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 17, 2024
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** **(Address of principal executive offices)**	**92130** **(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 1.01 Entry into a Material Definitive Agreement.

On September 17, 2024, ARS Pharmaceuticals Operations, Inc. ("ARS OpCo"), a wholly-owned subsidiary of ARS Pharmaceuticals, Inc. (collectively with ARS OpCo, the "Company"), entered into the second amendment (the "Amendment") to its manufacturing agreement with Renaissance Lakewood, LLC ("Renaissance"), dated as of September 9, 2020 and amended as of July 25, 2023 (as amended by the Amendment, the "Agreement"). Pursuant to the Amendment, among other things, the parties:

(i) revised the term of the Agreement such that the initial term commenced on the date it was entered into and continues (a) for ***neffy*** nasal unit dose sprays ("Product") designated for commercial sale in the U.S. on December 31st immediately following the five year anniversary of the U.S. initial launch date, and (b) for Product designated for commercial sale in the E.U., on December 31st immediately following the five year anniversary of the E.U. initial launch date, unless sooner terminated pursuant to the Agreement, with the initial terms automatically renewing for successive two-year terms, unless either party gives notice pursuant to the Agreement; and

(ii) revised the termination provisions of the Agreement such that either party may terminate the agreement (1) for uncured material breach of the other party, (2) upon notice for insolvency-related events of the other party that are not discharged within a defined time period, (3) on a product-by-product basis if the manufacture, distribution or sale would materially contravene any applicable law, (4) by providing the requisite notice if: (a) the Company's authorization and approval to distribute or sell Product in the U.S. is not granted on or before a specified date, (b) the Company's authorization and approval representing more than a certain number of units of Product sold in the U.S. during the last calendar year is withdrawn by the FDA, or (c) the Company at its sole discretion determines to cease commercializing all Product in the U.S., (5) in the case of a force majeure event that continues for six months or more, or (6) a violation by the other party of trade control or anti-corruption laws.

Forward-Looking Statements

This report contains "forward-looking statements" as that term is defined in the Private Securities Litigation Reform Act of 1995. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such 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 maintain regulatory approval for ***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***; ***neffy*** may fail to achieve the degree of market acceptance by allergists, pediatricians and other physicians, patients, caregivers, third-party payors and others in the medical community necessary for commercial success; if the Company is unable to fully develop sales, marketing and distribution capabilities, it may not be successful in commercializing ***neffy***; the labeling for ***neffy*** in any future indication or patient population; the scope, progress and expansion of developing and commercializing ***neffy***; the potential for payors to delay, limit or deny coverage for ***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 scope, progress and expansion of developing and commercializing ***neffy***, including the ability to enter into distribution and/or partnering arrangements and obtain favorable reimbursement; the Company's ability to protect its intellectual property position; and the impact of government laws, prescription drug price controls 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 the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2024, filed with the SEC on August 6, 2024.

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 23, 2024

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