,715	602,548	653,653	379,863	
GAAP-EPS	(0.01)	(0.01)	(0.00)	(0.00)	(0.02)	(0.00)	(0.00)	(0.00)	(0.00)	(0.01)	0.03	1.48	2.36	2.90	2.14	2.30	2.48	2.68	1.55	
GAAP EPS (dil)	(0.01)	(0.01)	(0.00)	(0.00)	(0.02)	(0.00)	(0.00)	(0.00)	(0.00)	(0.01)	0.03	1.48	2.36	2.90	2.14	2.30	2.48	2.68	1.55	
Wgtd Avg Shrs (Bas) - '000s	193,044	193,237	193,430	213,624	198,334	236,000	236,236	236,472	236,709	236,354	237,301	238,252	239,206	240,164	241,126	242,092	243,062	244,036	245,014	
Wgtd Avg Shrs (Dil) - '000s	193,044	193,237	193,430	213,624	198,334	236,000	236,236	236,472	236,709	236,354	237,301	238,252	239,206	240,164	241,126	242,092	243,062	244,036	245,014	

Source: Company reports and Dawson James

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

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As of: 27-Apr-21

	Company Coverage		Investment Banking	
Ratings Distribution	# of Companies	% of Total	# of Companies	% of Totals
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Market Perform (Neutral)	10	32%	0	0%
Market Underperform (Sell)	0	0%	0	0%
Total	31	100%	5	16%

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