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

January 13, 2025
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 2.02 Results of Operations and Financial Condition.

On January 13, 2025, ARS Pharmaceuticals, Inc. (the "Company") announced certain of its preliminary unaudited financial results for the three months ended December 31, 2024 in the press release attached hereto as Exhibit 99.1, which is incorporated herein by reference.

The information in this Item 2.02 of this Current Report on Form 8-K, including Exhibit 99.1, is furnished and 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 into any filing under the Exchange Act or the Securities Act of 1933, as amended (the "Securities Act"), whether made before or after today's date, regardless of any general incorporation language in such filing.

Item 7.01 Regulation FD Disclosure.

On January 13, 2025, the Company updated its corporate presentation for use with investors, analysts and others at the 43rd Annual J.P. Morgan Healthcare Conference. A copy of the presentation is attached as Exhibit 99.2 to this Current Report on Form 8-K.

The information in this Item 7.01 of this Current Report on 8-K, including Exhibit 99.2, is furnished and shall not be deemed "filed" for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities of that Section, nor shall it be deemed incorporated by reference into any filing under the Exchange Act or the Securities Act, whether made before or after today's date, regardless of any general incorporation language in such filing.

Item 9.01 Financial Statements and Exhibits

(d)

Exhibit Number	Description
99.1	Press Release dated January 13, 2025.
99.2	Company Presentation dated January 13, 2025.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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: January 13, 2025

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

ARS Pharmaceuticals Announces Preliminary Fourth Quarter 2024 Financial Results and 2025 Objectives for *neffy*® (epinephrine nasal spray)

*Preliminary fourth quarter **neffy**® net product revenue of approximately $6.5 million*

Preliminary cash, cash equivalents and short-term investments of $314.0 million at year-end 2024 to support an operating runway of at least three years

Company to present at 43rd Annual J.P. Morgan Healthcare Conference on Wednesday, January 15, 2025 at 7:30am PT

SAN DIEGO, January 13, 2025 – ARS Pharmaceuticals, Inc. (Nasdaq: SPRY), a biopharmaceutical company dedicated to empowering at-risk patients and caregivers to better protect themselves from allergic reactions that could lead to anaphylaxis, today announced preliminary, unaudited ***neffy***® (epinephrine nasal spray) net product revenue for the fourth quarter and full year 2024 and outlined its 2025 commercial and clinical objectives.

"For ARS Pharma, 2024 marked a pivotal year, securing regulatory approvals for ***neffy*** as the first and only intranasal epinephrine treatment, laying a solid foundation for our commercial success in the United States and expansion worldwide through partnerships. While early in the launch of ***neffy***, the first three months of sales have exceeded expectations with very positive demand indicators," said Richard Lowenthal, President and CEO of ARS Pharma. "Looking ahead to 2025, we are poised to accelerate the growth of ***neffy*** through targeted commercial initiatives, including advancing education and awareness among our key prescribers, achieving over 80 percent commercial insurance coverage and launching impactful direct-to-consumer marketing campaigns for the ***neffy*** brand. ***neffy*** is transforming the lives of patients by offering a simple, effective, and life-saving treatment option, and we are very pleased to be making such a meaningful difference in the lives of patients, families and caregivers."

Preliminary Fourth Quarter 2024 Financial Results

- **Product revenue:** Preliminary ***neffy*** net product revenue for the fourth quarter of 2024 was approximately $6.5 million, with total net product sales for 2024 of approximately $7.1 million since ***neffy*** became available to wholesalers and pharmacies on September 23, 2024. More than 14,500 ***neffy*** two-pack units were delivered in the fourth quarter of 2024, including more than 1,500 units in the last week of 2024.
- **Cash position:** Cash, cash equivalents and short-term investments were approximately $314.0 million as of December 31, 2024. ARS Pharma reiterates its guidance that the company expects its cash, cash equivalents and short-term investments to be sufficient to fund its current operating plan for at least three years.

2025 Key Strategic Priorities for Accelerating *neffy* U.S. Sales and Recent Highlights

- **Increase demand and traction among target prescribers**, with continued sales force and medical science liaison engagement, expansion of the company's ***neffy*** Experience Program, and rollout of additional continuing medical education (CME) programs
  - More than 3,000 healthcare providers have prescribed ***neffy*** to date, of which 80 percent are in the highest decile categories for prescribing epinephrine
  - More than 1,750 healthcare providers have participated in the ***neffy*** Experience Program

- **Expand commercial access of *neffy***
  - Express Scripts, the second largest pharmacy benefits manager in the U.S., added ***neffy*** to its commercial national formularies in November 2024
  - On track for more than 60 percent commercial coverage by the end of the first quarter of 2025, and more than 80 percent commercial coverage by the end of the third quarter of 2025
  - Contracting consistent with target long-term total gross-to-net revenue of 50 percent
- **Increase consumer awareness of *neffy* and availability of a needle-free option**
  - Preparations are underway to launch a branded ***neffy*** direct-to-consumer marketing campaign beginning in May 2025
  - Designed to build momentum ahead of the 'back-to-school' season, the campaign will extend throughout the summer, driving brand recognition and encouraging patients to request ***neffy*** by name
  - In parallel, to amplify public awareness of the needle-free epinephrine option, Food Allergy Research and Education (FARE) is set to launch a public service announcement campaign featuring a celebrity ambassador with ARS support later this year
- **Obtain approval of *neffy* 1 mg for children** who weigh 15 to 30 kg
  - The sNDA filed with the U.S. FDA for ***neffy*** for children who weigh 15 to 30 kg has a Prescription Drug User Fee Act (PDUFA) target action date of March 6, 2025
  - Based on review timelines and subject to approval, product availability of ***neffy* 1 mg** is expected in the second quarter of 2025

Presentation at the 43rd Annual J.P. Morgan Healthcare Conference

On Wednesday, January 15, 2025, at 7:30am PT, Richard Lowenthal, President and CEO of ARS Pharma, will present a company overview at the 43rd Annual J.P. Morgan Healthcare Conference. A live webcast of the presentation and Q&A session can be accessed here or by visiting the investors section of the company's website at www.ir.ars-pharma.com.

About Preliminary Financial Results

The preliminary results set forth above are unaudited, are based on management's initial review of the company's results for the quarter ended December 31, 2024, and are subject to revision based upon the company's year-end closing procedures and the completion and external audit of the company's year-end financial statements. Actual results may differ materially from these preliminary unaudited results following the completion of year-end closing procedures, final adjustments or other developments arising between now and the time that the company's financial results are finalized. In addition, these preliminary unaudited results are not a comprehensive statement of the company's financial results for the quarter and year ended December 31, 2024, should not be viewed as a substitute for full, audited financial statements prepared in accordance with generally accepted accounting principles, and are not necessarily indicative of the company's results for any future period.

About *neffy*®

neffy is an intranasal epinephrine product for patients with Type I allergic reactions due to insect stings or bites, foods, medicinal products, other allergens, as well as idiopathic or exercise induced anaphylaxis that could lead to life-threatening anaphylaxis.

INDICATION AND IMPORTANT SAFETY INFORMATION FOR ***neffy*** (epinephrine nasal spray)

INDICATION

neffy 2 mg is indicated for emergency treatment of Type I allergic reactions, including anaphylaxis, in adult and pediatric patients who weigh 30 kg or greater.

IMPORTANT SAFETY INFORMATION

It is recommended that patients are prescribed and have immediate access to two ***neffy*** nasal sprays at all times. In the absence of clinical improvement or if symptoms worsen after initial treatment, administer a second dose of ***neffy*** in the same nostril with a new nasal spray starting 5 minutes after the first dose.

neffy is for use in the nose only.

Advise patients when to seek emergency medical assistance for close monitoring of the anaphylactic episode and in the event further treatment is required.

Absorption of ***neffy*** may be affected by underlying structural or anatomical nasal conditions.

Administer with caution to patients who have heart disease; epinephrine may aggravate angina pectoris or produce ventricular arrhythmias. Arrhythmias, including fatal ventricular fibrillation, have been reported, particularly in patients with underlying cardiac disease or taking cardiac glycosides, diuretics, or anti-arrhythmics.

The presence of a sulfite in ***neffy*** should not deter use.

neffy may alter nasal mucosa for up to 2 weeks after administration and increase systemic absorption of nasal products, including ***neffy***.

Patients with certain medical conditions or who take certain medications for allergies, depression, thyroid disorders, diabetes, and hypertension, may be at greater risk for adverse reactions.

Epinephrine can temporarily exacerbate the underlying condition or increase symptoms in patients with the following: hyperthyroidism, Parkinson's disease, diabetes, renal impairment. Epinephrine should be administered with caution in patients with these conditions, including elderly patients and pregnant women.

Adverse reactions to ***neffy*** may include throat irritation, intranasal paresthesia, headache, nasal discomfort, feeling jittery, paresthesia, fatigue, tremor, rhinorrhea, nasal pruritus, sneezing, abdominal pain, gingival pain, hypoesthesia oral, nasal congestion, dizziness, nausea, and vomiting.

These are not all of the possible side effects of ***neffy***. To report suspected adverse reactions, contact ARS Pharmaceuticals Operations, Inc. at 1-877-MY-NEFFY (877-696-3339) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

For additional information on ***neffy***, please see Full Prescribing Information at www.***neffy***.com.

About Type I Allergic Reactions Including Anaphylaxis

Type I allergic reactions are serious and potentially life-threatening events that can occur within minutes of exposure to an allergen and require immediate treatment with epinephrine, the only FDA-approved medication for these reactions. While epinephrine autoinjectors have been shown to be highly effective, there are well published limitations that result in many patients and caregivers delaying or not administering treatment in an emergency situation. These limitations include fear of the needle, lack of portability, needle-related safety concerns, lack of reliability, and complexity of the devices. There are approximately 40 million people in the United States who experience Type I allergic reactions. Of this group, over the last three years, approximately 20 million people have been diagnosed and treated for severe Type I allergic reactions that may lead to anaphylaxis, but (in 2023, for example) only 3.2 million filled their active epinephrine autoinjector prescription, and of those, only half consistently carry their prescribed autoinjector. Even if patients or caregivers carry an autoinjector, more than half either delay or do not administer the device when needed in an emergency.

About ARS Pharmaceuticals, Inc.

ARS Pharmaceuticals is a biopharmaceutical company dedicated to empowering at-risk patients and their caregivers to better protect patients from allergic reactions that could lead to anaphylaxis. The company is commercializing ***neffy***® 2 mg (trade name **EUR*neffy***® in the EU) (previously referred to as ARS-1), an epinephrine nasal spray indicated in the U.S. for emergency treatment of Type I allergic reactions, including anaphylaxis, in adult and pediatric patients who weigh 30 kg or greater, and in the EU for emergency treatment of allergic reactions (anaphylaxis) due to insect stings or bites, foods, medicinal products, other allergens, as well as idiopathic or exercise induced anaphylaxis in adults and children who weigh 30 kg or greater. For more information, visit www.ars-pharma.com.

Forward-Looking Statements

Statements in this press release 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 expectation that ***neffy*** will save lives; the effectiveness of ***neffy***; ARS Pharmaceuticals' preliminary financials results for the quarter ended December 31, 2024; ARS Pharmaceuticals' projected operating runway; the belief that ARS Pharmaceuticals is poised to accelerate the growth of ***neffy*** and how it expects to do so; ARS Pharmaceuticals' commercial coverage goals and the timing thereof; the expected timing for product availability of ***neffy* 1 mg**; 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," "expects," "if," "may," "potential," "on track to," "plans," "will," "would," and similar expressions are intended to identify forward-looking statements. These forward-looking statements are based upon ARS Pharmaceuticals' 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: risks related to preliminary financial results, as described above; potential safety and other complications from ***neffy***; ARS Pharmaceuticals' reliance on its licensing partners; the ability to maintain regulatory approval for ***neffy*** in its currently approved indication and to obtain and maintain regulatory approval for ***neffy*** for additional indications; 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 governments and 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; ARS Pharmaceuticals' 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 Pharmaceuticals' Quarterly Report on Form 10-Q for the quarter ended September 30, 2024, filed with the Securities and Exchange Commission ("SEC") on November 13, 2024. These documents can also be accessed on ARS Pharmaceuticals' website at www.ars-pharma.com by clicking on the link "Financials & Filings" under the "Investors & Media" tab.

The forward-looking statements included in this press release are made only as of the date hereof. ARS Pharmaceuticals assumes no obligation and does not intend to update these forward-looking statements, except as required by law. For more information, visit www.ars-pharma.com, and follow us on LinkedIn and X.

ARS Pharma Investor Contact:
Justin Chakma
ARS Pharma
justinc@ars-pharma.com

ARS Pharma Media Contact:
Christy Curran
Sam Brown Inc.
615.414.8668
christycurran@sambrown.com

Exhibit 99.2
NASDAQ: SPRY

neffy – the transformative needle-free solution for severe allergic reactions

43rd Annual J.P. Morgan Healthcare Conference

January 2025

Forward-looking statements

Statements in this presentation that are not purely historical in nature are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements in this presentation include, without limitation, statements regarding: the design and potential benefits of neffy, including the likelihood allergy patients and caregivers will choose to carry and dose neffy compared to needle-bearing options; ARS Pharma's expected competitive position; the potential market, demand and expansion opportunities for neffy; the anticipated sales of neffy and gross-to-net percentage range; the anticipated timing for approval of the supplemental regulatory application for 1 mg neffy dose for children 15 kg to 30 kg; the timeline for commercialization of neffy outside of the United States; the potential ability of neffy to treat acute flares in patients with chronic spontaneous urticaria; the timing for initiating a single pivotal study in urticaria and potential launch; ARS Pharma's marketing and commercialization strategies; the expected composition and reach of ARS Pharma's commercial force; the potential for the neffy Experience Program; the likelihood of neffy attaining favorable coverage and the expected timing of coverage decisions; the timing and expected percentage of commercial coverage with unrestricted access; ARS Pharma's projected operating runway; the anticipated benefits of ARS Pharma's ex-U.S. partnerships; the expected intellectual property protection for neffy; and any statements of assumptions underlying any of the foregoing. These forward-looking statements are subject to the safe harbor provisions under 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. Words such as "anticipate," "demonstrate," "expect," "indicate," "plan," "potential," "target," "will" and similar expressions are intended to identify forward-looking statements. These forward-looking statements are based upon ARS Pharma'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: risks associated with preliminary financial results, which are subject to revision based upon the company's year-end closing procedures and the completion and external audit of ARS Pharma's year-end financial statements; the ability to maintain regulatory approval for neffy for its current indication and obtain and maintain regulatory approval for neffy for additional indications; results from clinical trials and non-clinical studies may not be indicative of results that may be observed in the future; potential safety and other complications from neffy; the labeling for neffy in any future indication or patient population; the scope, progress and expansion of developing and commercializing neffy; ARS Pharma's reliance on its licensing partners; the potential for payors and governments to delay, limit or deny coverage or reimbursements 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; net product sales may not be indicative of profitability or profitability at expected levels; reliance on survey results with small samples sizes; ARS Pharma'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 Pharma's Quarterly Report on Form 10-Q for the quarter ended September 30, 2024, filed with the Securities and Exchange Commission ("SEC") on November 13, 2024. This and other documents ARS Pharma files with the SEC can also be accessed on ARS Pharma's website at ir.ars-pharma.com by clicking on the link "Financials & Filings" under the "Investors & Media" tab.

The forward-looking statements included in this presentation are made only as of the date hereof. ARS Pharma assumes no obligation and does not intend to update these forward-looking statements, except as required by law.

Transforming the Treatment of Type I Allergic Reactions

- ***neffy®*: first and only FDA and EC approved "no needle, no injection" solution** for Type I allergic reactions
- **Strong execution during first 3 months of launch in Q4 2024 sets foundation for delivering significant *neffy* US sales in 2025**
  - Prescribing breadth: ~50% of high decile HCPs targeted to date have prescribed ***neffy***
  - Secured coverage with payers at ~50% total gross to net, and >80% commercial coverage anticipated by end of Q3 2025
- **Potential multi-billion US market opportunity ($3 billion Rx'ed segment, and up to $7 billion expansion segment)** driven by HCP and consumer preference and adoption[1]
- **NCE-like IP exclusivity** potential with issued composition of matter and method of treatment patents until at least 2039
- **Transformational launch supported by the team that launched NARCAN nasal spray (~95% peak share) and $314 million in cash,** cash equivalents and short-term investments as of 12/31/2024

References: 1. Company estimates

ARS PHARMA

Type I Allergy Patients Face Significant Limitations with Other Treatment Options that *neffy* may help to address

PROBLEM:

ONLY 10% - 20% of patients with active Rx use as indicated[7]

NO TREATMENT READILY AVAILABLE	REFUSAL OF TREATMENT	DELAY IN TREATMENT	USER ERROR IN TREATMENT
Only 50% carry one[1] **(<20% carry two)**	**~25% - 60% do not administer**[1,3 5, 6]	**~40% - 60% of patients delay**[2]	**23% - 35% fail to dose correctly**[4]

SOLUTION:

neffy

SMALL

- Fits in your pocket; easy to carry the recommended 2 devices
- ~10% of cases require repeat doses of epinephrine[1]

NO NEEDLE NO INJECTION

- Rapid administration without a needle
- No risk of needle-related injuries; lacerations[2] or cardiotoxic blood vessel injections
- Less hesitation to dose

EASIER AND MORE CONSISTENT DOSING

- Simple place and press administration (no hold time)
- 100% of adults and children dosed ***neffy*** successfully in human factors studies by reading the commercial instructions for use (IFU)

RELIABLE

- 99.999% delivery of effective dose in reliability testing; not obstructed by any anaphylaxis symptoms; no inhalation required
- 30-month shelf-life at room temperature, with *neffy* stored at up to 3 months at high temperatures (122°F)

References: 1. Warren CM, et al. *Ann Allergy Asthma Immunol.* 2018. **2.** Rooney E, et al. Poster Presentation at *ACAAI 2022* (Louisville, KY). **3.** Brooks C, et al. *Ann Allergy Asthma Immunol.* 2017. 4. El Turki A, et al. *Emerg Med J.* 2017. **5.** Asthma and Allergy Foundation of American Patient Survey Report 2019. 6. Mehta GD, et al. *Expert Rev Clin Immunol.* 2023. **7.** ARS company estimates based on IQVIA data and references 1 through 6.

ARS PHARMA

Addressing the Significant Unmet Needs in US Severe Allergic Reaction Patient Population

Epidemiology prevalence data estimates ~40M patients with type 1 allergic reactions[2-9]

~20M diagnosed and under physician care over the last 3 years[10]

6.5M prescribed epinephrine[10]
Primarily managed by allergists & pediatricians

~3.2M fill ~5M 2-pack units of injectables annually, but ~80-90% do not use as indicated[11]

~3.3M don't fill regularly, haven't refilled or haven't filled – an additional ~5M 2-pack unit opportunity[10]

~13.5M Type I diagnosed but not prescribed Rx (past 3 years)[10]
Primarily managed by non-allergists and non-pediatricians

Consistent Market Growth (Units)
+6.5% CAGR since 2010, +12.7% YoY in 2023[1]

Promotional Responsiveness
~50% increase over market growth trend with consumer promotion (2010 to 2015[1])

~10M two-packs **X $710** WAC/Rx **X ~50%** GTN Yield **=** **~$3B+ peak net sales potential** *in initial addressable segments alone* **+** **~$7B+ potential** *in expansion segment[12]*

Not including increased units/patient as market research indicates

References: 1. Based on IQVIA prescription data available through 2023 (~5.2 million two-packs sold in 2023). **2.** Gupta RS, et al. *Pediatrics.* 2011. **3.** Gupta RS, et al. Pediatrics 2018. **4.** McGowan EC, et al. *J Clin Allergy Immunol.* 2013. **5.** Jackson KD, et al. *NCHS Data Brief.* 2013. **6.** Black LJ, et al. CDC National Center for Health Statistics Data Brief. 2019. **7.** Gupta RS, et al. *JAMA Netw Open.* 2019. **8.** Verrill L, et al. *Allergy Asthma Pro.* 2015. **9.** Bilo BM, et al. *Current Opin Allergy Clin Immunol.* 2008. **10.** IQVIA Claims Data, 2023. **11.** Based on calculations from Warren CM, et al. *Ann Allergy Asthma Immunol.* 2018., Rooney E, et al. Poster Presentation at *ACAAI 2022* (Louisville, KY). Brooks C, et al. *Ann Allergy Asthma Immunol.* 2017., El Turki A, et al. *Emerg Med J.* 2017., Asthma and Allergy Foundation of American Patient Survey Report 2019, and Mehta GD, et al. *Expert Rev Clin Immunol.* 2023. **12.** Estimated based on 13.5M diagnosed, but not prescribed epinephrine Rx

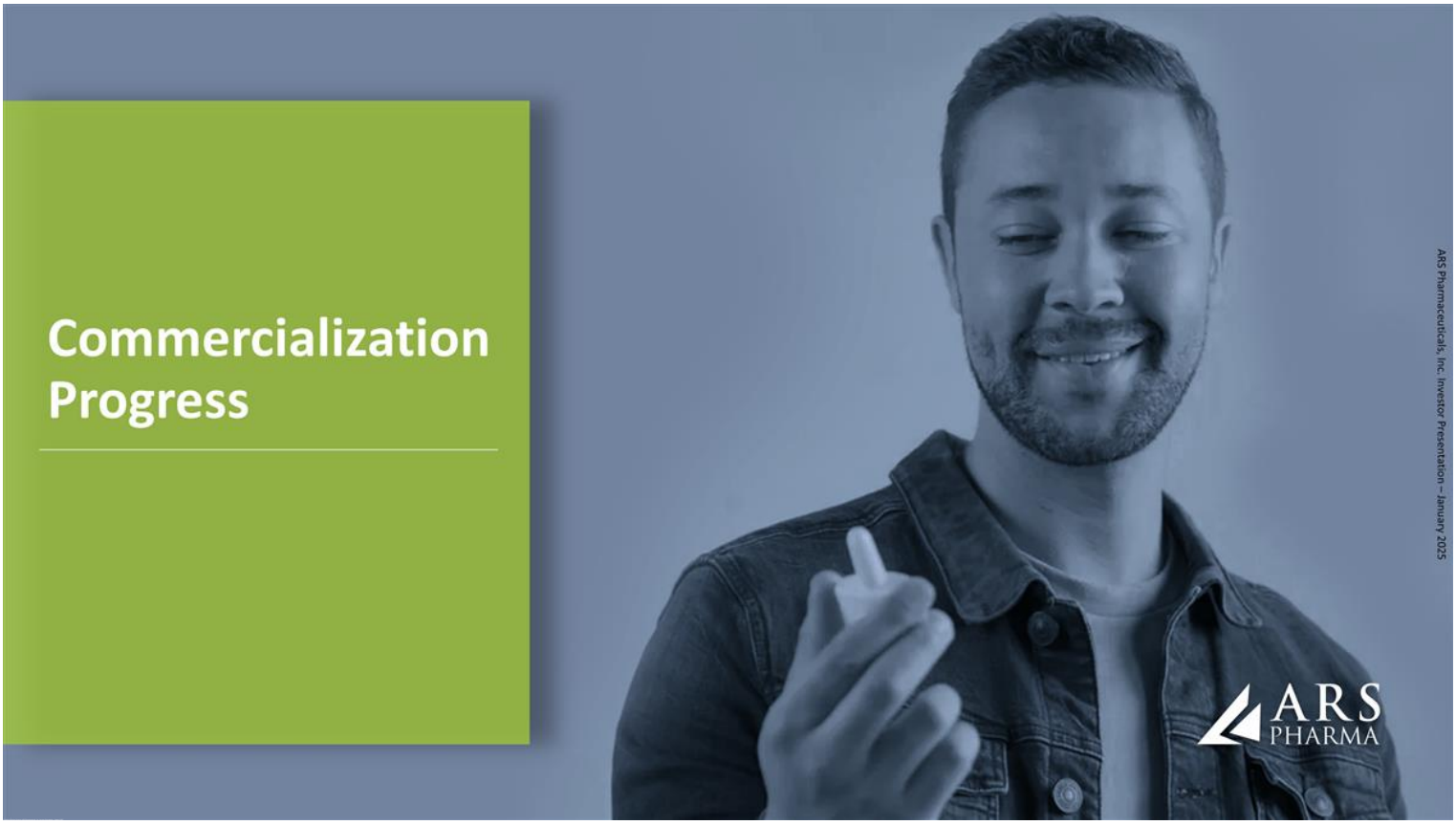
Ex-US partners enable ARS to focus exclusively on the United States

ARS has received FDA/EC approval and filed in UK, Canada, China, and AUS/NZ within 6 months of FDA approval; these regions represent 98% of global epinephrine autoinjector sales[1]

- Strong ex-US licensing partnering strategy with $570M in upfront & milestones in addition to attractive royalty streams on net sales
- Projected ~$425M USD *neffy* annual peak sales in ALK region for anaphylaxis only (excluding US, China, Japan, AUS/NZ)[2]

References: 1. 2023 IQVIA data based on estimated gross-to-net for generic and branded autoinjector products in the United States, **2.** ALK Press Release (Nov 9, 2024) ALK licenses rights to neffy®, the first approved adrenaline nasal spray for emergency treatment of allergic reactions (anaphylaxis) | ALK

Commercialization Progress



neffy Strategic Objectives for Commercialization

Q4 2024

✓ **Launch of 2 mg *neffy* within 9 weeks of FDA approval**

(Sept 23, 2024 launch)

Early to mid 2025

EDUCATE PRESCRIBERS
Drive adoption within specialty and high prescribers that have a long history of using injection

FACILITATE ACCESS
Obtain 60%, growing to 80%+ commercial coverage of ***neffy*** with a total gross to net yield of ~50%

Mid to late 2025

ACTIVATE PATIENTS
Accelerated DTC campaign prior to end of school year to increase awareness and motivate patients and caregivers to seek ***neffy***

REACH MORE PRESCRIBERS
Option to expand CME, direct HCP marketing and sales force to drive prescriber uptake

neffy: Delivering on Expectations

✓

$7.1 million

in preliminary net product sales

Thirteen weeks post launch
(ending Dec. 31, 2024)

neffy® (epinephrine nasal spray) 2 mg

$4.1 million

in consensus net product sales

Analyst estimates for FY2024[1]

$3.4 million

Internal forecast net product sales (budgeted)

Objective Insights for FY2024

References: 1. Analyst estimates as of January 10, 2025

EDUCATE

Strong demand to learn about *neffy* among HCPs targeted to date by ARS efforts

Approximately 50% of the ~4,000 initial priority targets of our sales organization have prescribed *neffy*

- Sales organization of 118 sales reps, virtual reps and area sales managers prioritized ~4,000 HCP targets representing 30% of all epinephrine Rx (deciles 8 to 10)
- Total reach of 12,500 targets representing 40-45% of epinephrine Rx from all HCPs
- >3,000 total HCPs have prescribed *neffy* to patients with ~200+ new HCPs being added every week

1,750+ HCPs and growing have enrolled in the *neffy* Experience Program

(rescue therapy at allergy challenge clinics)

- Enable real-world experience with ***neffy***
- Target allergist offices that conduct in-office food challenge testing
- HCPs will have the ability to gain first-hand knowledge of ***neffy's*** effectiveness
- Patients undergoing allergy challenge will also be exposed to ***neffy***

67%+ of *neffy* Experience HCPs have prescribed *neffy*

ARS PHARMA

FACILITATE

On track to ensuring broad *neffy* access for patients

Payers recognize the value of *neffy*

List price for two doses of ***neffy*** is $710
Co-pay buydown to $25 for commercial patients

- **Express Scripts** (2nd largest PBM)[1] added ***neffy*** to its commercial national formularies as of late November 2024 **(Tier 2 Preferred)** – 9 weeks after launch

- **Other key PBMs and insurers:** encouraging discussions with additional formulary additions expected in Q1 2025

Contract discussions with key payers on track for commercial coverage targets

- **>60%+ coverage anticipated by 6 months** post-launch (end of Q1 2025)
- **>80%+ coverage anticipated by 12 months** post-launch (end of Q3 2025)
- **>50% total gross to net yield to ARS preserved in agreements to date**

References: 1. Qato DM et al. Pharmacy Benefit Manager Market Concentration for Prescriptions Filled at US Retail Pharmacies. 2024;332(15): 1298-1299.

ACTIVATE

Plans to increase awareness & motivation to seek and prescribe *neffy* as access expands in 2025

Consumer Marketing Activities

Branded *neffy* DTC Campaign starting in Q2 2025 with celebrity spokesperson later in 2025

HCP Marketing Activities

Well-balanced marketing plan active since launch, with relative return on investment (ROI) of ***neffy*** marketing mix being measured in 2025

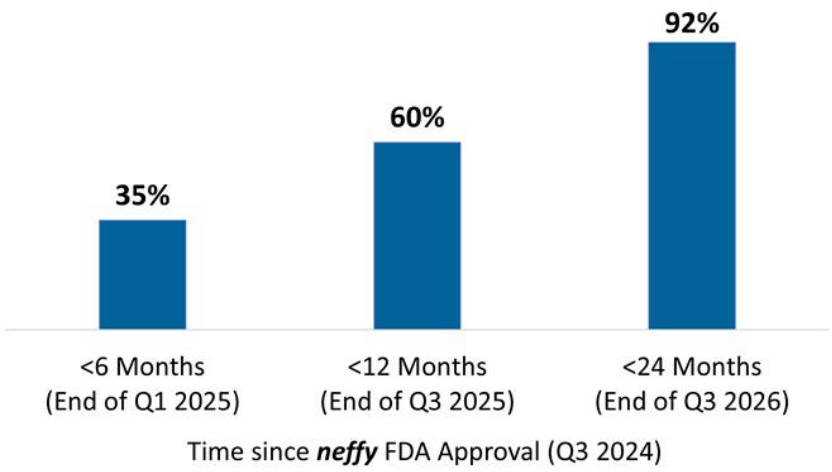
- Expand Direct **HCP Marketing**, **CME programs**, Conference Participation, high impact **publications** on ***neffy*** clinical data and potential to **expand sales organization to ~200** depending on ROI assessment late 2025/early 2026
- Expanded sales footprint expected to increase direct epinephrine Rx coverage to 60-65% from 40-45%, **with an estimated 80%+ Rx reach** including non-personal promotional efforts to HCPs
- **Marketing activity expansion is not expected to impact guidance of at least three years of operating runway** based on cash on hand

ARS PHARMA

Targeted Healthcare Providers Indicate Significant Uptake in 2025

December 2024 Survey[1], Sample = 150 HCPs from our 12,500 targets ~ 40-45% of epi Rx

% of target prescribers for whom *neffy* becomes the treatment of choice



Top 3 *neffy* barriers to becoming the treatment of choice today

1. Cost & Coverage (~37%)
   - Expected to be addressed by commercial coverage goal of 80% by Q3 '25 resulting in competitive co-pay versus generics EAIs ($25 vs. $40)
2. Clinical Experience (~33%)
   - Expected to be addressed by time in market and accelerated by ***neffy*** Experience, conferences, speaker programs, CME and peer-reviewed publications
3. None (~13%)

References: 1. HCP Market Research Study, December 2024

Treatment of acute flares in chronic spontaneous urticaria patients on antihistamines represents blockbuster opportunity

~2M diagnosed chronic urticaria patients based on 12 month US prevalence of 0.78%[1]

~1M US chronic urticaria patients reported to be treated with Rx medication[1]

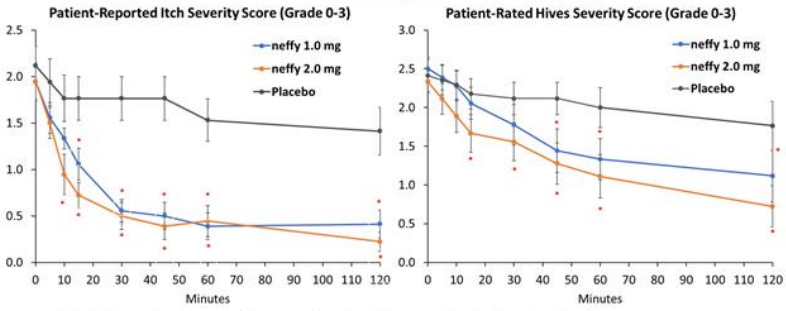
~8-9 HCP visits per year[1]
~4-5 ER visits per year[1,2]
~50% with angioedema[3]

x **$710** WAC/Rx

x **~50%** GTN Yield

= **$2-3B+ peak net sales potential[4]**

neffy Shows Robust and Rapid Clinical Responses in Treatment-Resistant Chronic Spontaneous Urticaria (CSU)



* p<0.05 based on pair t-test of 1 mg vs. placebo and 2 mg vs. placebo (n = 17 subjects)

***neffy* may provide episodic relief of acute flares in CSU patients who are stable on chronic antihistamines (Phase 2b clinical study to initiate in Q1 2025)**

Potential to improve quality of life without escalating to chronic use of costly systemic biologics with potentially more side effects or having to visit ER/hospital

References: 1. Patil D, et al. Prevalence and clinical profile of patients with chronic spontaneous urticaria in the USA. American Academy of Dermatology Associate Annual Meeting (March 2022). **2.** Barniol C, et al. Annals of Emergency Medicine (2018). **3.** Bernstein J, et al. Frequency of angioedema in chronic spontaneous urticaria: Report from the Urticaria Voices study. American Academy of Asthma and Immunology Annual Meeting (February 2024). **4.** Assuming one episode per month that requires treatment with ***neffy***

A Path to Blockbuster Potential for *neffy*

2 mg launch (30 kg+)

Q4 2024

A Strong Foundation

- Sales force targeting higher decile priority HCPs
- ***neffy*** experience and patient success stories creating positive feedback loop
- Payers recognizing value of ***neffy*** (e.g. Express Scripts)

1 mg launch (15-30 kg)

2025

Accelerated Impact

- Broad commercial coverage with 80%+ targeted by end of Q3 '25
- Accelerated activation of consumer awareness with branded DTC incl. celebrity
- Expand breadth and depth of Rx'ing, and targeting lower decile HCPs with sales force and CME

2026

Intensifying Growth

- Continued investment into consumer demand and seamless patient acquisition experience
- Steady-state total GTN in the ~50% range
- Potential initiation of pivotal trial for treatment of acute flares in CSU patients on antihistamines

Multi-blockbuster peak sales potential

driven by initial **$3B** segment, **~$7B** expansion segment and **~$2-3B+** CSU indication