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Arrowhead Pharmaceuticals, Inc. (ARWR-NASDAQ)

ARWR: License and Collaboration Deal with Sarepta Includes $825 Million Upon Closing…

Based on our probability adjusted DCF model that takes into account potential future revenues from the company's development products, ARWR is valued at $73/share. This model is highly dependent upon the continued clinical success of those programs and will be adjusted accordingly based upon future clinical outcomes.

Current Price (12/03/24)	$26.34
Valuation	**$73.00**

OUTLOOK

On November 26, 2024, Arrowhead Pharmaceuticals, Inc. (ARWR) announced a global licensing and collaboration agreement with Sarepta Therapeutics (SRPT) in which Arrowhead will receive $825 million on closing, consisting of a $500 million upfront payment and $325 million as an equity investment priced at a 35% premium. The agreement includes four clinical stage products (ARO-DUX4, ARO-DM1, ARO-MMP7, ARO-ATXN2), three preclinical programs (ARO-HTT, ARO-ATXN1, ARO-ATXN3), and during the five-year term of the agreement Sarepta can propose up to six new CNS or muscle targets, with Arrowhead responsible for discovery and preclinical development. This deal further validates Arrowheads technology and provides capital to fund operations into 2028.

SUMMARY DATA

52-Week High	**$39.48**
52-Week Low	**$17.70**
One-Year Return (%)	**5.66**
Beta	**0.91**
Average Daily Volume (sh)	**1,848,969**
Shares Outstanding (mil)	**124**
Market Capitalization ($mil)	**$3,278**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**63**
Insider Ownership (%)	**5**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2024 Estimate	**-9.1**
P/E using 2025 Estimate	**-9.2**

Risk Level	**Average**
Type of Stock	**Mid-Growth**
Industry	**Med-Drugs**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Dec)	Q2 (Mar)	Q3 (Jun)	Q4 (Sep)	Year (Sep)
2024	3.6 A	0.0 A	0.0 A	0.0 A	3.6 A
2025	0.0 E	25.0 E	25.0 E	27.0 E	77.0 E
2026					247.0 E
2027					295.0 E

Earnings per Share

	Q1 (Dec)	Q2 (Mar)	Q3 (Jun)	Q4 (Sep)	Year (Sep)
2024	-$1.24 A	$1.02 A	-$1.38 A	-$1.37 A	-$5.00 A
2025	-$1.23 E	-$0.97 E	-$0.99 E	-$1.00 E	-$4.18 E
2026					-$2.94 E
2027					-$2.61 E

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WHAT'S NEW

Business Update

Collaboration Deal with Sarepta Includes $825 Million Upon Closing

On November 26, 2024, Arrowhead Pharmaceuticals, Inc. (ARWR) announced a global license and collaboration agreement with Sarepta Therapeutics (SRPT) in which Arrowhead is set to receive $825 million, consisting of $500 million in cash and $325 million as an equity investment priced at a 35% premium. The agreement covers the following assets:

Clinical Stage
ARO-DUX4, which is being developed as a treatment for facioscapulohumeral muscular dystrophy type 1 and is currently in a Phase 1/2 clinical trial.
ARO-DM1, which is being developed as a treatment for type 1 myotonic dystrophy and is currently dosing patients in a Phase 1/2 clinical trial.
ARO-MMP7, which is being developed as a treatment for idiopathic pulmonary fibrosis and is currently dosing patients in a Phase 1/2 clinical trial.
ARO-ATXN2, which is being developed as a treatment for spinocerebellar ataxia 2 and is currently in a Phase 1/2 clinical trial.

Preclinical Stage
ARO-HTT, which is being developed as a treatment for Huntington's disease
ARO-ATXN1, which is being developed as a treatment for spinocerebellar ataxia 1
ARO-ATXN3, which is being developed as a treatment for spinocerebellar ataxia 3

Discovery Stage
During the five-year term of the agreement, Sarepta may propose up to six new CNS or muscle targets, with Arrowhead responsible for discovery and preclinical development. Sarepta would then have an exclusive license to the programs and take over responsibility for clinical development and commercialization.

The financial terms of the deal are as follows: Arrowhead will receive a $500 million upfront payment along with $325 million from an equity investment by Sarepta at $27.25 per share (a 35% premium to the 30-day volume weighted average price), $250 million payable as $50 per year for five years, and $300 million in near-term payments (likely within the next year), broken up into two separate payments of $100 million and $200 million, tied to enrollment of certain cohorts in the Phase 1 study of ARO-DM1. Arrowhead will be eligible for development milestones of $110 million to $410 million per program, sales milestones of $500 million to $700 million per program, and tiered royalties up to low double digits. The total potential value of the deal is in excess of $11 billion plus royalties.

'This deal helps to further validate Arrowheads technology and provides substantial capital that is currently expected to fund operations well into 2028, which could be past multiple commercial launches by Arrowhead and/or its partners. In addition, the company now has a more streamlined pipeline focused more on areas in which Arrowhead wishes to commercialize products on its own, for example in the cardiometabolic space.

The agreement also stipulates that Arrowhead will manufacture clinical drug supply for all programs covered under the license and collaboration along with commercial drug product for the four programs currently in clinical trials. This will help to utilize the excess manufacturing capacity at the company's plant and to cover some of its operating costs.

Overall, this is a fantastic deal for Arrowhead and should help to alleviate any concerns regarding the company's liquidity while simultaneously helping to focus attention on a more manageable development pipeline.

New Drug Application Submitted for Plozasiran for the Treatment of FCS

On November 18, 2024, Arrowhead announced it submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for plozasiran for the treatment of familial chylomicronemia syndrome (FCS). The company plans to submit applications for approval in other jurisdictions in 2025. The NDA is based in part on the successful Phase 3 PALISADE trial, the results of which were recently published in *The New England Journal of Medicine* (Watts *et al.*, 2024). The trial met its primary endpoint and showed that treatment with plozasiran led to a median change from baseline of 80% in fasting triglycerides along with a statistically significant 83% reduction in the risk of developing acute pancreatitis compared to placebo.

The FDA has 60 days to determine whether to accept the NDA and if accepted we will learn the PDUFA date at that time. Since plozasiran has Breakthrough Therapy designation there is the potential for priority review, which would decrease the total review time to six months from the standard ten months. The decision to grant priority review is made solely at the discretion of the FDA. In preparation for potential approval, the company has indicated that key commercial infrastructure appointments have been made, the commercial field team is in the process of being assembled, and (if approved) the company should be ready to launch in 2025.

In addition to FCS, Arrowhead is also developing plozasiran as a treatment for severe hypertriglyceridemia (SHTG), with the Phase 3 SHASTA-3 and SHASTA-4 studies expected to complete enrollment by mid-2025. This would put the final patient visits in mid-2026 and a potential sNDA filing at the end of 2026 or early 2027. The SHASTA-5 trial, which will have a primary outcome of reduction in acute pancreatitis in patients with SHTG and a history of pancreatitis, is expected to initiate soon. During the recent quarterly conference call the company announced that it is putting a potential cardiovascular outcomes trial (CVOT) on hold pending additional capital.

Financial Update

On November 26, 2023, Arrowhead announced financial results for fiscal year 2024 that ended September 30, 2024. The company reported revenue of $3.6 million for fiscal year 2024 compared to approximately $240.7 million for fiscal year 2023. The revenue in 2023 was primarily related to collaboration agreements with Takeda, GSK, and Amgen.

R&D expenses for the year ending September 30, 2024 were approximately $505.9 million compared to $353.2 million for the year ending September 30, 2023. The increase was primarily due to increased candidate costs, salaries, facilities-related expenses, and R&D discovery expenses. G&A expenses for fiscal year 2024 were $98.8 million compared to $92.5 million for fiscal year 2023. The increase was primarily due to increased salaries and professional services partially offset by decreased non-cash stock-based compensation.

Arrowhead exited fiscal year 2024 with approximately $681 million in cash, cash equivalents, and investments. As noted above, the collaboration agreement with Sarepta will include $500 million in upfront cash, $325 million as an equity investment, and additional near-term cash of $350 million. This leads to pro forma cash of approximately $1.5 billion and extends the company's cash runway into 2028. As of November 20, 2024, Arrowhead had approximately 124.4 million shares outstanding and, when factoring in stock options and restricted stock units, a fully diluted share count of approximately 131.3 million.

Conclusion

The agreement with Sarepta is a great achievement for the company as it helps to strengthen the balance sheet, provides additional validation to the company's discovery and early-stage capabilities, and helps to streamline the in-house development pipeline where Arrowhead intends to focus its attention. We look forward to the FDA's decision on whether it will accept the NDA for plozasiran for review as well as the PDUFA date, if accepted. After incorporating the Sarepta agreement into our model our valuation has increased slightly to $73 per share.

PROJECTED FINANCIALS

Arrowhead Pharmaceuticals, Inc.	FY2024 A	Q1FY25 E	Q2FY25 E	Q3FY25 E	Q4FY25 E	FY2025 E	FY2026 E	FY2027 E
Revenue	$3.55	$0.00	$25.00	$25.00	$27.00	$77.00	$247.00	$300.00
YOY Growth	*-53.5%*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*660.3%*	*-54.4%*	*738.6%*	*1175.0%*
Total Revenues	**$3.6**	**$0.0**	**$25.0**	**$25.0**	**$27.0**	**$77.0**	**$247.0**	**$300.0**
YOY Growth	*-53.5%*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*660.3%*	*-54.4%*	*738.6%*	*1175.0%*
Cost of Revenue	$0.0	$0.0	$0.0	$0.0	$0.2	$0.2	$2.5	$4.8
Gross Income	**$3.6**	**$0.0**	**$25.0**	**$25.0**	**$26.8**	**$76.8**	**$244.5**	**$295.2**
Gross Margin	*100.0%*	*#DIV/0!*	*100.0%*	*100.0%*	*99.3%*	*99.7%*	*99.0%*	*98.4%*
R&D	$505.9	$124.0	$128.0	$130.0	$132.0	$514.0	$525.0	$530.0
% R&D	*14245.8%*	*#DIV/0!*	*512.0%*	*520.0%*	*488.9%*	*667.5%*	*212.6%*	*176.7%*
Salary and G&A	$98.8	$25.0	$25.5	$26.0	$26.5	$103.0	$107.0	$110.0
% SG&A	*2781.2%*	*#DIV/0!*	*102.0%*	*104.0%*	*98.1%*	*133.8%*	*43.3%*	*36.7%*
Other expenses	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
% Other	*0.0%*	*#DIV/0!*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Operating Income	**($601.1)**	**($149.0)**	**($128.5)**	**($131.0)**	**($131.7)**	**($540.2)**	**($387.5)**	**($344.8)**
Operating Margin	*-16927.1%*	*-*	*-*	*-*	*-*	*-701.6%*	*-156.9%*	*-114.9%*
Other Income (Net)	($11.4)	($4.0)	($4.0)	($4.0)	($4.0)	($16.0)	($15.0)	($15.0)
Pre-Tax Income	**($612.5)**	**($153.0)**	**($132.5)**	**($135.0)**	**($135.7)**	**($556.2)**	**($402.5)**	**($359.8)**
Net Taxes (benefit)	$2.8	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Net Loss Attributable to Noncontrolling Interest	$10.2	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Reported Net Income	**($599.5)**	**($153.0)**	**($132.5)**	**($135.0)**	**($135.7)**	**($556.2)**	**($402.5)**	**($359.8)**
Net Margin	*-16882.4%*	*-*	*-*	*-*	*-*	*-722.3%*	*-163.0%*	*-119.9%*
Reported EPS	**($5.00)**	**($1.23)**	**($0.97)**	**($0.99)**	**($1.00)**	**($4.18)**	**($2.94)**	**($2.61)**
YOY Growth	*-*	*-*	*-*	*-*	*-*	*-*	*-*	*-*
Basic Shares Outstanding	119.8	124.2	136.0	136.0	136.0	133.1	137.0	138.0

Source: Zacks Investment Research, Inc. *David Bautz, PhD*

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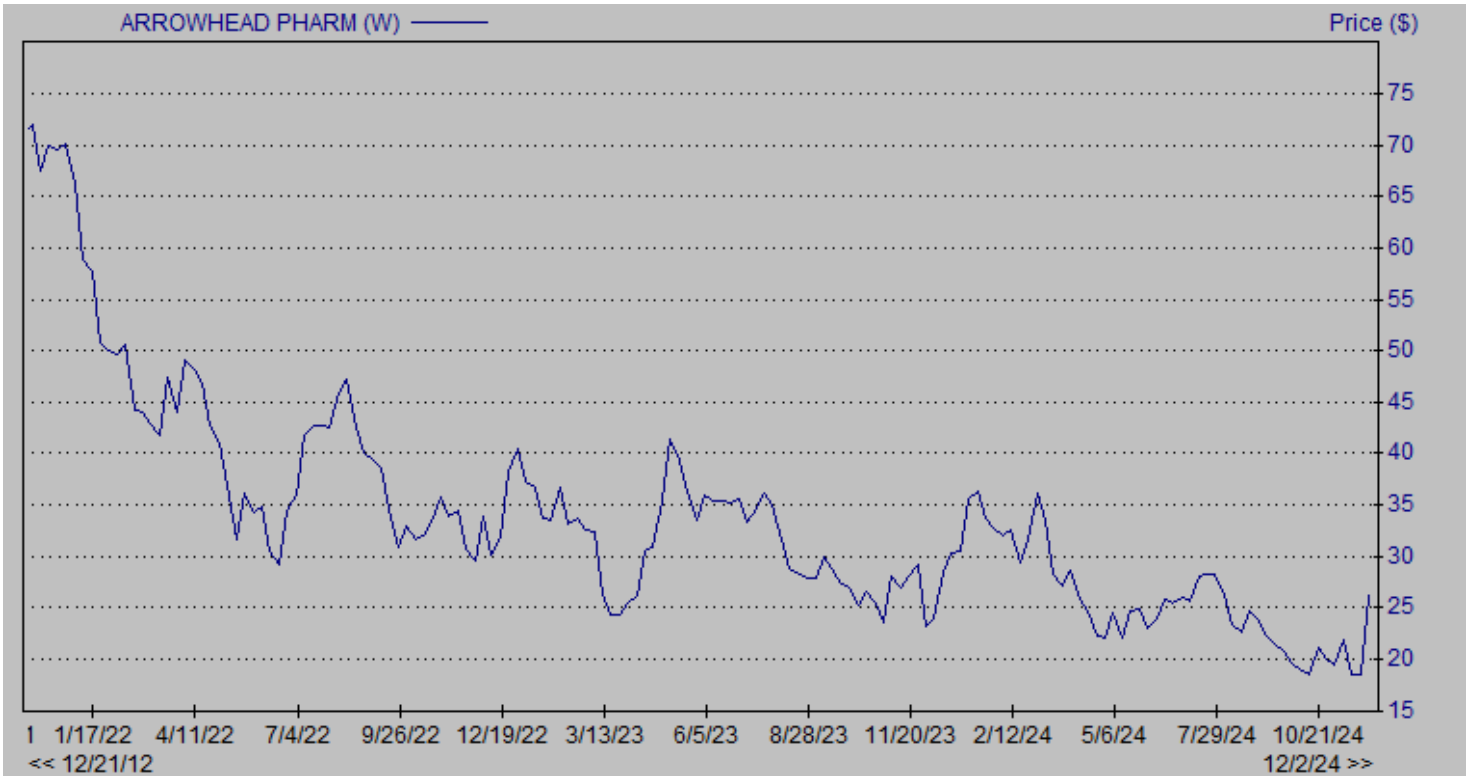

Source: Zacks SCR

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