



November 18, 2024

VIA EDGAR

U.S. Securities and Exchange Commission  
Division of Corporation Finance  
Office of Life Sciences  
100 F Street, N.E.  
Washington, D.C. 20549  
Attn: Bonnie Baynes  
Mary Mast

**Re: ARS Pharmaceuticals, Inc.  
Form 10-K for the Fiscal Year Ended December 31, 2023  
File No. 001-39756**

Dear Bonnie Baynes and Mary Mast:

We are writing in response to the comment received from the staff (the "**Staff**") of the Securities and Exchange Commission (the "**Commission**") by letter dated November 7, 2024 with respect to the above-referenced filing of ARS Pharmaceuticals, Inc. (the "**Company**"). For your convenience, we have repeated the Staff's comment before the Company's response below.

**Staff Comment:**

Form 10-K for the Fiscal Year Ended December 31, 2023  
Management's Discussion and Analysis of Financial Condition and Results of Operations  
Results of Operations, page 110

1. *We note your statements in your August 12, 2024 Neffy FDA Approval call that you have already manufactured lots of neffy prior to receiving the FDA approval, have begun assembling and packaging these lots to launch as soon as possible regarding your fourth quarter 2024 estimated launch date, and have had marketing, commercial operations and other items ready for over a year. We also note you do not disclose inventory yet, your drug stability studies show that neffy has a shelf-life of at least 18 months, and that your total research and development expense of \$6.9 million, \$7.3 million, \$20.3 million and \$18.4 million includes 72%, 60%, 55% & 52% from increasing manufacturing and non-clinical development costs at June 30, 2024, June 30, 2023, December 31, 2023 and December 31, 2022, respectively. Please provide to us, and to the extent material, revise future filings to disclose, the following:*

- *Tell us your accounting policy for pre-launch neffy manufacturing costs incurred prior to regulatory approval, including how they are classified in your financial statements and when you expect they will be recorded in cost of sales.*
- *Tell us the amount of revenues expected to be recognized relating to the zero cost inventories not capitalized.*

ARS Pharmaceuticals, Inc., 11682 El Camino Real, Suite 120, San Diego, CA 92130

- *Tell us the amounts of inventory expensed prior to regulatory approval and its anticipated impact on your results of operations.*
- *Tell us the estimated selling value of zero cost inventory on hand as of December 31, 2023 and June 30, 2024, and when you expect, based on your current estimated sales trends, the zero cost inventories to be depleted.*
- *Tell us the estimated shelf life of your zero cost inventory and how you considered when it will become obsolete in future periods.*

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**Company Response:**

We respectfully acknowledge the Staff's comment. Each bullet from your comment is specifically addressed below.

- *Tell us your accounting policy for pre-launch neffy manufacturing costs incurred prior to regulatory approval, including how they are classified in your financial statements and when you expect they will be recorded in cost of sales.*

The Company capitalizes inventory costs after regulatory approval, when future commercialization is considered probable and a future economic benefit is expected to be realized. Prior to regulatory approval, the Company records inventory costs as research and development expenses. As such, when regulatory approval is received, this may result in zero cost inventory. This inventory is available to the Company to utilize for commercial operations as well as ongoing research and development activities. We have disclosed this accounting policy on page 12 of our Form 10-Q for the quarter ended September 30, 2024 and will continue to include comparable disclosure, to the extent material, in future filings.

- *Tell us the amount of revenues expected to be recognized relating to the zero cost inventories not capitalized.*

At this time, the amount of revenues expected to be recognized relating to the zero cost inventories not capitalized cannot be reasonably estimated. We are still in the early stages of our U.S. commercial launch of *neffy* and consequently we are not in a position to provide guidance on future revenue expectations. In addition, it is uncertain how much of the raw materials within the zero cost inventories will be utilized in our future clinical trials and development projects. Accordingly, we have not included such disclosure in our Form 10-Q for the quarter ended September 30, 2024.

- *Tell us the amounts of inventory expensed prior to regulatory approval and its anticipated impact on your results of operations.*

Prior to the FDA regulatory approval of *neffy* in August 2024, costs incurred for the manufacture of *neffy* were recorded as research and development expenses, which resulted in zero cost inventory. As a result, the cost of goods sold related to *neffy* will initially reflect a lower average per unit cost of materials, as previously expensed zero cost inventory is utilized for commercial production and sold to customers. We expect the cost of goods sold for *neffy* to increase in relation to product revenues as we deplete these inventories. As of September 30, 2024, we had \$13.0 million in zero cost inventory remaining and we expect zero cost inventory to be depleted by mid-2026. We have included this disclosure on page 33 of our Form 10-Q for the quarter ended September 30, 2024 and will continue to include comparable disclosure, to the extent material, in future filings.

- Tell us the estimated selling value of zero cost inventory on hand as of December 31, 2023 and June 30, 2024, and when you expect, based on your current estimated sales trends, the zero cost inventories to be depleted.

At this time, the estimated selling value of zero cost inventory on hand as of December 31, 2023, June 30, 2024, and September 30, 2024 cannot be reasonably estimated. We are still in the early stages of our U.S. commercial launch of *neffy* and consequently we are not in a position to provide estimated selling value. In addition, it is uncertain how much of the raw materials within the zero cost inventory will be utilized in future clinical trials and development projects. Accordingly, we have not included such disclosure in our Form 10-Q for the quarter ended September 30, 2024.

The Company expects zero cost inventory to be depleted by mid-2026. We have included this disclosure on page 33 of our Form 10-Q for the quarter ended September 30, 2024 and will continue to include comparable disclosure, to the extent material, in future filings.

- Tell us the estimated shelf life of your zero cost inventory and how you considered when it will become obsolete in future periods.

The shelf life of our zero cost inventory varies depending on the inventory's current state. As of September 30, 2024, our raw materials included in zero cost inventory were \$11.4 million and, in their current state, will expire between May 2025 and December 2029. However, once these raw materials are used in our manufacturing process and properly tested, the current FDA approved shelf life of *neffy* is 30 months. As such, our work in process and finished goods included in zero cost inventory of \$0.3 million and \$1.3 million, respectively, will expire between November 2026 and March 2027. We expect to move all raw materials in zero cost inventory through the manufacturing process before their expiration. We do not view shelf-life on its own to be material to investors and therefore we have not included this disclosure in our Form 10-Q for the quarter ended September 30, 2024. However, to help a reader understand that we do consider shelf life when assessing how long we may be utilizing zero cost inventory, we have included the following disclosure on page 33 of our Form 10-Q for the quarter ended September 30, 2024, and will continue to include comparable disclosure, to the extent material, in future filings.

The Company periodically evaluates zero cost inventory for obsolescence. This evaluation considers the shelf life of raw materials, work in process, and finished goods as well as estimated sales trends. As of September 30, 2024, no zero cost inventory was determined to be obsolete.

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The Company respectfully requests the Staff's assistance in completing the review of the Company's response as soon as possible. Please advise us if we can provide any further information or assistance to facilitate your review. Please direct any further comments or questions regarding this response letter to the undersigned.

Sincerely,

**ARS Pharmaceuticals, Inc.**

By: /s/ Kathleen D. Scott  
Kathleen D. Scott  
Chief Financial Officer

Cc: Richard Lowenthal, M.S., MSEL  
President and Chief Executive Officer  
ARS Pharmaceuticals, Inc.

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