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

May 16, 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 7.01 Regulation FD Disclosure.

On May 16, 2023, ARS Pharmaceuticals, Inc. released a revised corporate presentation which it made available on its website. A copy of the corporate presentation is attached as Exhibit 99.1 to this Current Report on Form 8-K.

The information under this Item 7.01 of this Current Report on 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, or otherwise subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information shall not be deemed incorporated by reference into any other filing with the Securities and Exchange Commission made by the Company, whether made before or after today's date, regardless of any general incorporation language in such filing, except as shall be expressly set forth by specific references in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Corporate Presentation
104	Cover Page of 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.

Date: May 16, 2023

ARS Pharmaceuticals, Inc.

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

Exhibit 99.1

neffy® 2 mg
(epinephrine nasal spray)

THE FIRST NO-NEEDLE, NO-INJECTION SOLUTION for Type I Allergic Reactions

Q2 2023

ARS PHARMA

Forward-looking statements

This presentation contains forward-looking statements which include, but are not limited to, statements regarding the design and potential benefits of *neffy*; the anticipated Prescription Drug User Fee Act (PDUFA) date for *neffy*; the timing of regulatory approval for and the commercial launch of *neffy*, if approved; ARS Pharma's commercialization strategy; the potential market opportunity for *neffy*; the projected growth thereof and *neffy*'s ability to capture and grow that market; ARS Pharma's expected competitive position; ARS Pharma's potential to become the standard in treatment and transform the treatment of allergic reactions; the likelihood of *neffy* attaining favorable coverage; 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. ARS Pharma's expectations and beliefs regarding these matters may not materialize. Actual outcomes and results may differ materially from those contemplated by these forward-looking statements as a result of uncertainties, risks, and changes in circumstances, including but not limited to risks and uncertainties related to: the ability to obtain and maintain regulatory approval for *neffy*; results from clinical trials may not be indicative of results that may be observed in the future; the FDA advisory committee's decision should not be relied on as an indication that *neffy* will ultimately be approved; the FDA is not bound by decision of its advisory committee or any of its recommendations and there are a number of instances where the FDA has voted against the recommendations of advisory committees; 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 ARS Pharma's ability to protect its intellectual property position; the impact of health epidemics or pandemics on ARS Pharma's business and the actions ARS Pharma may take in response thereto; 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 the company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2023, filed with the Securities and Exchange Commission ("SEC") on May 15, 2023. This and other documents ARS files with the SEC can also be accessed on ARS's web page at ir.ars-pharma.com by clicking on the link "Financials & Filings." The forward-looking statements included in this presentation are made only as of the date hereof. ARS Pharma does not assume any obligation and does not intend to update these forward-looking statements, except as required by law.

Potential to Transform the Treatment of Type I Allergic Reactions

- ***neffy®:* first "no needle, no injection" solution** for Type I allergic reactions to address an unmet market need
- **Registration program** demonstrates comparable PK and PD, without risk of needle-related safety concerns, fear and hesitation
- **Rapid and statistically significant response on PD surrogates for efficacy (SBP, HR)** observed even 1 minute after dosing with *neffy* vs. injection
- **Significant opportunity to disrupt** current epinephrine injectables market
- **Mid-2023 PDUFA anticipated; FDA AdCom supports favorable benefit-risk assessment of *neffy***
- **Potential multi-billion-dollar market** driven by HCP and consumer preference and adoption
- **NCE-like IP exclusivity** potential until at least 2038
- **$264.5 million in cash and securities** as of 3/31/2023

Proven leadership team with track record developing and commercializing intranasal and consumer-driven medicines

Richard Lowenthal, M.S.
Chief Executive Officer, Co-Founder
Led FDA approvals for multiple nasal spray products
25+ years of experience

NARCAN® (naloxone HCl) NASAL SPRAY · VALTOCO® (diazepam nasal spray) C · tosymra® (sumatriptan nasal spray) 10 mg

Sarina Tanimoto, M.D.
Chief Medical Officer, Co-Founder
Led FDA approvals for multiple nasal spray products
20+ years of experience

NARCAN® (naloxone HCl) NASAL SPRAY · VALTOCO® (diazepam nasal spray) C · tosymra® (sumatriptan nasal spray) 10 mg

Eric Karas
Chief Commercial Officer
Led Narcan® commercial ops at Emergent/Adapt, and Auxilium specialty
25+ years of experience

NARCAN® (naloxone HCl) NASAL SPRAY · Testim® (testosterone gel) · XIAFLEX®

Harris Kaplan
EVP, Commercial Strategy
40+ years of commercial strategy across more than 125 product launches

Allegra® · Nexium® · VIAGRA®

Dan Relovsky
SVP, Marketing
30+ years of marketing, sales and operational experience across specialty and consumer markets

Brian Dorsey
Chief Operating Officer
25+ years of R&D experience as including multiple head of R&D roles including Pernix, Apricus and Somaxon

Kathy Scott
Chief Financial Officer
30+ years of finance experience with multiple CFO roles including Neurana, Recros and Oncternal

Alex Fitzpatrick
Chief Legal Officer
30+ years of legal experience with multiple GC roles including Evofem, Kyriba, Verenium, Blackbaud

Justin Chakma
Chief Business Officer
10+ years of M&A, licensing, financing and strategy experience including Celgene, Receptos and Auspex

Robert Bell, Ph.D.
Chief Scientific Officer, Co-Founder
30+ years of senior R&D leadership experience including Barr and Somerset

Top-tier board of directors

Pratik Shah, Ph.D.
Chairman of Board of Directors
Executive Chairman at Design, Former Chairman of Synthorx (acq. $2.5B), Former CEO at Auspex (acq. $3.5B)

Richard Lowenthal, M.S.
Chief Executive Officer, Co-Founder
Led FDA approvals for multiple nasal spray products
25+ years of experience

Laura Shawver, Ph.D.
CEO at Capstan, former CEO at Silverback, Synthorx (acq. $2.5B)

Peter Kolchinsky, Ph.D.
Managing Partner and Founder at RA Capital

Brent Saunders
Chairman at The Beauty Health Co., Former CEO of Allergan (acq. $63B), Actavis, Forest Labs, and Bausch + Lomb (acq. $8.7B)

Jonathan Leff
Partner at Deerfield Management
Chairman of Deerfield Institute

Peter Thompson, M.D.
Private Equity Partner at Orbimed

Rajeev Dadoo, Ph.D.
Managing Partner at SR One

Michael Kelly
Former President, US Operations at Adapt (acq. $735M), CEO at Covis (acq. $1.2B), founder at Azur

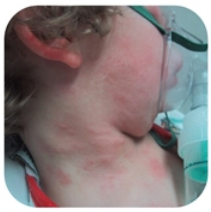
Philip Schneider
Former CFO at IDEC, former Board member at Arena (acq. $6.7B), Auspex (acq. $3.5B), GenProbe (acq. $3.7B)

Saqib Islam, J.D.
CEO of Springworks, former CBO at Moderna and EVP at Alexion

Type I allergic reactions: a life-threatening hypersensitivity reaction

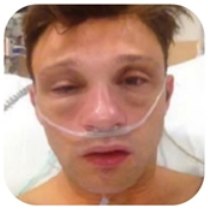
Caused by exposure to a **specific allergen**, most commonly **food**, **venom**, **drugs**

~25 to 40 million people in US with systemic Type I allergic reaction to allergens (e.g., 2+ organ systems involved)



10+ million people with other Type I allergy indications (e.g. urticaria flares, asthma exacerbations)

Significant co-morbidities and symptomatic impact on patient quality of life



More than half a million[1] ER visits each year due to systemic Type I allergic reactions, costing an average of $1600+ per visit[2]

Carrillo-Martin et al. J Allergy Clin Immunol Pract (2020), BlueCross BlueShield of America. Childhood Allergies in America (2018) Images Reproduced with permission from Allergy & Anaphylaxis Australia

Epinephrine is effective, but significant device limitations exist

Epinephrine recognized as the **only first-line therapy** by allergy society treatment guidelines[1], but…

- Apprehension to dose due to needle
- Lack of portability
- Reluctance to use in public
- Safety concerns: lacerations, caregiver self-injection, blood vessel hits
- Lack of reliability
- Not user friendly

FDA U.S. FOOD & DRUG ADMINISTRATION

Epinephrine Auto-Injector Devices by Amneal and Impax: CDER Alert - FDA Alerts Patients and Health Care Professionals About Device Malfunction

FDA alerts patients and health care professionals of EpiPen auto-injector errors related to device malfunctions and user administration

Bloomberg

7 fatalities and 35 hospitalizations reported due to failures

Early intervention with epinephrine is critical in a Type I allergic reaction

ANTIGEN EXPOSURE

FIRST 15 MINUTES

TYPE I SEVERE ALLERGIC REACTION

- Hypotension, dizziness, faintness
- Rhinitis, watery red eyes
- Rashes, itching (urticaria)
- Rapid swelling (angioedema) including lips, tongue, throat
- Bronchospasm, difficulty breathing, wheezing
- Abdominal and chest pain, vomiting

15 TO 30 MINUTES

LIKELIHOOD OF LIFE-THREATENING REACTION

Time to respiratory arrest or shock[1]

- **FOOD:** 30–35 minutes
- **INSECT STINGS:** 10–15 minutes
- **DRUGS:** <10 minutes

30 MINUTES

ANAPHYLAXIS

- Sudden drop in blood pressure leads to anaphylactic shock and cardiovascular failure
- Airways narrow blocking breathing, leading to loss of consciousness
- Possible death

Up to 18 minutes average wait to dose epinephrine[5]
among the ~50% who have injection available and are willing to inject themselves

1. Emergency treatment of anaphylactic reactions: guidelines for healthcare providers. Resuscitation Council (UK); 2016, 2. JF Philips et al. Allergy Asthma Proc (2011), 3. JT Fleming et al. J Allergy Clin Immunol Pract (2014), 4. E. Andrew et al. Prehospital Emergency Care (2018), 5. Data on file from ARS market research

Limitations of injection lead to hesitation and decreased or ineffective usage *neffy* may address these limitations to transform the treatment paradigm

PROBLEM

Only 10% - 20% of Rx filled or used as indicated[6]

***neffy®* SOLUTIONS**

NO TREATMENT AVAILABLE	REFUSAL OF TREATMENT	DELAY IN TREATMENT	FAILURE OF TREATMENT
~50% of patients carry[1] (<20% carry two)	~25% - 50%[1, 3, 5] do not administer	~40 - 60%[2] of patients delay	23 - 35%[4] fail to dose correctly
1	2	3	4
SMALL	**NO NEEDLE NO INJECTION**	**EASIER AND MORE CONSISTENT DOSING**	**RELIABLE**
• Fits in your pocket; can carry more than 1 • ~10% of cases require multiple doses of epinephrine[1]	• Rapid administration without a needle • No risk of needle-related injuries; lacerations[2] or cardiotoxic blood vessel injections • Less hesitation to dose	• 0% critical dosing errors in registration self-administration study • Low 2 mg dose of epinephrine achieves comparable PK without overexposure risk	• 99.999% delivery of effective dose in reliability testing; no inhalation required • Stability data up to 24 months, including at high temperature for up to 3 months

Demonstrated PK/PD comparable to injection with PD response observed 1 min after dosing

Warren et al. Ann Allergy Asthma Immunol (2018), Data on file from ARS market research, Brooks et al. Ann Allergy Asthma Immunol (2017), El Turki et al. Emerg Med J (2017), Asthma and Allergy Foundation of America Patient Survey Report (2019), Company estimates based on prior references (1) through (5) and IQVIA data

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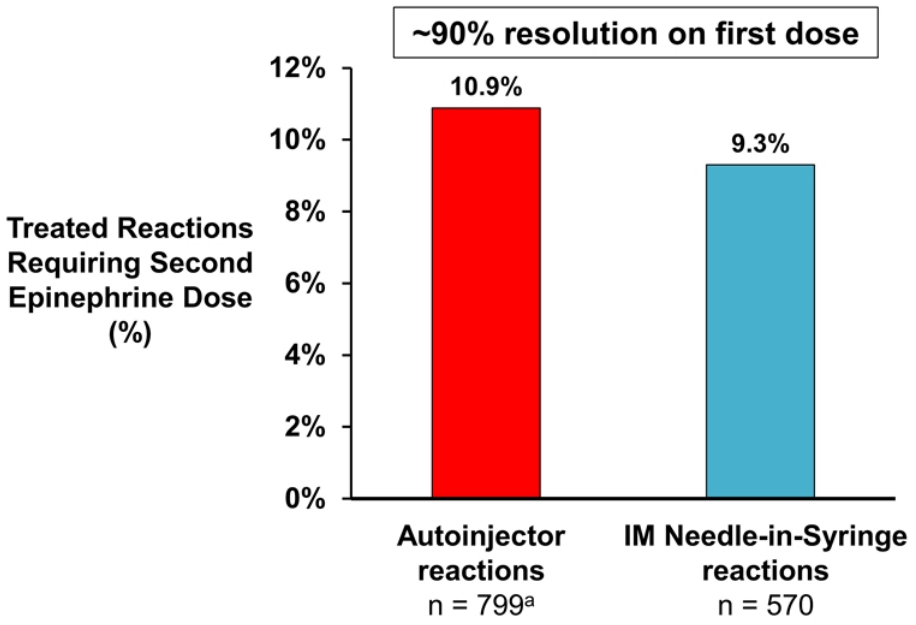
neffy Designed for Needle-free, Easier Carriage

Approved injection products have a range of PK profiles, but are all deemed efficacious (no known difference across products)

Treatment	Source	N	Mean Study C_{max} (pg/mL)	Median or Mean Study T_{max} (min)	Study T_{max} Range (min)
EpiPen 0.3 mg	Literature and ARS	507	**288 – 869**	5 – 40	1 – 240
IM 0.3 mg	Literature and ARS	381	209 – 489	30 to 60	3 – 360
Auvi-Q 0.3 mg	Literature	67	486	20	5 – 60
Symjepi 0.3 mg	ARS data	88	337 – 438	30	4 – 240
SC 0.3 mg	ARS	36	246	45	4 – 180
Total Range			**209 to 869**	**5 to 60**	**1 to 360**

- 0.3 mg IM (needle & syringe) is considered to be the gold standard, and autoinjectors were approved based on literature support from 0.3 mg IM for efficacy and safety[1, 2]
- Autoinjectors are a variable mix of IV, SC or IM dosing depending on technique
- All approved products have indistinguishable clinical effect and time to observed clinical benefit
- All products approved without any PK or PD data required

Differences in PK (including tmax - time to max concentration) do not translate to any meaningful difference in efficacy among injection products



- Analysis of 12 studies with 100% autoinjector (≥ 80% EpiPen) or 100% IM-needle-and-syringe use in community or emergency room or hospital setting, respectively[1]
- Differences in PK profile across products do not impact efficacy based on need for repeat dosing to resolve symptoms
- Cases in emergency room or hospital settings are typically more severe or advanced (where IM is administered) than those in a community setting, but still no difference in efficacy is observed with IM vs. auto-injector

[a.] 79.6% of the autoinjector treated reactions are specifically identified occurring with EpiPen

Systolic blood pressure and heart rate are surrogates for efficacy, and most important to clinicians given the high variability of PK

Adrenergic Receptor	Pharmacological Effect of Epinephrine	Clinical Effect of Epinephrine
α_1	• Increases **systolic blood pressure** • Causes blood vessel constriction • Decreases mucosal edema	• Relieves hypotension and shock • Relieves upper airway obstruction
β_1	• Increases **blood pressure** and **heart rate**	• Relieves hypotension and shock
β_2	• Relaxation of bronchial smooth muscles • Vasodilation in skeletal vasculature • Inhibits inflammatory mediator release from mast cells and basophils	• Increase in bronchial airflow • Increases blood flow to skeletal muscle • Reverses pathological histamine cascade

PD responses show that *neffy* activates the receptors that reverse anaphylaxis symptoms

neffy clinical program under NDA review; FDA Advisory Committee voted that data supports favorable benefit-risk for allergic reactions (type I)

FDA confirmed three primary registration studies required for ***neffy*** approval

- EPI-15: Single dose and twice dosing in healthy volunteers (n=42)
- EPI-16: Nasal challenge in allergic rhinitis patients (n=36)
- EPI-17: Self-administration in Type I allergy patients (n=42)

IM needle & syringe is the gold standard and reference-listed drug

Primary outcomes for all trials: ***PD (SBP, HR)*** and ***PK (bioavailability)***

EPI-10 pediatric trial interim data included in NDA submission, FDA requested

neffy **meets the endpoints discussed with FDA** in completed clinical studies*

Criteria is comparability to epinephrine injection products: **PD (SBP, HR ≥ approved products)** and **PK bracketed (exposures ≥ IM/SC for efficacy, < EpiPen for safety)**

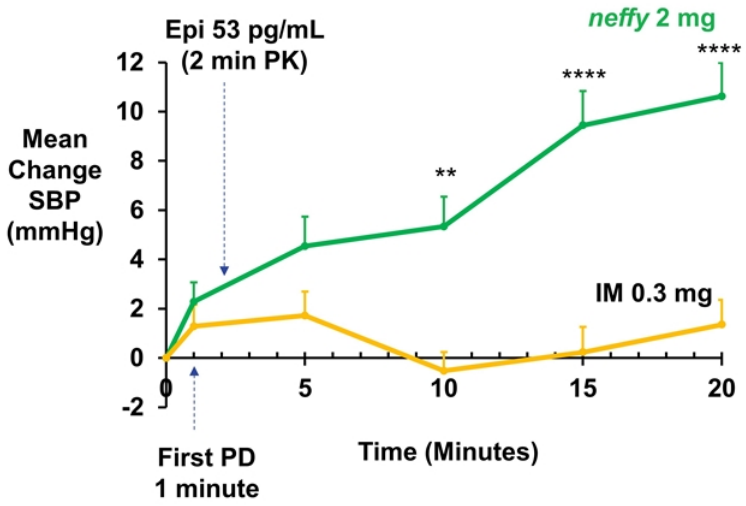
Target PDUFA action date anticipated in mid-2023

FDA Advisory Committee / PADAC (May 11) voted 16:6 and 17:5 in favor of adults and children <18 years of age and ≥30 kg that available data support a favorable benefit-risk assessment

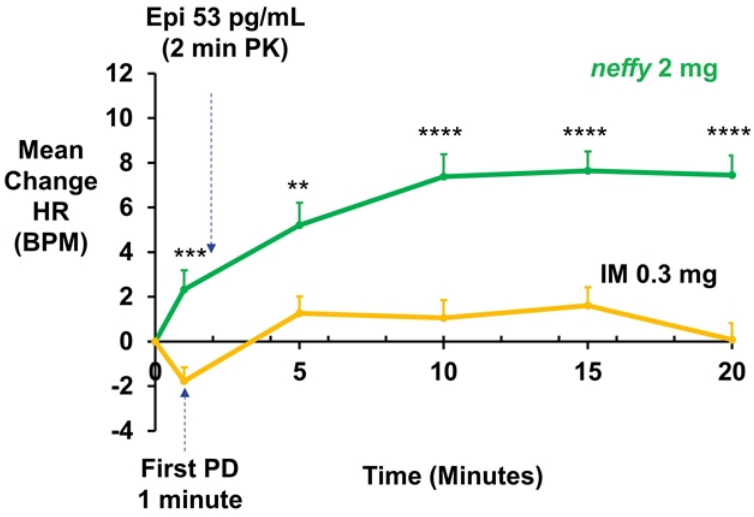
Data in subjects aged 4 to 18 (single-arm, non-comparative expected in 2022) to support pediatric labeling

Notable PD response observed with ***neffy*** even at 1 minute after dosing, and comparable to or significantly higher than 0.3 mg IM injection

Systolic Blood Pressure Response

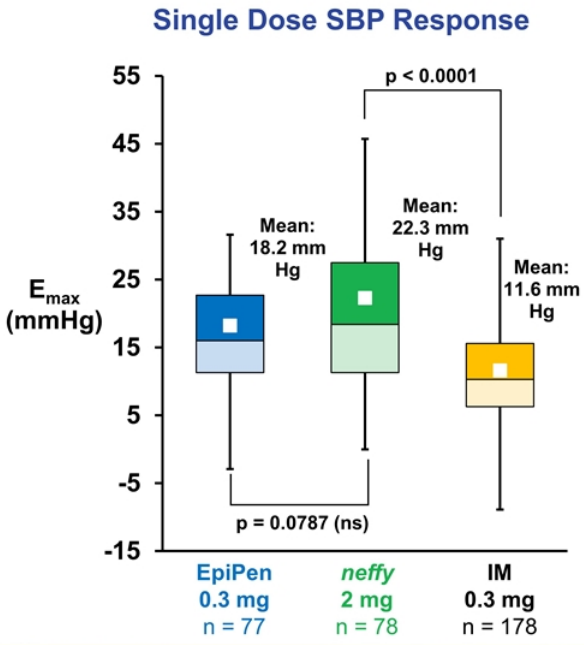


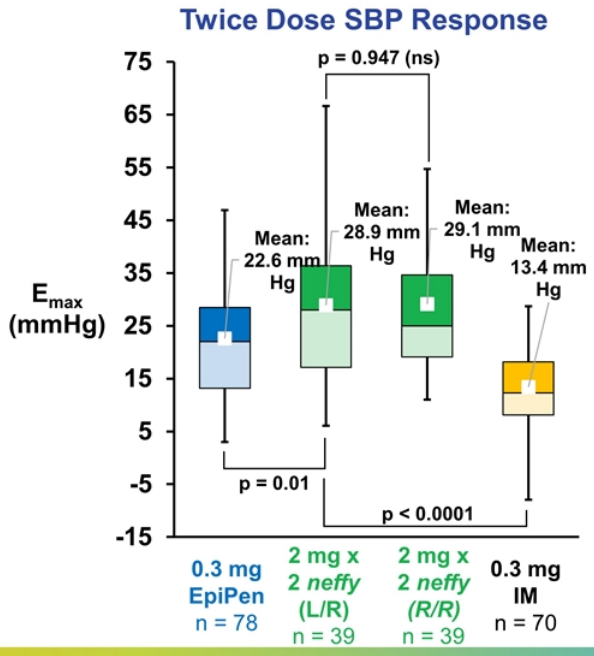
Heart Rate Response



Significance level: ** p <0.01, *** p <0.001 **** p <0.0001

PD response is comparable to EpiPen on single dose, with significantly higher response on second dose

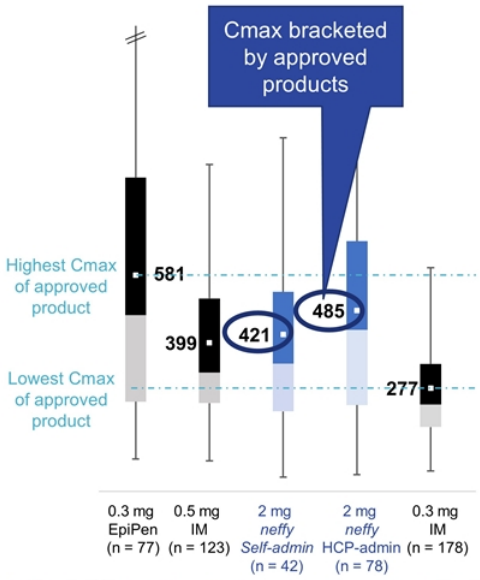




neffy meets PK endpoints agreed with FDA in 3 primary studies*

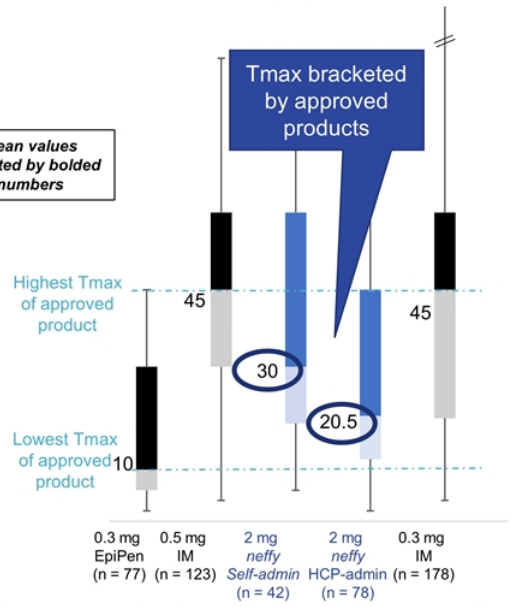
Integrated PK data summary for *neffy* and comparators

Plasma Epinephrine C_{max} (pg/mL)



Median t_{max} (minutes)

Mean values denoted by bolded numbers



Mean Early Partial AUCs

Mean early partial AUCs bracketed by approved products

Treatment	pAUC (0-20)	pAUC (0-45)
0.3 mg IM (n=178)	2,090 (86)	6,290 (61)
2 mg *neffy* (n=78) HCP-admin	**3,610 (84)**	**11,000 (76)**
2 mg *neffy* (n=42) Self-admin	**3,128 (79)**	**11,006 (63)**
0.3 mg EpiPen (n=77)	5,640 (73)	12,000 (53)

Overall mean AUC(0-t) bracketed by approved products

Treatment	AUC_{0-t}
0.5 mg IM (n=123)	43,700 (34)
2 mg *neffy* (n=36)	**37,700 (64)**
0.3 mg IM (n=178)	27,900 (39)

% CV shown in parentheses in tables above

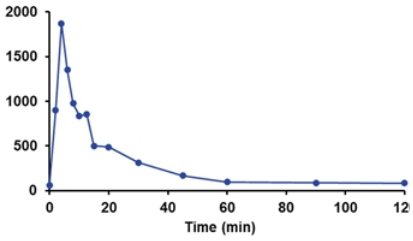
All data from ARS clinical studies

neffy PK is Bracketed by EpiPen Studies (high variability)

Treatment	Study Reference	N	Mean Study C_{max} (pg/mL)	Median Study T_{max} (min)
EpiPen (0.3 mg)	AQST-109 EPIPHAST II Results (2022)	22	869	22
	ARS EPI-JP01 Data (2020)	30	676	10
	ARS EPI-15 (2022)	35	612	8
	Tal et al. EAACI (2022)	12	550	9
	ARS EPI-11b Data (2021)	9	537	6
	Edwards et al. NDA #201739 (2012)	67	520	10.2
	Chen et al. AAAAI (2019)	11	511	5
	ARS EPI-12 Data (2021)	36	493	8
	ARS EPI-13 Data (2022)	39	490	6
***neffy* (2.0 mg)**	ARS EPI-16 data (2022)	36	491	20
	ARS integrated analysis (2022) EPI-15/16	**78**	**485**	**20.5**
	ARS EPI-15 data (2022)	42	481	30
	ARS EPI-17 data (2022)	42	421	30
EpiPen (0.3 mg)	Worm et al. Clin Transl Allergy (2020)	12	390 to 530	9 to 30
	Turner et al. Clin Exp Allergy (2021)	37	386	40
	Amphastar US2021/030502 (2021)	56	364 - 458	7-15
	ARS EPI-07 Data (2019)	35	375	24
	Dworaczyk et al. AAAAI (2020)	55	308 to 440	10-16
	Oppenheimer et al. AAAAI (2022)	10	341	22
	ARS EPI-01 Data (2018)	12	333	20
	Aquestive R&D Day (2021)	9	300	10^4
	Dworaczyk et al. AAAAI (2021)	25	288	10

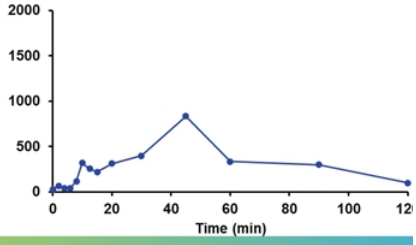
IV Like PK profile with EpiPen

T_{max} = 4 min

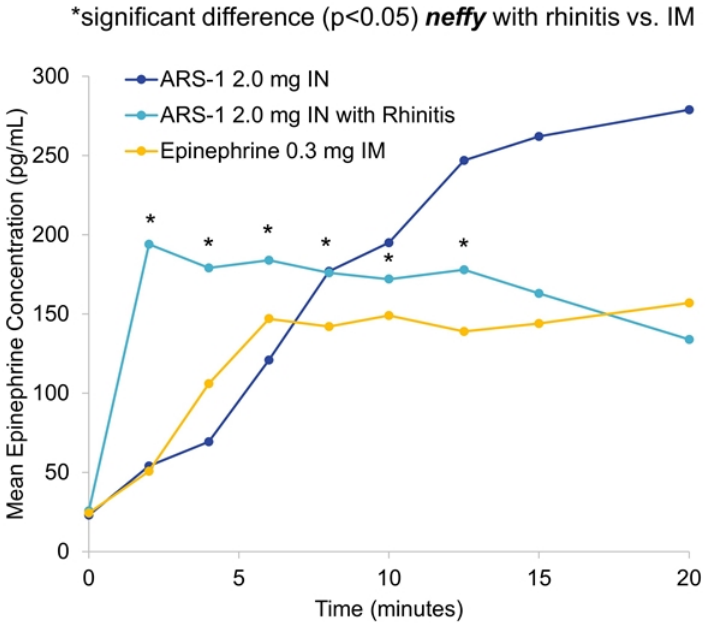


IM Like PK profile with EpiPen

T_{max} = 45 min



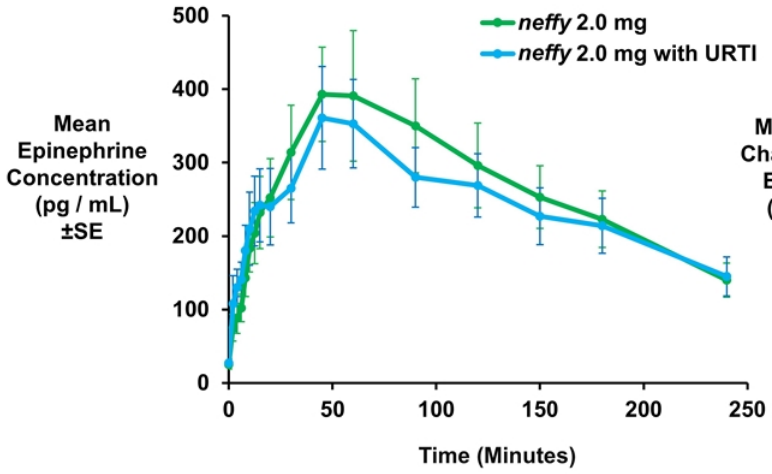
Dosing neffy immediately following nasal allergen challenge (worst-case conditions) shows no clinically meaningful impact on PK or PD



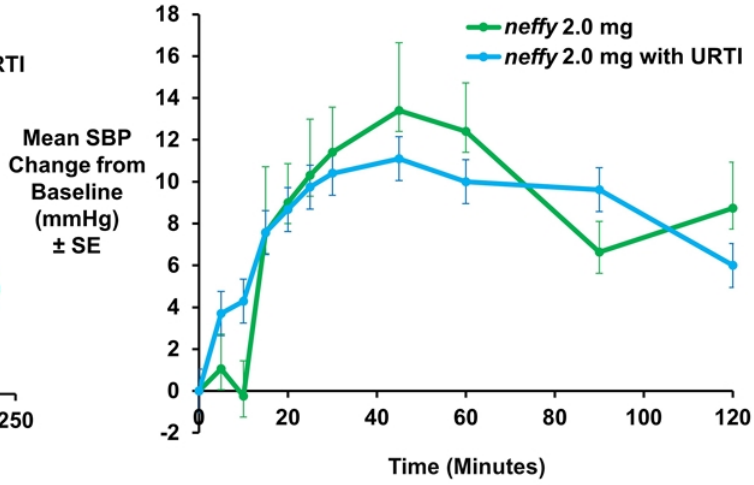
- ~2 to 11% of patients experience nasal symptoms during an allergic reaction[1]
- Congestion accelerates absorption, and rhinorrhea accelerates drainage
- ***neffy*** during moderate to severe congestion and rhinorrhea following nasal allergen challenge in allergic rhinitis patients has significantly higher exposures than IM during early time points when treatment response is observed
- If no response is observed within 15 minutes, a second dose of epinephrine is given
- Regardless, PD response after one dose of ***neffy*** (with rhinitis) is comparable to injection (no rhinitis) through 60 min despite the systemic inflammation reported to be triggered by allergic rhinitis[2]

Dosing *neffy* during congestion/rhinitis due to an upper respiratory tract infection (e.g. cold or flu) has no clinically meaningful impact on PK or PD

Mean Epinephrine Plasma



Mean Systolic Blood Pressure Change

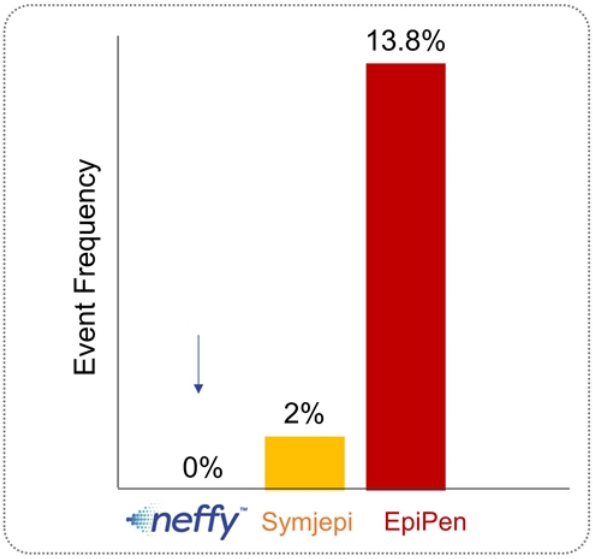


N = 21 URTI / 16 Normal (returned)

neffy well-tolerated across 600+ individuals dosed in clinical program

- Well-tolerated at all single-doses (0.5 mg to 2 mg) and repeat doses up to 4 mg within 10 minutes
- Mostly grade 1 events and comparable to injection products
- Low Pain Scores: recorded by VAS (100mm scale) with mean scores between 5 and 8 out of a score of 100 across studies
- No irritation based on formal scoring in all studies
- No serious treatment-related adverse events
- No risk of needle-related injuries or blood vessel injections

Risk of blood vessel injection during self-administration that could lead to adverse events

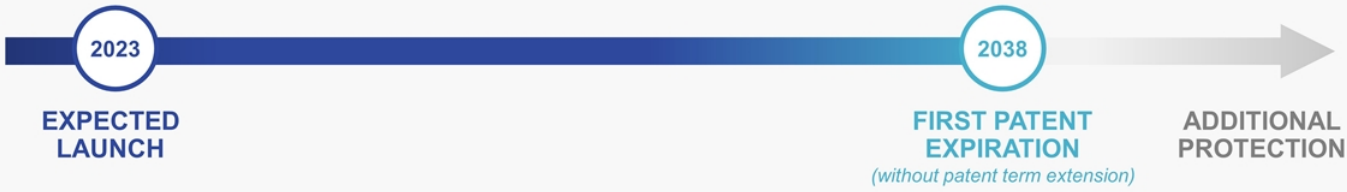


All data from ARS clinical studies

neffy market exclusivity potential until at least 2038

Extensive studies in the lab and clinic completed to develop a proprietary product with expected NCE-like exclusivity

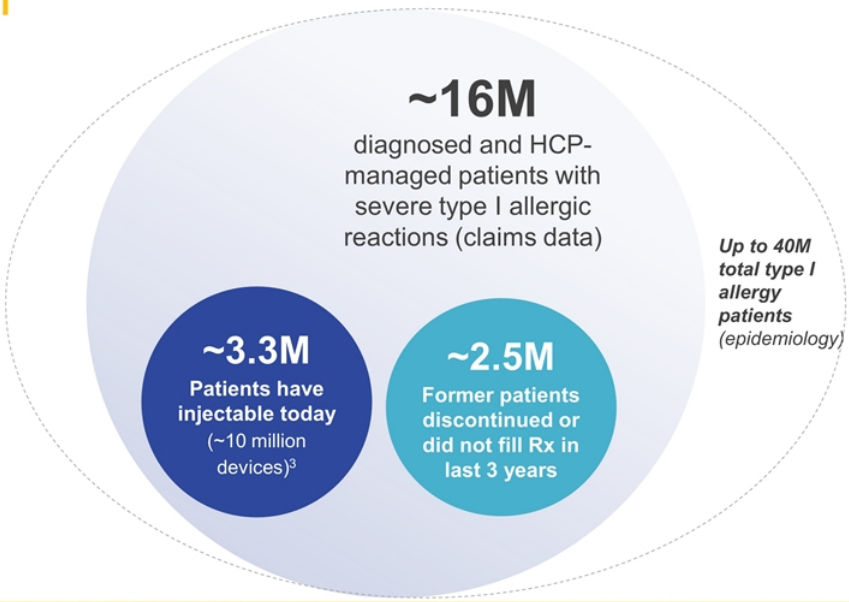
- ✓ **Issued composition of matter patent (US10,576,156) on Intravail® + epinephrine** provides foundational exclusivity blocking any generic products. **Method of treatment patents (US11,173,209; US11,191,838)** block other alkyl glycosides.
- ✓ **Issued method of treatment patent (US10,682,414)** blocks any intranasal epinephrine product using a different technology using a low dose (<2.5 mg)
- ✓ **PCT patent granted in Europe (EP19751807), UK (GB2583051), Japan (JP6941224), Canada (3088909), Australia (AUS2019217643), Korea (10-2375232), China (2019800010042),** with same claims as the US



Commercial Opportunity and Strategy

Significant existing US market opportunity for ***neffy*** penetration

CURRENT ~$1 BILLION[1] ANNUAL EPINEPHRINE MARKET IS THE IMMEDIATE OPPORTUNITY



MULTIPLE LEVERS OF CURRENT MARKET GROWTH

Consistent market growth
+5% y/y in the last ~15 years

Promotional responsiveness
+31% historic lift from Mylan
No meaningful promotion today

More devices per patient
Potential for twice as many ***neffy*** devices annually vs. injectables

1. SEC filings, IQVIA data and ARS payer research data on file
ARS market research data on file (n = 75 physicians, n = 150 patients), [3] IQVIA extended unit data

Physicians supportive of adopting ***neffy*** into practice

n = 75 Physicians

8.5 out of 10 rating

viewed as a major advance in therapy

10 = MAJOR ADVANCE / **1** = NOT AN ADVANCE AT ALL

100%

Would prescribe *neffy* if their patients asked for it

*No difference in uptake of **neffy** by physician specialty*

neffy addresses the unmet need and is better aligned with what healthcare providers, patients and parents want

n = 150
Current Users

~80% OF PATIENTS EXPECTED TO SWITCH TO ***neffy***

75% OF NON-FILLING PATIENTS STATED THEY WOULD ASK THEIR PHYSICIAN ABOUT ***neffy*** RX

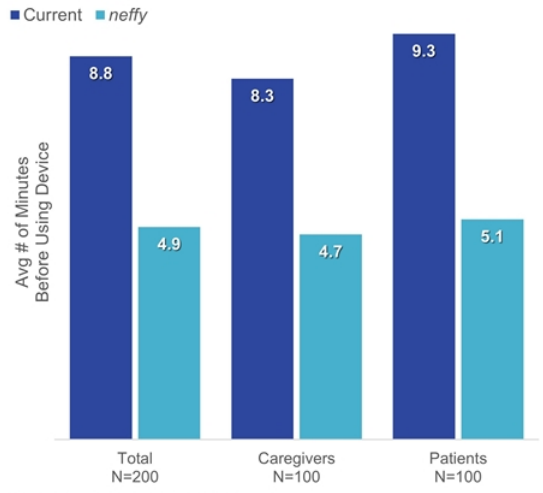
n = 100
Non-fillers

65% to 72%
OF THE TIME,
PEOPLE WHO USE AN OTC WOULD USE ***neffy*** FIRST

69%
OF PEOPLE
WOULD USE ***neffy*** SOONER THAN CURRENT AUTOINJECTOR

Caregivers are enthusiastic about ***neffy*** and its benefits

Time from Onset of Symptoms to Epinephrine Administration



Source: ARS Consumer Quant Research, 2022

> This is fantastic. **Much easier than jabbing the thigh.**
>
> *– Father*

> **I want this. Is it available yet?** Let me know when it is, I will literally call the doctor from my car.
>
> *– Mother*

> We are talking about someone's life and lifestyle here. **Great improvement.**
>
> *– Mother*

> I don't have a co-pay, but I'd get this for my daughters **even if I have to pay $50.**
>
> *– Mother*

Guidelines recommend immediate treatment with epinephrine. Earlier administration is associated with improved clinical outcomes and decreased likelihood of hospitalizations.

By Addressing Needle Injector Deficiencies
neffy can Become the Standard in Treatment

Propensity of Current SAR Patients Prescribed a Needle Injector

Don't Use Properly[1]

Don't Keep On Hand[2]

Delay Treatment[3]

neffy Patient Research Shows…

45% ↑ Faster Treatment Time[3]

↑ More Likely to Fill Rx[3]

Would Keep On Hand[3]

Used Device Correctly[4]

(1) ARS Consumer Quant Research, 2022, (2) Warren et al. Ann Allergy Asthma Immunol (2018), (3) Data on file from ARS market research, (4) ARS human factors studies

Payer research supports positive reimbursement environment

Key findings from discussions with ~50 decision-makers within the major payers and PBMs:

- Category is generally not restricted, unlike biologics and orphan disease drugs with high WACs
- Payers view ***neffy*** as a valuable and differentiated treatment option
- High likelihood of attaining favorable coverage (Tier 2 or 3) for ~80% of lives

*"This is a **game-changer**; it really addresses the unmet needs we currently have in this space, specifically the safety and tolerability issues."*
– Payer

"Nasal delivery will overcome some negative perceived factors of an injection."
– Payer

*"If this is priced properly, this could be a '**state-of-the-art therapy**' for patients."*
– PBM

"There is no value in delaying access to a product like this and nothing to prior authorize (PA). We can't PA if the patient needs it."
– PBM

Commercial strategy and imperatives

From needle to neffy:

- Convert the existing market
- Bring back patients that are lapsed
- Bring in patients who should be carrying epinephrine now, but do not carry

1. Ensure broad and rapid ***neffy*** coverage as well as affordable access for patients
2. Change HCP habits and switch prescribing from needle to ***neffy***
3. Drive ***neffy*** awareness and new patient growth (into and back into) the market

Strategic Imperatives and CSFs: From Needle to ***neffy***

	1	2	3
STRATEGIC IMPERATIVES	**Ensure broad and rapid *neffy* coverage as well as affordable access for patients**	**Change HCP habits and switch prescribing from needle to *neffy***	**Drive *neffy* awareness and new patient growth (into and back into) the market**
CRITICAL SUCCESS FACTORS	• Payers recognize the value proposition of ***neffy*** • Patients can access ***neffy*** • Prescriptions are filled seamlessly	• HCP awareness at launch • Confidence in ***neffy*** and intranasal delivery • Allergists and KOL endorsement	• Consumer awareness of ***neffy*** • Patient understanding of effectiveness and safety • Patients will ask for ***neffy*** proactively

Integrated HCP Promotion to Drive Awareness and Reach with Current Epinephrine Prescribers Representing >40% of Prescriptions*

Specialty Salesforce

Virtual Salesforce

Non-Personal Promotion

FTEs	**~125 FTEs**	**Top 50,000** *Decile 5 to 10*
HCP Reach	**~ 15,000 HCPs**	

HCP promotion will be supported by DTC promotion to drive expansion within the addressable SAR market

** Reaching >80% of Prescriptions from Allergists, ENTs, and Pediatricians*

neffy is positioned potentially to transform the treatment of serious allergic reactions

PK comparable or superior to IM (reference listed drug) and less than EpiPen (upper limit for safety) offers therapeutic exposures and makes it easy to switch

Effective

Less Hesitation to Dose

No needle, no fear, no wait
Easier to use and more reliable delivery than with autoinjectors (less chance of failed dosing)

No meaningful side effects
No needle-related injuries possible

Safe

Compact

Always available with child, parent and caregiver

No serious safety risks associated with injection devices (needle)
No blood vessel injections, no lacerations, no bone injections

No Needle

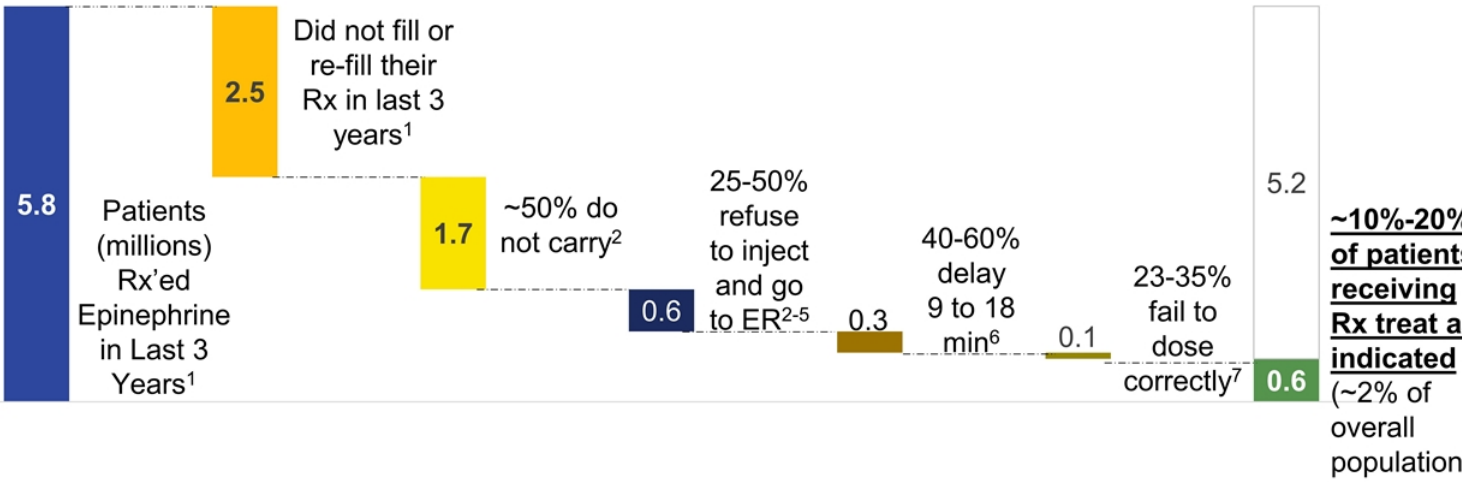
Easy to Use

100% of adults (N=105) successfully dosed in human factors studies

Supplemental Slides

Many patients/caregivers do not administer treatment or delay use during reaction

Approx. 40,000,000 people with serious Type I Allergic Reactions
~5,800,000 people received Rx from a Physician in Last 3 Years



1. IQVIA Claims Data 2022, 2. Warren 2018, 3. Brooks 2018, 4. Asthma and Allergy Foundation of America 2019, 5. Casale 2022, 6. ARS data presented at AAAAI 2023, 7. El Turki 2017

Basis of Approval for Community Use Products

- Approved community use products include IM and SC dosing (FDA briefing book)
- Almost all approved without PK data

Device	Approval Basis	Pharmacokinetics (any data including literature)	FDA Approved Route and Dose
EpiPen® (1987)	No PK Data	Significant differences (EpiPen vs. IM) only known for ~10 yrs Blood vessel injection risk (IV bolus) known last 5 yrs	IM & SC 0.15 & 0.3 mg
Twinject® (2003)	No PK Data	No PK data known to date	IM & SC 0.15 & 0.3 mg
Adrenaclick® (2003)	No PK Data	No PK data known to date	IM & SC 0.15 & 0.3 mg
Auvi-Q® (2012)	Single PK Study	More rapid PK vs. IM, but slower PK vs. EpiPen (T_{max} = 20 min vs 10 min)	IM & SC 0.1, 0.15 & 0.3 mg
Symjepi® (2017)	No PK Data	ARS studies show slower PK vs ***neffy*** or other autoinjectors	IM & SC 0.15 & 0.3 mg
Teva EpiPen® (2018)	No PK Data	None to date; shorter needle and different activation force	IM & SC 0.15 & 0.3 mg