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Arrowhead Pharmaceuticals, Inc. (ARWR-NASDAQ)

ARWR: Multiple Value Drivers for Long-Term Growth…

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 (05/15/25)	$14.91
Valuation	**$73.00**

OUTLOOK

On May 12, 2024, Arrowhead Pharmaceuticals, Inc. (ARWR) announced financial results for the second quarter of fiscal year 2025 that ended March 31, 2025. Arrowhead is set up with multiple value drivers in both the near- and long-term. Most importantly, the NDA for plozasiran for the treatment of familial chylomicronemia syndrome (FCS) is currently under review by the FDA and has a PDUFA date of November 18, 2025. The submission of a MAA with the EMA is complete and additional regulatory filings are expected in other jurisdictions. The Phase 3 trials for plozasiran in SHTG should be fully enrolled this summer. The Phase 1/2 trial of ARO-INHBE is enrolling, the Phase 1/2 trial of ARO-ALK7 will begin enrolling shortly, and data for ARO-INHBE could be available before the end of 2025, with data for ARO-ALK7 following shortly thereafter. The company currently has approximately $1.1 billion in cash and investments and is funded into 2028.

SUMMARY DATA

52-Week High	**$29.54**
52-Week Low	**$9.99**
One-Year Return (%)	**-40.46**
Beta	**0.89**
Average Daily Volume (sh)	**1,627,309**
Shares Outstanding (mil)	**138**
Market Capitalization ($mil)	**$2,059**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**63**
Insider Ownership (%)	**4**
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 2025 Estimate	**48.1**
P/E using 2026 Estimate	**-4.7**

Risk Level	**Above Avg.**
Type of Stock	**Mid-Blend**
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	2.5 A	542.7 A	50.0 E	50.0 E	645.2 E
2026					350.0 E
2027					300.0 E

Earnings per Share

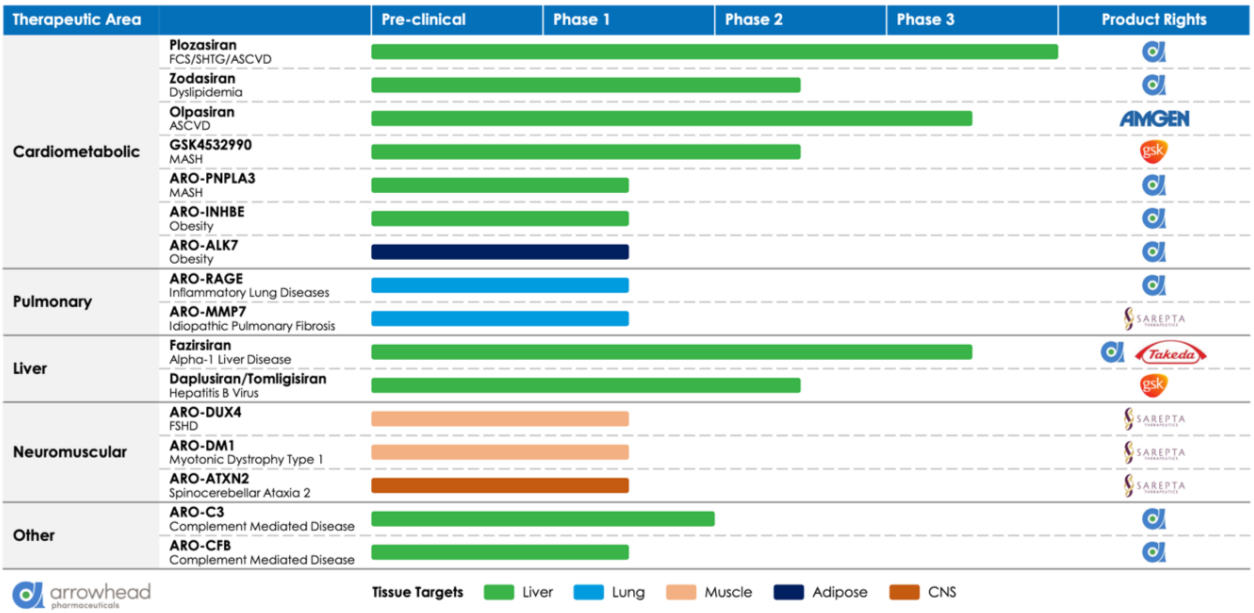
	Q1 (Dec)	Q2 (Mar)	Q3 (Jun)	Q4 (Sep)	Year (Sep)
2024	-$1.24 A	$1.02 A	-$1.38 A	-$1.37 A	-$5.00 A
2025	-$1.39 A	$2.78 A	-$0.83 E	-$0.83 E	-$0.22 E
2026					-$2.30 E
2027					-$2.75 E

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WHAT'S NEW

Business Update

Arrowhead Pharmaceuticals, Inc. (ARWR) has a robust pipeline of RNA interference (RNAi) therapies utilizing the company's TRiM™ platform. The TRiM platform allows for targeting of RNAi therapeutics to seven different cell types, including liver, lung, skeletal muscle, CNS, adipose, ocular, and cardiomyocyte. This has enabled the company to build a large and diverse pipeline that currently has multiple products in different stages of clinical development along with a new drug application (NDA) under review for plozasiran.



Source: Arrowhead Pharmaceuticals, Inc.

Plozasiran Update

In January 2025, Arrowhead announced that the U.S. Food and Drug Administration (FDA) accepted the NDA for plozasiran for the treatment of familial chylomycronemia syndrome (FCS), with a Prescription Drug User Fee Act (PDUFA) action date of November 18, 2025. The agency also indicated that it did not currently plan to hold an advisory committee meeting. Subsequently, in February 2025 the company submitted a Marketing Authorization Application (MAA) with the European Medicines Agency (EMA), which was confirmed to be valid for review on March 20, 2025. Arrowhead is planning to file for approval in the UK after approval in either the U.S. or E.U. by leveraging the International Recognition Procedure (IRP). Pre-filing meetings have also taken place with Canadian and Japanese regulatory authorities.

The NDA for plozasiran is based in part on the successful Phase 3 PALISADE trial, the results of which were 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.

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 in mid-2025. The company is also performing the MUIR-3 study in patients with mixed hyperlipidemia, which is also expected to complete enrollment around the same time as the SHASTA studies. All three studies should complete in 2026 and lead to a subsequent sNDA filing. 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 currently

underway. However, the company can't provide guidance on the precise timing for when that study will complete given the uncertainty with how long the trial will take to enroll along with the fact that it is an outcomes-based study and treatment will continue until the required number of events have been collected. Importantly, completion of SHASTA-5 will not hold back the sNDA filing and will likely not complete before those filings take place. The company continues to believe that plozasiran could have peak revenues of $2-$3 billion/year just in SHTG.

Obesity Program Update

Arrowhead has two early stage programs in obesity, ARO-INHBE and ARO-ALK7. ARO-INHBE is designed to reduce the expression of activin E, which is a ligand for ALK7, while ARO-ALK7 is designed to reduce the expression of the ALK7 receptor. Activin E (dimeric *INHBE* protein) is a hepatokine that is secreted by the liver and promotes adipose storage by suppressing lipolysis in adipose tissue. The receptor for activin E is ALK7, which is a TGF-β superfamily member that is expressed in adipocytes. Support for targeting *INHBE* comes from genome wide association studies (GWAS) that show loss of function (LOF) variants of *INHBE* are associated with reduced abdominal fat and a lower risk of cardiovascular disease and type 2 diabetes (Deaton *et al*., 2022). In addition, *Inhbe* knockout mice show reduced body weight gain on a high fat diet (Adam *et al*., 2023).

The company has initiated a Phase 1/2a trial of ARO-INHBE. This is a dose-escalating study designed to evaluate the safety, tolerability, pharmacokinetics, and pharmacodynamics of ARO-INHBE in up to 78 adult volunteers with obesity. Part 1 of the trial will assess single and multiple doses of ARO-INHBE monotherapy, while Part 2 of the study will assess ARO-INHBE in combination with tirzepatide. We anticipate results from Part 1 of the trial in late 2025.

Arrowhead received clearance in New Zealand to initiate a Phase 1/2a dose-escalating study to evaluate the safety, tolerability, pharmacokinetics, and pharmacodynamics of ARO-ALK7 in up to 90 adult volunteers with obesity. We anticipate this trial getting underway soon.

CNS Program Update

In addition to plozasiran and the obesity pipeline, the third area that Arrowhead believes will be a near-term growth driver is the company's central nervous system (CNS) pipeline, which includes a new TRiM platform that appears capable, in animal models, of delivering RNAi therapies across the blood-brain-barrier (BBB) following a subcutaneous injection. The initial efforts are focused on three development products: ARO-HTT (Huntington's), ARO-MAPT (Alzheimer's), and ARO-SNCA (Parkinson's disease). Sarepta has the right to advance ARO-HTT forward through the collaboration agreement, Arrowhead is planning to keep ARO-MAPT in-house, and a decision on ARO-SNCA has not been made yet. CTA's are expected to be filed for ARO-HTT and ARO-MAPT by the end of 2025 and in the first quarter of 2026 for ARO-SNCA.

Muscle Programs Update

ARO-DUX4 and ARO-DM1 are two muscle-targeting development products and both are part of the Sarepta collaboration. Each of these is currently in a Phase 1/2a trial that Arrowhead will continue to run until completion, at which time Sarepta will assume responsibility for clinical development and commercialization.

For ARO-DM1, a Phase 1/2a dose-escalating study is currently underway that is evaluating single and multiple ascending doses in up to 48 subjects with myotonic dystrophy. The company expects to reach enrollment targets in the Sarepta agreement, which will trigger an additional $300 million in payments. ARO-DUX4 is also in a Phase 1/2a dose-escalating study in up to 52 subjects with FSHD type 1. For both studies, data could be available to report in 2025, pending discussion and agreement with Sarepta on disclosure timing.

Zodasiran Update

In the cardiometabolic space, Arrowhead will be initiating a Phase 3 trial of zodasiran (which targets ANGPTL3) in 2025 in patients with homozygous familial hypercholesterolemia (HoFH). The company believes there is sufficient clinical data to support advancing it for that indication, and if approved would fit nicely as an

add-on to the FCS and SHTG sales representative's portfolio. In addition, the Phase 3 study will only utilize limited resources.

Financial Update

On May 12, 2025, Arrowhead announced financial results for the second quarter of fiscal year 2025 that ended March 31, 2025. The company reported revenue of $542.7 million for the quarter ending March 31, 2025 compared to no revenue for the quarter ending March 31, 2024. The revenue in the current period is related to the license and collaboration agreement with Sarepta. For accounting purposes, there is approximately $291 million left to be recognized stemming from the Sarepta agreement, with $90 to $125 million to be recognized over the next 12 months and the balance will be recognized over the next approximately five years, with most of it being recognized in the first half of that time period. There is also a near term milestone of $300 million expected related to the DM1 program and that is expected to be recorded in its entirety toward the end of the calendar year.

R&D expenses for the quarter ending March 31, 2025 were approximately $133.1 million compared to $101.1 million for the quarter ending March 31, 2024. The increase was primarily due to increased candidate costs and salaries as the company's pipeline increased and advanced into later stages of development. G&A expenses for the second quarter of fiscal year 2025 were $28.4 million compared to $25.1 million for the second quarter of fiscal year 2024. The increase was primarily due to higher salaries and professional services.

Arrowhead exited the second quarter of fiscal year 2025 with approximately $1.1 billion in cash, cash equivalents, and investments. We estimate the company is financed into 2028. As of May 1, 2025, Arrowhead had approximately 138.1 million shares outstanding and, when factoring in stock options and restricted stock units, a fully diluted share count of approximately 145.6 million.

Conclusion

Arrowhead continues to lay the groundwork for a successful commercial launch of plozasiran, if approved, as well as building the pipeline to ensure continued near-term and long-term growth. The company's balance sheet has been strengthened by the Sarepta agreement and there is sufficient cash to fund operations into 2028, which could be past multiple commercial launches. With no changes to our model our valuation remains at $73 per share.

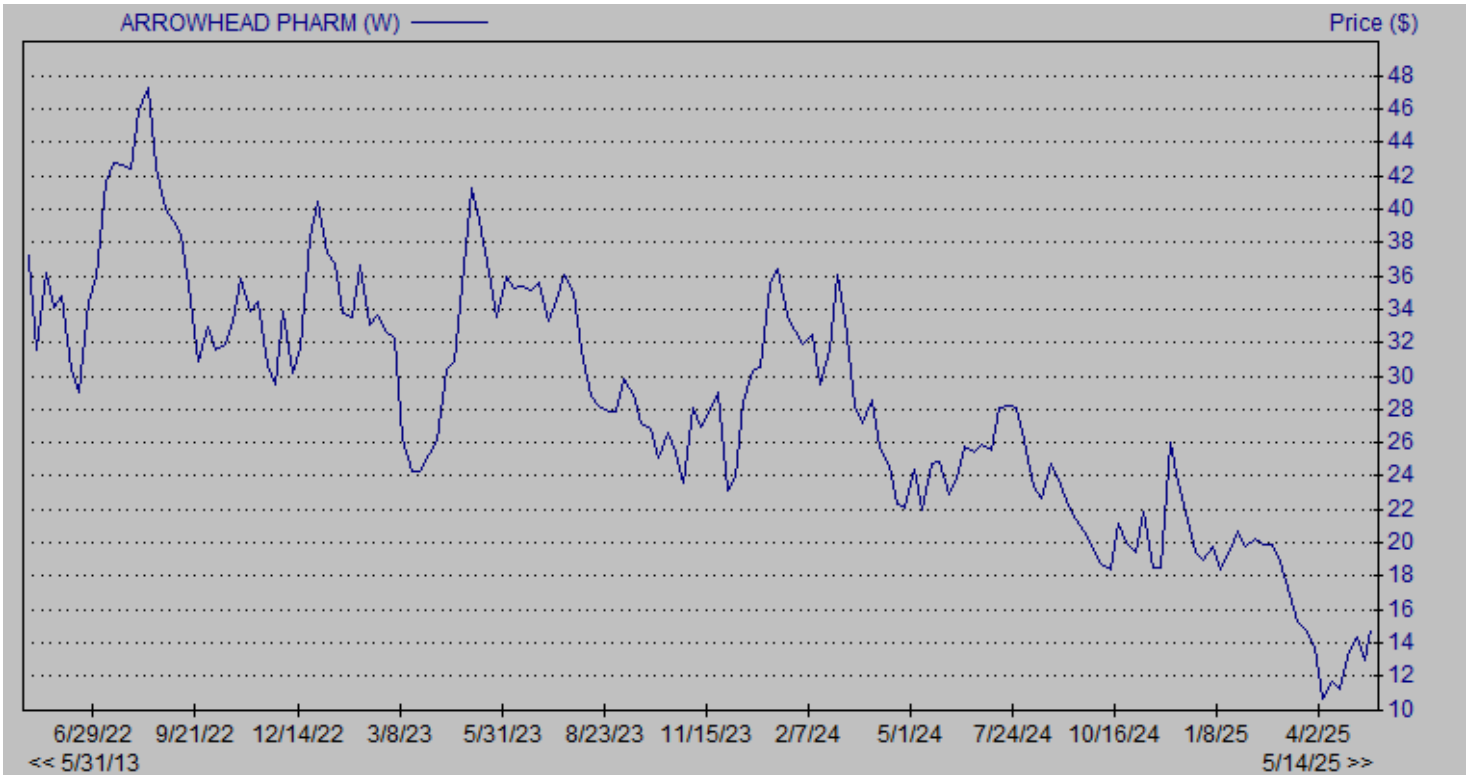
PROJECTED FINANCIALS

Arrowhead Pharmaceuticals, Inc.	FY2024 A	Q1FY25 A	Q2FY25 A	Q3FY25 E	Q4FY25 E	FY2025 E	FY2026 E	FY2027 E
Revenue	$3.55	$2.50	$542.71	$50.00	$50.00	$645.21	$350.00	$300.00
YOY Growth	*-53.5%*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*1308.1%*	*282.2%*	*1088.3%*	*1175.0%*
Total Revenues	**$3.6**	**$2.5**	**$542.7**	**$50.0**	**$50.0**	**$645.2**	**$350.0**	**$300.0**
YOY Growth	*-53.5%*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*1308.1%*	*282.2%*	*1088.3%*	*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**	**$2.5**	**$542.7**	**$50.0**	**$49.8**	**$645.0**	**$347.5**	**$295.2**
Gross Margin	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*99.6%*	*100.0%*	*99.3%*	*98.4%*
R&D	$505.9	$137.0	$133.1	$132.0	$132.0	$534.1	$540.0	$550.0
% R&D	*14245.8%*	*5480.1%*	*24.5%*	*264.0%*	*264.0%*	*82.8%*	*154.3%*	*183.3%*
Salary and G&A	$98.8	$26.9	$28.4	$27.0	$27.0	$109.3	$110.0	$115.0
% SG&A	*2781.2%*	*1076.4%*	*5.2%*	*54.0%*	*54.0%*	*16.9%*	*31.4%*	*38.3%*
Other expenses	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
% Other	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Operating Income	**($601.1)**	**($161.4)**	**$381.2**	**($109.0)**	**($109.2)**	**$1.6**	**($302.5)**	**($369.8)**
Operating Margin	*-16927.1%*	-	-	-	-	*0.2%*	*-86.4%*	*-123.3%*
Other Income (Net)	($11.4)	($13.7)	($11.6)	($4.0)	($4.0)	($33.3)	($15.0)	($15.0)
Pre-Tax Income	**($612.5)**	**($175.1)**	**$369.6**	**($113.0)**	**($113.2)**	**($31.7)**	**($317.5)**	**($384.8)**
Net Taxes (benefit)	$2.8	$0.1	$1.8	$0.0	$0.0	$1.9	$0.0	$0.0
Net Loss Attributable to Noncontrolling Interest	$10.2	$2.1	$2.6	$0.0	$0.0	$4.7	$0.0	$0.0
Reported Net Income	**($599.5)**	**($173.1)**	**$370.4**	**($113.0)**	**($113.2)**	**($28.8)**	**($317.5)**	**($384.8)**
Net Margin	*-16882.4%*	-	-	-	-	*-4.5%*	*-90.7%*	*-128.3%*
Reported EPS	**($5.00)**	**($1.39)**	**$2.78**	**($0.83)**	**($0.83)**	**($0.22)**	**($2.30)**	**($2.75)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	119.8	124.8	133.4	136.0	136.0	132.6	138.0	140.0

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

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HISTORICAL STOCK PRICE



Source: Zacks SCR

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