

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 8-K

**CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(D) OF
THE SECURITIES EXCHANGE ACT OF 1934**

November 26, 2024

Date of Report
(Date of earliest event reported)

Arrowhead Pharmaceuticals, Inc.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-38042
(Commission
File Number)

46-0408024
(IRS Employer
Identification No.)

177 E. Colorado Blvd, Suite 700, Pasadena, CA 91105
(Address of principal executive offices, including Zip Code)
(626) 304-3400
(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4 (c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.001 per share	ARWR	The Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02 Results of Operations and Financial Condition

On November 26, 2024, Arrowhead Pharmaceuticals, Inc. announced and commented on its fiscal 2024 financial results for the period ended September 30, 2024. A copy of the press release is furnished herewith as Exhibit 99.1.

In accordance with General Instruction B.2 of Form 8-K, the information in this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, except as expressly set forth by specific reference in such filing to this Current Report on Form 8-K.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release, dated November 26, 2024.
104	Cover Page Interactive Data File (the cover page tags are embedded within the Inline XBRL document).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Date: November 26, 2024

ARROWHEAD PHARMACEUTICALS, INC.

By: /s/ Kenneth Myszkowski
Kenneth Myszkowski
Chief Financial Officer



PRESS RELEASE
November 26, 2024

Arrowhead Pharmaceuticals Reports 2024 Fiscal Year-End Results

Conference Call and Webcast Today, November 26, 2024 at 4:30 p.m. ET

PASADENA, Calif., November 26, 2024 — Arrowhead Pharmaceuticals, Inc. (NASDAQ: ARWR) today announced financial results for its 2024 fiscal year ended September 30, 2024. The Company is hosting a conference call today, November 26, 2024, at 4:30 p.m. ET to discuss the results.

“Arrowhead is well positioned, both individually and with partners, to advance and ultimately commercialize important new medicines using our proprietary TRiM™ technology. We have the potential to impact the lives of millions of patients in need. We believe we now have all the necessary pieces in place to drive significant value for shareholders in the short-term, mid-term, and, more importantly, over the long-term as we seek to build a sustainable, financially sound business,” said Christopher Anzalone, Ph.D., President and CEO at Arrowhead. “Key events have occurred during the recent period that we see as potentially transformational for Arrowhead. Earlier this month, we submitted our first NDA to the U.S. FDA for investigational plozasiran, paving the way for Arrowhead to potentially launch our first commercial product in 2025, subject to FDA review and approval. We also took steps to meaningfully strengthen our balance sheet, including entering into a large licensing and collaboration agreement with Sarepta Therapeutics, which was announced today. Sarepta is an important new partner with extensive clinical, regulatory, and commercial expertise and this collaboration will help us advance and commercialize multiple promising Arrowhead-discovered drug candidates that fall outside of our current commercial focus on the cardiometabolic therapeutic area.”

Selected Recent Financial Events

- Strengthened the balance sheet through a strategic financing agreement and licensing and collaboration agreement. We estimate that together, these transactions extend Arrowhead’s cash runway into 2028 and potentially through multiple new drug launches, including wholly owned and partnered programs. These two events were:
 - Signed a licensing and collaboration agreement with Sarepta Therapeutics. Upon closing, Arrowhead will receive \$825 million, consisting of \$500 million cash and \$325 million as an equity investment priced at \$27.2507, representing a 35% premium to the 30-day volume weighted average price. Arrowhead also receives \$250 million to be paid over five years and is eligible to receive an additional \$300 million in near-term payments. Arrowhead is also eligible to receive royalties on commercial sales and approximately \$10 billion in potential milestone payments.
 - Closed a strategic financing agreement with Sixth Street for significant, long-term, non-dilutive capital. The \$500 million senior secured credit facility includes \$400 million funded at close with an additional \$100 million available at Arrowhead’s option, subject to mutual agreement between Sixth Street and Arrowhead, during the seven-year term of the agreement.

Selected Recent R&D Events

- Submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for investigational plozasiran for the treatment of familial chylomicronemia syndrome, a severe and rare genetic disease which currently has no FDA approved treatments.
- Received Breakthrough Therapy designation from the FDA for investigational plozasiran as an adjunct to diet to reduce triglycerides in adults with familial chylomicronemia syndrome.

- Announced new results from the Phase 3 PALISADE study and the open-label extension from the Phase 2 MUIR and SHASTA-2 studies of investigational plozasiran. These data were presented in two oral presentations at the American Heart Association Scientific Sessions 2024 (AHA24) and PALISADE data was simultaneously published in the AHA journal, *Circulation*. Key results include the following:
 - Plozasiran induced deep and sustained reductions in triglycerides and impacted a wide spectrum of lipoproteins that may be involved with atherosclerotic cardiovascular disease
 - Similar responses were observed in patients with genetically confirmed and clinically diagnosed familial chylomicronemia syndrome
 - Mean reductions in triglycerides of up to -73% in patients from MUIR and -86% in patients from SHASTA-2 with favorable reductions in remnant cholesterol and non-HDL-cholesterol were observed through 15 months follow up in the open-label extension
 - Overall, plozasiran has been generally well-tolerated to date. In the PALISADE study, the most frequently reported treatment emergent adverse events for the 25 mg dose were abdominal pain, COVID-19, nasopharyngitis, and nausea. Across clinical studies and study populations, the most frequently reported treatment emergent adverse events for the 25 mg dose were COVID-19, upper respiratory tract infection, headache, Type 2 diabetes mellitus, and abdominal pain.
- Initiated pivotal Phase 3 SHASTA-3 and SHASTA-4 studies of plozasiran in patients with severe hypertriglyceridemia.
- Launched a new disease awareness campaign, ‘We’ll Get There Soon,’ to inspire hope for the rare disease community affected by familial chylomicronemia syndrome.
- Presented data from the Phase 3 PALISADE study of plozasiran in a late-breaking oral presentation at the European Society of Cardiology (ESC) Congress 2024 and simultaneously published in [The New England Journal of Medicine](#).
- Arrowhead’s Verona, WI manufacturing and testing facility successfully completed requirements to manufacture GMP drug substance to support clinical trials conducted in the United States and many other countries abroad, and recently successfully completed a Qualified Person (QP) audit, which allows for internally produced drug substance to be used in support of clinical programs in EU countries and the United Kingdom.
- Filed for regulatory clearance in New Zealand to initiate a Phase 1/2a clinical trial of ARO-INHBE, the company’s investigational RNAi therapeutic being developed as a potential treatment for obesity.
 - In preclinical studies ARO-INHBE reduced body weight and fat mass with a novel mechanism of action that may preserve lean muscle mass compared to currently approved obesity therapies.
- Completed the 2024 Summer Series of R&D webinars, each highlighting a specific therapeutic area in Arrowhead’s pipeline, including the following events:
 - May 23, 2024 – Muscular
 - June 25, 2024 – Cardiometabolic
 - July 16, 2024 – Pulmonary
 - August 14, 2024 – Obesity/Metabolic
 - September 25, 2024 – Central Nervous System

Selected Fiscal 2024 Financial Results

ARROWHEAD PHARMACEUTICALS, INC.
CONSOLIDATED CONDENSED FINANCIAL INFORMATION
(in thousands, except per share amounts)

<u>OPERATING SUMMARY</u>	Year Ended September 30,	
	2024	2023
Revenue	\$ 3,551	\$ 240,735
Operating Expenses:		
Research and development	505,870	353,188
General and administrative expenses	98,761	92,549
Total Operating Expenses	604,631	445,737
Operating loss	(601,080)	(205,002)
Total other expense	(11,380)	(1,489)
Loss before income tax expense and noncontrolling interest	(612,460)	(206,491)
Income tax (benefit) expense	(2,767)	2,784
Net loss including noncontrolling interest	(609,693)	(209,275)
Net loss attributable to noncontrolling interest, net of tax	(10,200)	(4,000)
Net loss attributable to Arrowhead Pharmaceuticals, Inc.	\$ (599,493)	\$ (205,275)
Net loss per share attributable to Arrowhead Pharmaceuticals, Inc. - Diluted	\$ (5.00)	\$ (1.92)
Weighted-average shares used in calculating - Diluted	119,784	106,750
<u>FINANCIAL POSITION SUMMARY</u>	September 30,	
	2024	2023
Cash, cash equivalents and restricted cash	\$ 102,685	\$ 110,891
Investments	578,276	292,735
Total cash resources	680,961	403,626
Other assets	458,841	361,926
Total Assets	\$ 1,139,802	\$ 765,552
Current deferred revenue	\$ —	\$ 866
Credit Facility	393,183	—
Other liabilities	555,556	477,524
Total Liabilities	\$ 948,739	\$ 478,390
Total Arrowhead Pharmaceuticals, Inc. Stockholders' Equity	\$ 185,444	\$ 271,343
Noncontrolling Interest	5,619	15,819
Total Noncontrolling Interest and Stockholders' Equity	\$ 191,063	\$ 287,162
Total Liabilities, Noncontrolling Interest and Stockholders' Equity	\$ 1,139,802	\$ 765,552
Shares Outstanding	124,376	107,312

Webcast and Conference Call and Details

Investors may access a live audio webcast on the [Events and Presentations](#) page under the Investors section of the Arrowhead website. A replay of the webcast will be available approximately two hours after the conclusion of the call.

For analysts that wish to participate in the conference call, please register at <https://register.vevent.com/register/B1c060a13ae8224934aac09d48abe7b2f6>. Once registered, you will receive the dial-in number and a personalized PIN code that will be required to access the call.

About Plozasiran

Plozasiran, previously called ARO-APOC3, is a first-in-class investigational RNA interference (RNAi) therapeutic designed to reduce production of apolipoprotein C-III (APOC3) which is a component of triglyceride rich lipoproteins (TRLs) and a key regulator of triglyceride metabolism. APOC3 increases triglyceride levels in the blood by inhibiting breakdown of TRLs by lipoprotein lipase and uptake of TRL remnants by hepatic receptors in the liver. The goal of treatment with plozasiran is to reduce the level of APOC3, thereby reducing triglycerides and restoring lipids to more normal levels.

In multiple clinical studies, investigational plozasiran has demonstrated reductions in triglycerides and multiple atherogenic lipoproteins in patients with familial chylomicronemia syndrome (FCS), severe hypertriglyceridemia (SHTG), and mixed hyperlipidemia. Plozasiran has been generally well tolerated to date with treatment emergent adverse events reported that generally reflect the comorbidities and underlying conditions of the study populations. Across clinical studies and study populations, the most frequently reported treatment emergent adverse events for the 25 mg dose were COVID-19, upper respiratory tract infection, headache, Type 2 diabetes mellitus, and abdominal pain.

Plozasiran is being investigated in the SUMMIT program of clinical studies, including the PALISADE Phase 3 study in patients with FCS, the SHASTA studies in patients with SHTG, and the MUIR and CAPITAN studies in patients with mixed hyperlipidemia.

Plozasiran in the treatment of patients with FCS has been granted Breakthrough Therapy Designation, Orphan Drug Designation, and Fast Track Designation by the U.S. Food and Drug Administration and Orphan Drug Designation by the European Medicines Agency. Investigational plozasiran has not been reviewed or approved to treat any disease.

About Arrowhead Pharmaceuticals

Arrowhead Pharmaceuticals develops medicines that treat intractable diseases by silencing the genes that cause them. Using a broad portfolio of RNA chemistries and efficient modes of delivery, Arrowhead therapies trigger the RNA interference mechanism to induce rapid, deep, and durable knockdown of target genes. RNA interference, or RNAi, is a mechanism present in living cells that inhibits the expression of a specific gene, thereby affecting the production of a specific protein. Arrowhead's RNAi-based therapeutics leverage this natural pathway of gene silencing.

For more information, please visit www.arrowheadpharma.com, or follow us on X (formerly Twitter) at [@ArrowheadPharma](#), [LinkedIn](#), [Facebook](#), and [Instagram](#). To be added to the Company's email list and receive news directly, please visit <http://ir.arrowheadpharma.com/email-alerts>.

Safe Harbor Statement under the Private Securities Litigation Reform Act:

This news release contains forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. Any statements contained in this release except for historical information may be deemed to be forward-looking statements. Without limiting the generality of the foregoing, words such as "may," "will," "expect," "believe," "anticipate," "hope," "intend," "plan," "project," "could," "estimate," "continue," "target," "forecast" or "continue" or the negative of these words or other variations thereof or comparable terminology are intended to identify such forward-looking statements. In addition, any statements that refer to projections of our future financial performance, trends in our business, expectations for our product pipeline or product candidates, including anticipated regulatory submissions and clinical program results, prospects or benefits of our collaborations with other companies, or other characterizations of future events or circumstances are forward-looking statements. These forward-looking statements include, but are not limited to, statements about the initiation, timing, progress and results of our preclinical studies and clinical trials, and our research and development programs; our expectations regarding the potential benefits of the partnership, licensing and/or collaboration arrangements and other strategic arrangements and transactions we have entered into or may enter into in the future; our beliefs and expectations regarding milestone, royalty or other payments that could be due to or from third parties under existing agreements; and our estimates regarding future revenues, research and development expenses, capital requirements and payments to third parties. These statements are

based upon our current expectations and speak only as of the date hereof. Our actual results may differ materially and adversely from those expressed in any forward-looking statements as a result of numerous factors and uncertainties, including the impact of the ongoing COVID-19 pandemic on our business, the safety and efficacy of our product candidates, decisions of regulatory authorities and the timing thereof, the duration and impact of regulatory delays in our clinical programs, our ability to finance our operations, the likelihood and timing of the receipt of future milestone and licensing fees, the future success of our scientific studies, our ability to successfully develop and commercialize drug candidates, the timing for starting and completing clinical trials, rapid technological change in our markets, the enforcement of our intellectual property rights, and the other risks and uncertainties described in our most recent Annual Report on Form 10-K, subsequent Quarterly Reports on Form 10-Q and other documents filed with the Securities and Exchange Commission from time to time. We assume no obligation to update or revise forward-looking statements to reflect new events or circumstances.

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