# 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 9, 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**<br>**San Diego, California**<br>**(Address of principal executive offices)** | **92130**<br>**(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 November 9, 2024, ARS Pharmaceuticals, Inc. ("ARS"), through its wholly owned subsidiary ARS Pharmaceuticals Operations, Inc. (the "Company"), entered into a collaboration, license and distribution agreement (the "Collaboration Agreement") with ALK-Abelló A/S ("ALK"). Pursuant to the Collaboration Agreement, the Company granted to ALK a worldwide (other than the United States, Japan, mainland China, Hong Kong, Taiwan, Macau, Australia and New Zealand), exclusive license under certain of the Company's patents and know-how to develop, manufacture and commercialize products containing epinephrine administered intranasally, including EUR*neffy* (the trade name for *neffy* in the European Union) (epinephrine nasal spray) ("Products"), for all human uses, including the immediate or emergency treatment of allergic reactions (including Type I) and anaphylaxis and urticaria, and other future indications as agreed by the parties. If the Company develops any new intranasally administered product that contains epinephrine and files a new drug application in the United States for such product, upon ALK's request such new product will be included as a Product under the Collaboration Agreement, subject to ALK bearing the costs of development of such new product for its licensed territory. ALK will not conduct clinical trials for, manufacture or commercialize any product containing epinephrine that is not an injection product (a "Non-Injectable Product"), and the Company will not conduct clinical trials for or commercialize (or manufacture in support of the foregoing) any Non-Injectable Product in the licensed territory. The Company and ALK also entered into a commercial supply agreement (the "Supply Agreement"), under which the Company will supply ALK's requirements (and ALK will purchase from the Company its requirements) of Products for five years for a specified supply price, after which ALK may elect to transition to itself or its contract manufacturer the manufacture and supply of Products.

Under the Collaboration Agreement, the Company is obligated to transfer to ALK the existing marketing authorizations for the Products in ALK's territory. The Company is also required to conduct certain development and regulatory activities for Products in support of obtaining further regulatory approval of Products in ALK's territory, and will transfer such regulatory approvals to ALK. ALK is obligated to use commercially reasonable efforts to obtain and maintain regulatory approval for Products through the European Commission and within specified countries within ALK's territory. Following such approval for a Product in each indication within specified countries within ALK's territory, ALK is obligated to use commercially reasonable efforts to commercialize such Product in such indication in such countries and to achieve first commercial sale of a Product in certain countries in accordance with a timeline specified in the Collaboration Agreement.

Under the Collaboration Agreement, ALK is obligated to make an upfront payment to the Company of $145.0 million. The Company is eligible to receive regulatory and commercialization milestones of up to $20.0 million and sales-based milestones of up to $300.0 million, provided that $55.0 million of such sales-based milestones are contingent upon the Company obtaining regulatory approval for the Product in Canada by a specified time. The Company is entitled to receive tiered royalty payments on net sales in the mid- to high-teens, subject to certain standard reductions and offsets. Royalties will be payable, on a Product-by-Product and country-by-country basis, until the latest of the expiration of the licensed patents covering such Product in such country, 15 years from first commercial sale of such Product in such country, or expiration of regulatory exclusivity for such Product in such country.

Either party may terminate the Collaboration Agreement in the case of the other party's insolvency or in the event of an uncured material breach of the other party, except that the Company may not terminate the Collaboration Agreement for ALK's material breach of its commercial diligence obligations. ALK may terminate the Collaboration Agreement for convenience upon prior written notice or for a safety or regulatory concern. The Company may terminate the Collaboration Agreement in the event ALK makes certain challenges to certain of the Company's patents. Prior to a change of control of the Company and outside of a set period of time after which the Company commences change of control negotiations, the Company may terminate the Collaboration Agreement with respect to all countries in the European Economic Area upon prior written notice to ALK and payment of a termination fee that is the higher of an agreed mid-nine digit amount and the fair market value of the Products business in the European Economic Area at the time of such termination. The Company may also terminate the Collaboration Agreement if ALK commercializes a Non-Injectable Product or manufactures a Non-Injectable Product (other than a Product pursuant to the Collaboration Agreement) in the United States.

**Forward-Looking Statements**

Statements contained in this report regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements include statements regarding potential payments and activities under the Collaboration Agreement, the potential benefits of ARS's technology platforms and product and ARS's plans and strategy with respect to developing its technologies and product. 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 ARS's current expectations and involve assumptions that may never materialize or may prove to be incorrect. Actual results could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties, which include, without limitation, the fact that the Collaboration Agreement may be terminated early, the fact that ARS and the Company will have limited control over the efforts and resources that ALK devotes to commercialization activities under the Collaboration Agreement, ARS's reliance on ALK for the commercialization of *neffy* outside the United States in previously unpartnered territories; the potential that the Company may not receive milestone payments or royalty payments under the Collaboration Agreement in the amounts and at the times expected, if at all; potential safety and other complications from *neffy*; the labelling for *neffy* in any future indication or patient population, if approved; the scope, progress and expansion of developing and commercializing *neffy*; the potential for government and private third-party payors to delay, limit or deny coverage or reimbursement 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; ARS'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, 2024, filed with the Securities and Exchange Commission on August 6, 2024. All forward-looking statements contained in this report speak only as of the date on which they were made. ARS undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made, except as required by law.

**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 hereunto duly authorized.

**ARS Pharmaceuticals, Inc.**

Date: November 12, 2024

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