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Arrowhead Pharmaceuticals, Inc. (ARWR-NASDAQ)

ARWR: Countdown to Nov. 18, 2025 PDUFA for Plozasiran for FCS…

Based on our probability adjusted DCF model that takes into account potential future revenues from the company's development products, ARWR is valued at $72/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 (08/08/25)	$16.06
Valuation	**$72.00**

OUTLOOK

On August 7, 2025, Arrowhead Pharmaceuticals, Inc. (ARWR) announced financial results for the third quarter of fiscal year 2025 that ended June 30, 2025. The company is continuing preparations ahead of the November 18, 2025 PDUFA date for plozasiran for the treatment of familial chylomycronemia syndrome (FCS). These preparations include hiring a National Sales Leader, a full team of Regional Sales Leaders, and a field force of rare disease specialists. The company will begin engaging key healthcare professionals to advance FCS disease education by the end of this month. The SHASTA-3, SHASTA-4, and MUIR-3 studies of plozasiran in severe hypertriglyceridemia (sHTG) are fully enrolled, with results anticipated next year. The company's wholly-owned subsidiary, Visirna Therapeutics, signed an asset purchase agreement with Sanofi that grants rights to develop plozasiran for FCS and sHTG in Greater China. Visirna will receive $130 million upfront and be eligible to receive milestone payments of up to $265 million along with royalties on net sales.

SUMMARY DATA

52-Week High	**$26.34**
52-Week Low	**$9.99**
One-Year Return (%)	**-37.87**
Beta	**0.94**
Average Daily Volume (sh)	**2,030,270**
Shares Outstanding (mil)	**138**
Market Capitalization ($mil)	**$2,218**
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	**-624.9**
P/E using 2026 Estimate	**-4.9**

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	27.8 A	185.0 E	758.0 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	-$1.26 A	$0.13 E	$0.30 E
2026					-$2.19 E
2027					-$2.57 E

WHAT'S NEW

Business Update

Countdown Begins to November 18, 2025 PDUFA for Plozasiran

Arrowhead Pharmaceuticals, Inc. (ARWR) is developing plozasiran for the treatment of familial chylomycronemia syndrome (FCS) and severe hypertriglyceridemia (sHTG). The company has filed a new drug application (NDA) with the U.S. Food and Drug Administration (FDA) for plozasiran for the treatment of FCS, which has a Prescription Drug User Fee Act (PDUFA) action date of November 18, 2025. The FDA has indicated it does not currently plan to hold an advisory committee meeting. Arrowhead has also filed a Marketing Authorization Application (MAA) with the European Medicines Agency (EMA).

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 preparation for the potential commercial launch of plozasiran, the company has hired a National Sales Leader, a full team of Regional Sales Leaders, and a field force of rare disease specialists. This month, the company intends to begin engaging with key healthcare professionals to advance FCS disease education. Arrowhead has connected with payers representing over 85% of U.S. covered lives, and payer interest is reported to be high based on plozasiran's ability to deeply lower triglycerides and significantly reduce the risk of acute pancreatitis.

Update on SHASTA-3, SHASTA-4, and MUIR-3 Studies

Arrowhead is conducting the Phase 3 SHASTA-3 and SHASTA-4 studies of plozasiran in patients with sHTG and the MUIR-3 study in patients with mixed hyperlipidemia. All three studies are fully enrolled with results expected next year. The SHASTA Phase 3 studies total approximately 700 patients and are very highly powered to demonstrate statistical significance in improvement in triglycerides with 25 mg plozasiran compared to placebo over 12 months. The MUIR-3 study was designed to demonstrate statistical significance in triglyceride improvement for 25 mg plozasiran compared with placebo over 12 months of treatment while primarily serving to enhance the safety database for the sHTG sNDA filing, which (assuming positive data) would likely occur in the fourth quarter of 2026.

The sHTG program will also feature the SHASTA-5 study, which is designed to directly asses the ability of plozasiran to reduce the time to first event of positively adjudicated acute pancreatitis in high risk sHTG patients. While the results may be included in a regulatory filing for potential inclusion in labeling, the primary driver for the study is national health technology assessment organizations. The company believes that fewer than 150 patients will need to be recruited in order to have sufficient events in the study. Details on the design and rationale for the study will be presented at an upcoming medical conference.

Plozasiran Agreement in Greater China

On August 1, 2025, Arrowhead announced an asset purchase agreement between Sanofi and Visirna Therapeutics, a majority-owned subsidiary of Arrowhead (~56% owner) that was created to develop and commercialize four of Arrowhead's cardiometabolic development candidates in Greater China. Sanofi will acquire rights to develop and commercialize plozasiran for FCS and sHTG in Greater China. Visirna will receive an upfront payment of $130 million and be eligible to receive further milestone payments of up to $265 million upon approval of plozasiran across various indications in mainland China. Arrowhead will also be eligible to receive royalties on net commercial product sales in Greater China.

Update on Zodasiran

In addition to plozasiran, Arrowhead is also developing zodasiran, which is designed to reduce expression of angiopoietin protein like 3 (ANGPTL3), for the treatment of homozygous familial hypercholesterolemia (HoFH), a rare genetic disorder characterized by exceptionally high LDL cholesterol levels due to very low or absent LDL receptor function. The Phase 3 YOSEMITE study of zodasiran in HoFH began earlier this year and the first patient was randomized in July 2025. Approximately 60 patients age >12 will receive four quarterly doses of 200 mg zodasiran or placebo, with the primary endpoint being the percent change in fasting LDL cholesterol from baseline to month 12. Successful results could support regulatory filings for zodasiran as early as 2028 or 2029.

The rationale for the YOSEMITE study hinges on the fact that the company believes that a relatively low risk Phase 3 trial (based on the very strong Phase 2 data) will enable a commercial opportunity that overlaps well with the opportunity for plozasiran. Thus, a relatively small investment in this Phase 3 trial could allow the company to extract additional value from the commercial infrastructure that is already being put into place.

Update on Sarepta Agreement

In November 2024, Arrowhead announced a global license and collaboration agreement with Sarepta Therapeutics (SRPT). Arrowhead received a $500 million upfront payment along with $325 million from an equity investment by Sarepta at $27.25 per share. In addition, Sarepta is scheduled to pay $50 million per year for a total of five years (payable in February of each of the next five years) along with two separate payments of $100 million and $200 million that are tied to enrollment of certain cohorts in the Phase 1 study of ARO-DM1. The $100 million payment has been triggered (and is expected to be received before the end of fiscal year 2025) and the $200 million payment is expected to be triggered before the end of calendar 2025.

Sarepta has recently faced a number of setbacks related to its lead drug Elevidys. Following the report of two patient deaths, the FDA temporarily requested a pause on Elevidys shipments, however the agency has since recommended resuming shipments for ambulatory DMD patients. Sarepta's stock is down >85% over the past year amid the uncertainty surrounding Elevidys. The company recently announced a strategic restructuring that includes cost saving measures and a prioritization of the programs that were in-licensed from Arrowhead. At this juncture Sarepta is continuing to meet its obligations, however if for some reason Sarepta was unable to meet its obligations in the future the agreement has clear termination provisions that would allow the assets and intellectual property to be returned to Arrowhead without Arrowhead needing to repay any of the capital that is has received thus far from Sarepta.

Update on Early-Stage Assets

Arrowhead is currently evaluating ARO-INHBE and ARO-ALK7 as treatments for obesity in Phase 1 studies. 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 INHBE study is currently enrolling patients in the multi-dose cohorts in combination with tirzepatide. The ALK7 study is currently in the single dose escalation phase, with multi-dose and combination cohorts expected to open soon. Data from both studies are expected at the end of calendar 2025.

For the muscle clinical programs partnered with Sarepta, the ARO-DM1 Phase 1/2a study has started enrolling the multi-dose cohorts of patients with myotonic dystrophy. The ARO-DUX4 Phase 1/2a study is almost complete with single dose cohorts and the first year-long multidose cohort is open for enrollment. These studies are on track for potential data availability by the end of the year, however the timing of data release will be determined by Sarepta.

The ARO-MAPT program, which is wholly owned by Arrowhead, is on track for CTA submission by the end of calendar 2025. This program is designed to deliver a siRNA that crosses the blood-brain barrier to target CNS-expressed Tau protein. Preclinical data in monkeys showed that subcutaneous administration of ARO-MAPT resulted in >75% knockdown of tissue level MAPT mRNA, with subsequent CSF Tau protein reductions of >75% and the potential for monthly or quarterly injections. We anticipate the full preclinical data set for ARO-MAPT being presented at an upcoming scientific conference.

Financial Update

On August 7, 2025, Arrowhead announced financial results for the third quarter of fiscal year 2025 that ended June 30, 2025. The company reported revenue of $27.8 million for the quarter ending June 30, 2025 compared to no revenue for the quarter ending June 30, 2024. The revenue in the current period is related to the license and collaboration agreement with Sarepta, with approximately $20 million related to the on-going recognition of the initial Sarepta consideration and approximately $7 million related to reimbursement of collaboration-related costs. Subsequent to the end of the quarter, Arrowhead announced both the $100 million milestone payment from Sarepta was triggered, which will be recognized in fiscal fourth quarter of 2025, and the $130 million upfront payment from Sanofi to Visirna, which will also be recognized in fiscal fourth quarter of 2025.

R&D expenses for the quarter ending June 30, 2025 were approximately $162.4 million compared to $152.4 million for the quarter ending June 30, 2024. The increase was primarily due to increased candidate costs, discovery costs, and salaries. G&A expenses for the third quarter of fiscal year 2025 were $30.9 million compared to $23.7 million for the third quarter of fiscal year 2024. The increase was primarily due to higher professional services, salaries, and facilities costs.

Arrowhead exited the third quarter of fiscal year 2025 with approximately $900.4 million in cash, cash equivalents, and investments. We estimate the company is financed into 2028. As of August 1, 2025, Arrowhead had approximately 138.3 million shares outstanding and, when factoring in stock options and restricted stock units, a fully diluted share count of approximately 145.7 million.

Conclusion

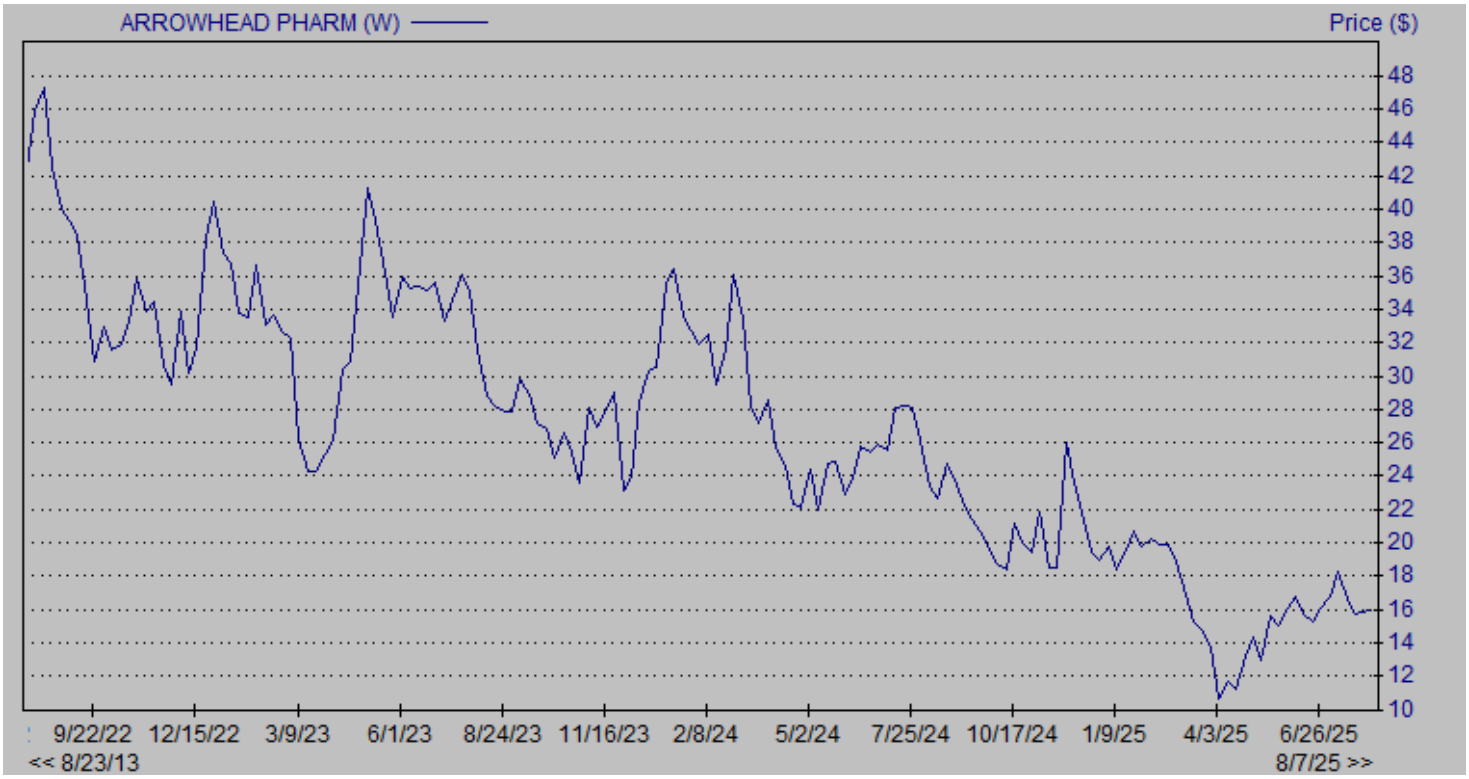
We don’t anticipate that Sarepta will be unable to fulfill its obligations regarding its agreement with Arrowhead as Sarepta has prioritized the development of the partnered assets. Thus, we trust that all milestones will be paid when due, which will continue to help strengthen Arrowhead’s balance sheet. We eagerly await the FDA’s decision on plozasiran for the treatment of FCS, which we expect on or before the PDUFA date of Nov. 18, 2025. The company continues to build out its commercial infrastructure, which we believe will put it in a position to rapidly launch the drug, if approved. Following a few minor modifications to our model, our valuation now stands at $72 per share.

PROJECTED FINANCIALS

Arrowhead Pharmaceuticals, Inc.	FY2024 A	Q1FY25 A	Q2FY25 A	Q3FY25 A	Q4FY25 E	FY2025 E	FY2026 E	FY2027 E
Revenue	$3.55	$2.50	$542.7	$27.8	$185.0	$758.0	$350.0	$300.0
YOY Growth	*-53.5%*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*5109.8%*	*349.0%*	*1088.3%*	*1175.0%*
Total Revenues	**$3.6**	**$2.5**	**$542.7**	**$27.8**	**$185.0**	**$758.0**	**$350.0**	**$300.0**
YOY Growth	*-53.5%*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*5109.8%*	*349.0%*	*1088.3%*	*1175.0%*
Cost of Revenue	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$2.5	$4.8
Gross Income	**$3.6**	**$2.5**	**$542.7**	**$27.8**	**$185.0**	**$758.0**	**$347.5**	**$295.2**
Gross Margin	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*99.3%*	*98.4%*
R&D	$505.9	$137.0	$133.1	$162.4	$132.0	$564.5	$540.0	$550.0
% R&D	*14245.8%*	*5480.1%*	*24.5%*	*584.8%*	*71.4%*	*74.5%*	*154.3%*	*183.3%*
Salary and G&A	$98.8	$26.9	$28.4	$30.9	$31.0	$117.3	$110.0	$115.0
% SG&A	*2781.2%*	*1076.4%*	*5.2%*	*111.5%*	*16.8%*	*15.5%*	*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**	**($165.6)**	**$22.0**	**$76.2**	**($302.5)**	**($369.8)**
Operating Margin	*-16927.1%*	-	-	-	-	*10.1%*	*-86.4%*	*-123.3%*
Other Income (Net)	($11.4)	($13.7)	($11.6)	($13.5)	($4.0)	($42.8)	($15.0)	($15.0)
Pre-Tax Income	**($612.5)**	**($175.1)**	**$369.6**	**($179.1)**	**$18.0**	**$33.4**	**($317.5)**	**($384.8)**
Net Taxes (benefit)	$2.8	$0.1	$1.8	$0.4	$0.0	$1.4	$0.0	$0.0
Net Loss Attributable to Noncontrolling Interest	$10.2	$2.1	$2.6	$3.4	$0.0	$8.1	$0.0	$0.0
Reported Net Income	**($599.5)**	**($173.1)**	**$370.4**	**($175.2)**	**$18.0**	**$40.1**	**($317.5)**	**($384.8)**
Net Margin	*-16882.4%*	-	-	-	-	*5.3%*	*-90.7%*	*-128.3%*
Reported EPS	**($5.00)**	**($1.39)**	**$2.78**	**($1.26)**	**$0.13**	**$0.30**	**($2.19)**	**($2.57)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	119.8	124.8	133.4	139.0	140.0	134.3	145.0	150.0

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

HISTORICAL STOCK PRICE



Source: Zacks SCR

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