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

September 19, 2023
Date of Report (Date of earliest event reported)

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

Delaware	**001-39756**	**81-1489190**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

11682 El Camino Real, Suite 120 **San Diego, California**	**92130**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (858) 771-9307

Not Applicable
(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligations 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, $0.0001 par value per share	SPRY	The Nasdaq Stock Market LLC

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 8.01 Other Events.

On September 19, 2023, ARS Pharmaceuticals, Inc. (the "Company") announced the receipt of a Complete Response Letter ("CRL") from the U.S. Food and Drug Administration (the "FDA") regarding the Company's New Drug Application ("NDA") for ***neffy*** (epinephrine nasal spray) in the treatment of allergic reactions (Type 1), including anaphylaxis for adults and children ≥30 kg. The Company plans to submit a Formal Dispute Resolution Request to appeal the issuance of the CRL.

In the CRL, the FDA requested completion of a pharmacokinetic/pharmacodynamic study assessing repeat doses of ***neffy*** compared to repeat doses of an epinephrine injection product under allergen-induced allergic rhinitis conditions to support approval. This request comes after the recommendation of the FDA Advisory Committee (PADAC) in May 2023 to approve ***neffy*** without the need for additional studies to demonstrate its efficacy or safety. Further, the FDA and the Company previously aligned in August 2023 on final physician's labeling and a post-marketing requirement to conduct this study as informative for labeling.

The PADAC meeting was held on May 11, 2023, and concluded a favorable benefit-risk profile of ***neffy***, with a 16:6 vote in favor for adults and 17:5 vote in favor for children (≥30 kg) for the treatment of patients with allergic reactions (Type I), including anaphylaxis. In that session, no member of the PADAC raised specific concerns about the result of the completed study in people with allergen-induced acute rhinitis with single-dose ***neffy***, which showed enhanced absorption during the time period when a clinical response would be expected.

The Company previously agreed with FDA to conduct a repeat-dose study under allergen-induced allergic rhinitis conditions as a post-marketing commitment, and anticipates a resubmission to the FDA in the first half of 2024, positioning the Company for an anticipated FDA action date in the second half of 2024.

The CRL requested additional information on nitrosamine impurities to be tested for based on new draft guidance issued after the ***neffy*** NDA submission. The Company does not believe the additional testing would be a rate-limiting step for the resubmission to the FDA.

Forward-Looking Statements

Statements in this report that are not purely historical in nature are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These statements include, but are not limited to, the Company's ability to complete the newly required trial and provide the additional information requested by the FDA in the CRL on the timing anticipated, or at all; the timing for the anticipated FDA action date; the potential approval of ***neffy***; the Company's belief that additional testing for nitrosamine impurities based on new draft guidance issued after the Company's NDA submission will not be a rate-limiting step for the resubmission to the FDA; and other statements that are not historical fact. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Words such as "anticipate," "plans," "expects," "will," "potential" and similar expressions are intended to identify forward-looking statements. These forward-looking statements are based upon the Company's current expectations and involve assumptions that may never materialize or may prove to be incorrect. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties, which include, without limitation, the ability to obtain and maintain regulatory approval for ***neffy***; the ability to successfully complete the newly requested trial on the timeframe anticipated, or at all, as a result of challenges inherent to enrolling, conducting and completing clinical trials; the results of the new clinical trial may not support the approval of ***neffy***; results from clinical trials may not be indicative of results that may be observed in the future; potential safety and other complications from ***neffy***; the labelling for ***neffy***, if approved; the scope, progress and expansion of developing and commercializing ***neffy***; the size and growth of the market therefor and the rate and degree of market acceptance thereof vis-à-vis intramuscular injectable products; the Company's ability to protect its intellectual property position; and the impact of government laws and regulations. Additional risks and uncertainties that could cause actual outcomes and results to differ materially from those contemplated by the forward-looking statements are included under the caption "Risk Factors" in ARS's Quarterly Report on Form 10-Q for the quarter ended June 30, 2023, filed with the Securities and Exchange Commission on August 10, 2023.

SIGNATURES

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

ARS PHARMACEUTICALS, INC.

Date: September 20, 2023

By: /s/ Richard Lowenthal
Richard Lowenthal, M.S., MBA
President and Chief Executive Officer