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Arrowhead Pharmaceuticals, Inc. (ARWR-NASDAQ)

ARWR: Pipeline Reprioritization to Reduce Cash Burn by up to $100 Million This Fiscal Year…

Based on our probability adjusted DCF model that takes into account potential future revenues from the company's development products, ARWR is valued at $74/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 (02/08/24)	$33.20
Valuation	**$74.00**

OUTLOOK

On February 6, 2024, Arrowhead Pharmaceuticals, Inc. (ARWR) announced financial results for the first quarter of fiscal year 2024 that ended December 31, 2023. The company announced a reprioritization of its pipeline in order to reduce cash burn (estimated at up to $100 million) and allocate resources where they are needed (e.g., building out the infrastructure for the cardiometabolic programs). The Phase 3 PALISADE study of plozasiran is expected to read out soon after the final patient visit in May 2024. Positive results would lead to an NDA filing in late 2024/early 2025. Arrowhead will be initiating the Phase 3 SHASTA-3 and SHASTA-4 trials of plozasiran in patients with severe hypertriglyceridemia (SHTG) in 2Q24. A decision about whether to move plozasiran or zodasiran into a cardiovascular outcomes trial (CVOT) is expected soon.

SUMMARY DATA

52-Week High	**$41.38**
52-Week Low	**$21.20**
One-Year Return (%)	**-1.25**
Beta	**0.78**
Average Daily Volume (sh)	**1,061,364**
Shares Outstanding (mil)	**107**
Market Capitalization ($mil)	**$3,567**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**66**
Insider Ownership (%)	**5**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**28.7**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2024 Estimate	**-10.9**
P/E using 2025 Estimate	**-11.4**

Risk Level	**Above Avg.**
Type of Stock	**Large-Growth**
Industry	**Med-Drugs**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Dec)	Q2 (Mar)	Q3 (Jun)	Q4 (Sep)	Year (Sep)
2023	62.6 A	146.3 A	15.8 A	16.1 A	240.7 A
2024	3.6 A	50.0 E	50.0 E	50.0 E	153.5 E
2025					250.0 E
2026					300.0 E

Earnings per Share

	Q1 (Dec)	Q2 (Mar)	Q3 (Jun)	Q4 (Sep)	Year (Sep)
2023	-$0.39 A	$0.46 A	-$0.96 A	-$1.04 A	-$1.92 A
2024	-$1.24 A	-$0.47 E	-$0.48 E	-$0.48 E	-$2.58 E
2025					-$1.76 E
2026					-$1.42 E

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WHAT'S NEW

Business Update

Pipeline Reprioritization to Cut ~$100 Million in Expenses

Arrowhead Pharmaceuticals, Inc. (ARWR) recently provided an update on the company's plans to prioritize resources as more of its development products enter late-stage trials that will require significant capital, expertise, and (potentially) commercial infrastructure. The two areas of focus right now are in the cardiometabolic and pulmonary space. While the company plans to continue to develop new candidates outside these focus areas, the cardiometabolic and pulmonary candidates are the near-term value drivers. Outside of these core focus areas, Arrowhead is planning to move ahead with clinical trials for the complement program (ARO-C3 and ARO-CFB) and the muscle targeted program (ARO-DUX4 and ARO-DM1). The company is also continuing to assess a clinical path and designing a Phase 1b/2a trial for the MASH candidate, ARO-PNPLA3. However, two programs are being terminated: HZN-457, which was returned by Amgen following the acquisition of Horizon, and ARO-SOD1, which was being developed to treat SOD1 ALS. Additional undisclosed preclinical programs were also discontinued. In total, the company expects to reduce fiscal year operating burn by up to $100 million while continuing to fully fund investment in its cardiometabolic and pulmonary programs.

Cardiometabolic Update

Arrowhead has not made any decision about whether plozasiran or zodasiran will be used in a cardiovascular outcome trial, however the company is expecting to finish up that analysis in the current quarter. For plozasiran, Arrowhead has decided to make a few changes to the proposed SHASTA Phase 3 program for patients with severe hypertriglyceridemia (SHTG). Originally the company had planned to conduct two similar Phase 3 studies: SHASTA-3 and SHASTA-4 in approximately 700 patients with triglycerides (TGs) > 500 mg/dl with the primary endpoint of lowering TGs after one year of treatment. While the general design for those studies is remaining the same, the company had previously wanted to include a predefined number of patients at higher risk for severe abdominal pain and acute pancreatitis events. However, that cohort of patients will now be enrolled into a separate study designed specifically for that purpose and will be called SHASTA-5. The company is estimating that the changes will result in a more rapid enrollment for SHASTA-3 and SHASTA-4 and potentially get to an NDA filing approximately six to ten months faster. SHASTA-3 and SHASTA-4 should initiate in the second quarter of 2024 and SHASTA-5 shortly thereafter.

The Phase 3 PALISADE study of plozasiran in patients with familial chylomicronemia syndrome (FCS) is expected to have the last study visit in May 2024, with topline results being reported in the third quarter of 2024. Positive results will lead to an NDA filing either at the end of 2024 or early in 2025.

Pipeline Update

In regards to new programs, the company recently disclosed the cardiometabolic candidate ARO-INHBE, which targets the *INHBE* gene that encodes inhibin subunit βE. This is an interesting target as two papers came out in 2022 that described loss of function mutations in *INHBE* that were associated with favorable fat distribution. Deaton *et al*. reported a genome-wide association study (GWAS) from 362,679 individuals that showed a predicted loss of function variant in *INHBE* associated with a lower waist-to-hip ratio adjusted for BMI (WHRadjBMI), which they used as a surrogate for abdominal fat that is causally linked to type 2 diabetes and coronary heart disease (Deaton *et al*., 2022). Akbari *et al*. performed a GWAS in 618,375 individuals and identified an association with favorable fat distribution, favorable metabolic profile, and protection from type 2 diabetes for heterozygous protein-truncating mutations in *INHBE* (Akbari *et al*., 2022). Arrowhead has conducted studies of *Inhbe* silencing in mouse obesity models with results showing reduced weight gain compared to controls. Importantly, the difference in weight gain was primarily due to changes in fat mass with no difference in lean mass. The company believes *INHBE* silencing could be a good adjunct to GLP-1 agonists and could include the ability to lower the dose of the GLP-1 agonist and thus reducing lean mass

loss, gastrointestinal side effects, and prevention or slowing of weight regain following cessation of GLP-1 agonist therapy.

Arrowhead is continuing its evaluation of the pulmonary programs ARO-RAGE, ARO-MUC5AC, and ARO-MMP7, with each of those candidates having clinical readouts in 2024:

- The Phase 1/2 study of ARO-RAGE is fully enrolled and all healthy volunteers and mild-to-moderate asthma patients have been dosed. Additional pharmacodynamic (PD) data should be available by the end of the first quarter. The company is currently in the process of enrolling three cohorts of asthma patients with high baseline levels of fractional exhaled nitric oxide, FeNO, which is a biomarker for IL-13-driven type II inflammation in the lungs. The initial FeNO data should be available in the third quarter of 2024.

- For ARO-MUC5AC and ARO-MMP7, both Phase 1/2 trials for each compound have enrolled and dosed healthy volunteers and the company is estimating that patient cohorts will be enrolled and dosed such that clinical readouts could occur in the second half of 2024.

Arrowhead currently has two muscle-targeted programs; ARO-DUX4 for patients with facioscapulohumeral muscular dystrophy (FSHD), and ARO-DM1 for patients with type 1 myotonic dystrophy. Both of those candidates will be evaluated in Phase 1/2 dose-escalating trials and the first-patient-in for both studies should occur in the first or second quarter of 2024.

The company also has two complement programs; ARO-CFB for the treatment of various complement-mediated diseases through reduction in hepatic expression of complement factor B, and ARO-C3 for the treatment of various complement-mediated diseases. Preclinical data shows that treatment with ARO-CFB results in deep and durable reductions in liver production of complement factor B, which plays a key role in the pathogenesis of renal diseases such as IgA nephropathy. A Phase 1/2 study is likely to initiate for ARO-CFB in the second quarter of 2024. Part 2 of the ongoing Phase 1/2 study of ARO-C3 is currently enrolling and the company is planning to present patient data near the end of 2024.

Financial Update

On February 6, 2024, Arrowhead announced financial results for the first quarter of fiscal year 2024 that ended December 31, 2023. The company reported revenue of approximately $3.6 million for the first quarter of fiscal year 2024 compared to approximately $62.5 million for the first quarter of fiscal year 2023. The revenue was mainly driven by the revenue recognition associated with the collaboration agreements with GSK and Takeda. All upfront payments from existing agreements have now been fully recognized.

R&D expenses for the quarter ending December 31, 2023 were approximately $116.5 million compared to $83.7 million for the quarter ending December 31, 2022. 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 first quarter of fiscal year 2024 were $23.6 million compared to $21.0 million for the first quarter of fiscal year 2023. The increase was primarily due to higher salaries and professional services.

Arrowhead exited the first quarter of fiscal year 2024 with approximately $220.3 million in cash, cash equivalents, and investments. Subsequent to the end of the quarter, Arrowhead completed an underwritten registered offering of 15,790,00 shares at a price of $28.50 that resulted in gross proceeds of $450 million ($429 million net). Proforma cash and investments following the capital raise are approximately $649 million. R&D cash burn is expected to be approximately $80 million per quarter this fiscal year with G&A cash burn being approximately $10 million per quarter. As of January 31, 2024, Arrowhead had approximately 123.9 million shares outstanding and, when factoring in stock options and restricted stock units, a fully diluted share count of approximately 130.7 million.

Conclusion

This could be a transformative year for Arrowhead with the expected topline results for the Phase 3 PALISADE study in mid-2024. Positive results will lead to the company's first NDA filing in late 2024/early 2025 and potential approval in 2025. There will be a host of other data readouts and trial initiations this year and the reprioritization of company resources is a smart strategic move as the pipeline candidates move toward more cost intensive late-stage trials. The company indicated that the recent financing is the first step of an overall strategy to increase the balance sheet. The second step will likely be a structured finance transaction that may be based around a capital infusion in return for royalties on a future product and may or may not have a debt component to it. The third step is one or more partnership transactions, with the goal being to do one or more "economically meaningful" deals this year. After incorporating the recent financing into our model our valuation now stands at $74 per share.

PROJECTED FINANCIALS

Arrowhead Pharmaceuticals, Inc.	FY2023 A	Q1FY24 A	Q2FY24 E	Q3FY24 E	Q4FY24 E	FY2024 E	FY2025 E	FY2026 E
Revenue	$240.74	$3.55	$50.00	$50.00	$50.00	$153.55	$250.00	$300.00
YOY Growth	*456.1%*	*-97.6%*	*216.0%*	*210.6%*	*-79.2%*	*1911.7%*	*48.1%*	*918.5%*
Total Revenues	**$240.7**	**$3.6**	**$50.0**	**$50.0**	**$50.0**	**$153.6**	**$250.0**	**$300.0**
YOY Growth	*456.1%*	*-97.6%*	*216.0%*	*210.6%*	*-79.2%*	*1911.7%*	*48.1%*	*918.5%*
Cost of Revenue	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Gross Income	**$240.7**	**$3.6**	**$50.0**	**$50.0**	**$50.0**	**$153.6**	**$250.0**	**$300.0**
Gross Margin	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*
R&D	$353.2	$116.5	$85.0	$85.0	$85.0	$371.5	$375.0	$380.0
% R&D	*146.7%*	*3280.5%*	*170.0%*	*170.0%*	*170.0%*	*241.9%*	*150.0%*	*126.7%*
Salary and G&A	$92.5	$23.6	$23.0	$24.0	$24.0	$94.6	$95.0	$100.0
% SG&A	*38.4%*	*664.7%*	*46.0%*	*48.0%*	*48.0%*	*61.6%*	*38.0%*	*33.3%*
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	**($205.0)**	**($136.5)**	**($58.0)**	**($59.0)**	**($59.0)**	**($312.5)**	**($220.0)**	**($180.0)**
Operating Margin	*-85.2%*	-	-	-	-	*-203.5%*	*-88.0%*	*-60.0%*
Other Income (Net)	($1.5)	($2.1)	$0.0	$0.0	$0.0	($2.1)	$0.0	$0.0
Pre-Tax Income	**($206.5)**	**($138.7)**	**($58.0)**	**($59.0)**	**($59.0)**	**($314.7)**	**($220.0)**	**($180.0)**
Net Taxes (benefit)	$2.8	$3.3	$0.0	$0.0	$0.0	$3.3	$0.0	$0.0
Net Loss Attributable to Noncontrolling Interest	$4.0	$2.5	$0.0	$0.0	$0.0	$2.5	$0.0	$0.0
Reported Net Income	**($205.3)**	**($132.9)**	**($58.0)**	**($59.0)**	**($59.0)**	**($308.9)**	**($220.0)**	**($180.0)**
Net Margin	*-85.3%*	-	-	-	-	*-201.1%*	*-88.0%*	*-60.0%*
Reported EPS	**($1.92)**	**($1.24)**	**($0.47)**	**($0.48)**	**($0.48)**	**($2.58)**	**($1.76)**	**($1.42)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	106.8	107.4	123.9	124.0	124.0	119.8	125.0	127.0

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

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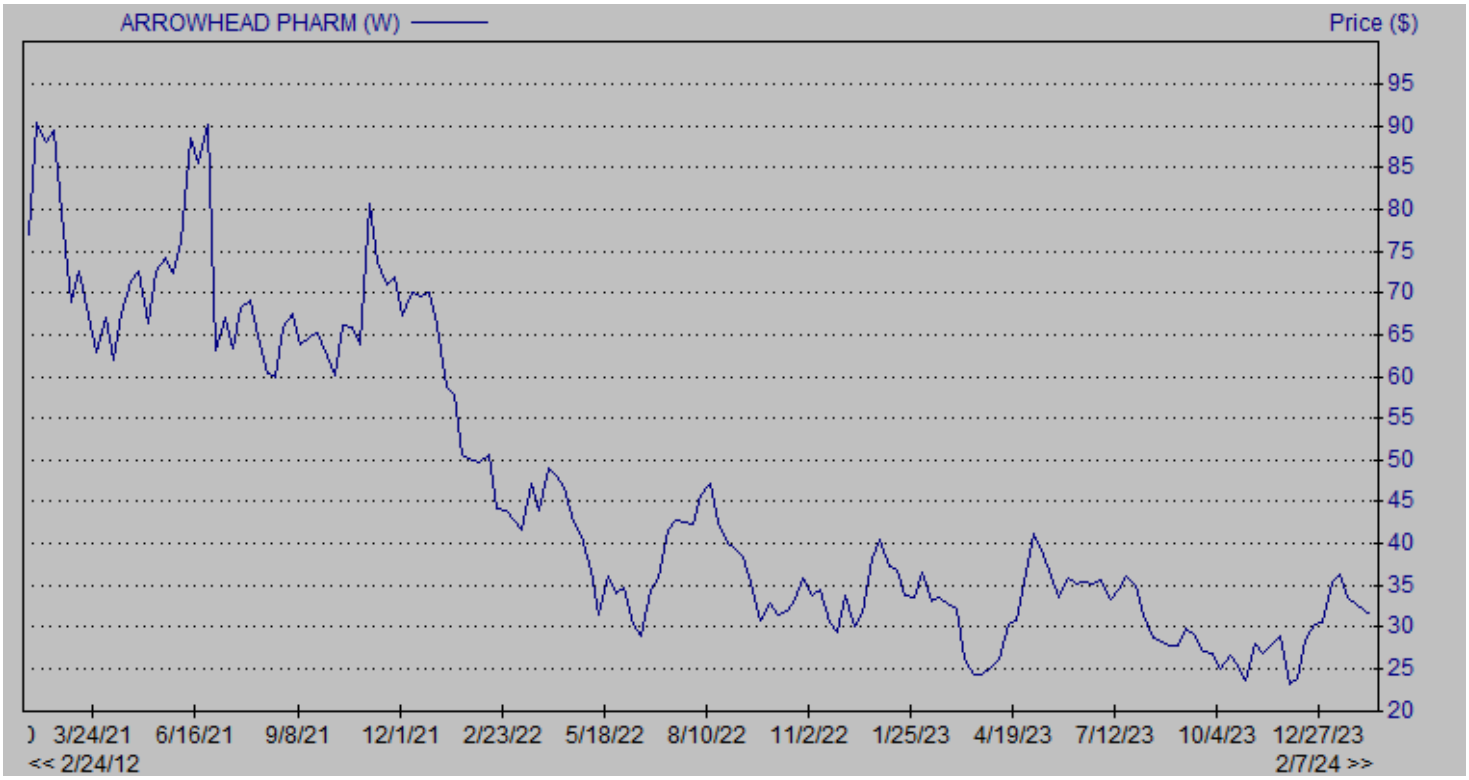

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