

Initiating Coverage:

ARS Pharmaceuticals

Adoption is Right on the Nose

Key Take-away: ARS Pharmaceuticals seeks to penetrate the \$2bn Type 1 allergy treatment market with a new form of epinephrine administration called Neffy. Neffy administers epinephrine through nasal injection instead of intramuscular and subcutaneous injection like competitors EpiPen and Adrenaclick. We expect recent FDA approval to generate positive earnings as soon as Q4 2024.

FDA Approval: SPRY gained FDA approval for Neffy as of August 9th, 2024, jumping 13% on the day. This is a positive signal to investors as SPRY is likely to begin the manufacturing and selling of Neffy devices, leading to the company's first possible quarter of positive EBITDA. ARS expects the product to be available in just 8 weeks. Since the risk of a negative phase 3 trial has been entirely priced out of \$SPRY, we believe now is a great time to capitalize and invest in the future of allergy care. The company also plans to file FDA approval for small children in Q3 2024 and launch in Europe in Q4 after it receives approval.

ARS has now hired 110 sales representatives to call on more than 11,000 allergy specialists and prescribers to reach more than 40% of Health Care Providers and 80%+ of all Allergists and Pediatricians within the United States.

Large TAM: 40m patients experience type I allergic reactions each year giving Neffy a huge TAM. The market is currently controlled in majority by EpiPens, however according to a study in the Journal of Allergy and Clinical Immunology, epinephrine is not used as frequently as optimal by those prescribed EpiPens. This suggests EpiPen users are hesitant to administer the drug. The study found that 31% of anaphylactic reactions are treated with epinephrine prior to hospitalization, despite being the most optimal pre-hospitalization remedy. 46% of anaphylactic reactions are treated with antihistamines, like Benadryl, instead prior to hospitalization due to their ease of administration. Given the low adoption rates due to fear of injectables, there is an opportunity for a less invasive form of administering epinephrine to enter the market – Neffy.

Valuation: We initiate coverage with a \$20.00 PT and an **Overweight** rating.



Consortium Equity Research
Healthcare | Pharmaceuticals
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Stock Rating: Overweight

Price Target: USD \$20.00

Price: \$10.95

Potential Upside/Downside: 82.6%

Ticker: SPRY

Market Cap: \$0.927bn

Shares Outstanding: 96.14m

Dividend Yield: N/A

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Industry Overview

Epinephrine Market: The total epinephrine market is valued at almost \$2bn with an expected CAGR of 10.2% for the next ten years (Fortune). The FDA has approved intramuscular and subcutaneous injections with notable brands such as EpiPen, Twinject, and Adrenaclick alongside generics. Within 5-15 minutes, there should be a clinical response in the patient. Users are instructed to inject a second dose if the first is not efficacious. All current products are injectables leading to delayed and potentially improper use (Epinephrine injections outside of the ideal regions can lead to complications and death). ARS's Neffy intends to curb this problem through a portable nasal device, leading to greater adoption and ease of use.

Investment Thesis

Efficacy and Ease of Use: Neffy's product is the unequivocal best compared to its competitors from both an efficacy standpoint as well as on an ease-of-use standard. According to the Pulmonary Allergy Drugs Advisory Committee,

"Taken together, Neffy 2 mg after single administration demonstrated comparable pharmacokinetic, pharmacodynamic, and safety profile to that of injection products. Therefore, patients and caregivers would benefit from this easy-to-use and needle-free option when they need emergency treatment. Twice dosing with Neffy 2 mg resulted in dose proportional epinephrine exposure and greater pharmacodynamic effect than twice dosing with injection product, which is appropriate given a second dose is generally needed due to more severe events. The many patients and caregivers who cannot accept use of a needle-bearing device currently have no other treatment options. Neffy can potentially fill that unmet medical need."

To summarize: Neffy meets the standard set by injectable epinephrine products while also being a more effective solution for severe events that require double dosing. In addition, Neffy is more portable and psychologically easier to use compared to an injectable.

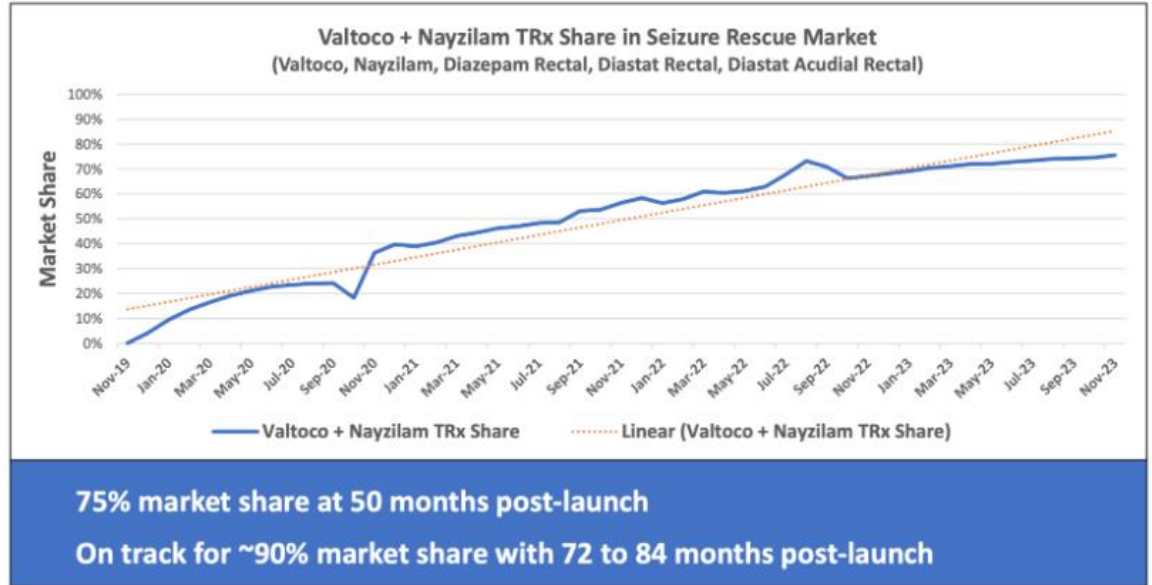
Market Share Takeover: Autoinjectors struggle with patient adoption: 40% of patients never refill them, 50% don't carry it around daily, 50%+ of parents are afraid to administer it to their children, and 70% of patients incorrectly administer them. Neffy addresses all these issues through its ease of use and portability. Within ARS's own studies, they expect an increase from 50% of people actively carrying epinephrine to more than 855 (n = 150). In addition, 87% of HCP said they would "definitely prescribe" Neffy upon availability (n = 202).

We expect Neffy to see similar adaptation rates to Valtoco and Nayzilam, two nasally administered seizure medications who have all but replaced previous autoinjectors. Within 4 years, the two products saw a combined market share of 75% with an expected 90%+ market share after 6 years. ARS has recently brought the mastermind behind the widespread adoption of Narcan on their team, meaning we foresee similar market share penetration from the product with his expertise.

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Investment Thesis & Valuation

Our analysis gives \$SPRY a price target of \$20.00 and an Overweight rating.

Football Field Valuation Range



Potential Downsides to Our Rating

Lack of Adoption: Our model factors in an adoption rate of 35% in the worst case – an unprecedented market share penetration rate looking at historical data from other nasal sprays that have entered the market. However, if ARS is unable to convince users to switch or encounters manufacturing issues with CDMOs, problems may arise that would lead to a lower-than-expected valuation.

Approval in Foreign Markets: While Neffy has been approved for use by the FDA within the United States, approval is still pending within EMEA and Asia. Our model does not factor in the risk associated with the lack of approval and our downside case may be far lower than expected if Neffy is unable to expand outside of the United States, significantly lowering overall TAM.

Our Price Target: \$20.00

Our PT is based on neffy gaining 55% market share within five years and maintaining that market share until exclusivity loss. We've also modeled slower market share penetration relative to Narcan, Valtoco, and Nayzilam. Expenses were modeled to be in line with other nasal sprays. We see this as a conservative estimate given the 75%-90% peak-adoption rate we've seen in similar products.

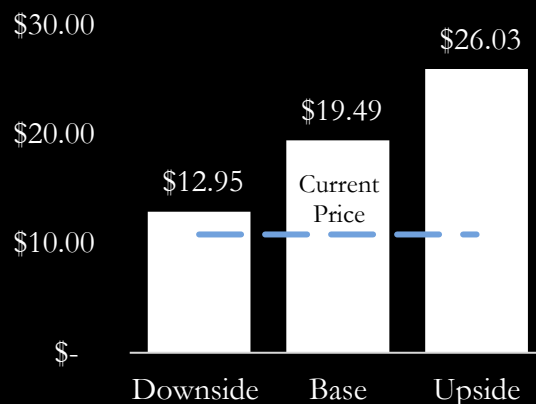
Our Upside Case: \$26.03

Our upside case is based on market share penetration figures from Valtoco and Nayzilam, with peak adoption rates of 80%+. In addition, we've factored in the ease-of-use and portability of neffy leading to an increased number of prescriptions being filled, which would be a substantial driver of growth.

Our Downside Case: \$12.95

Our downside case is based on a 35% market share estimate. If ARS fails to convince HCPs and Allergists to switch from injectables to neffy at the same rates as precedent nasal treatments, we will see much lower market share penetration. However, we foresee this as a very low likelihood outcome given the hiring of Eric Karas – the previous CCO for Emergent, the creators of Narcan.

DCF Case Values



Valuation Assumptions

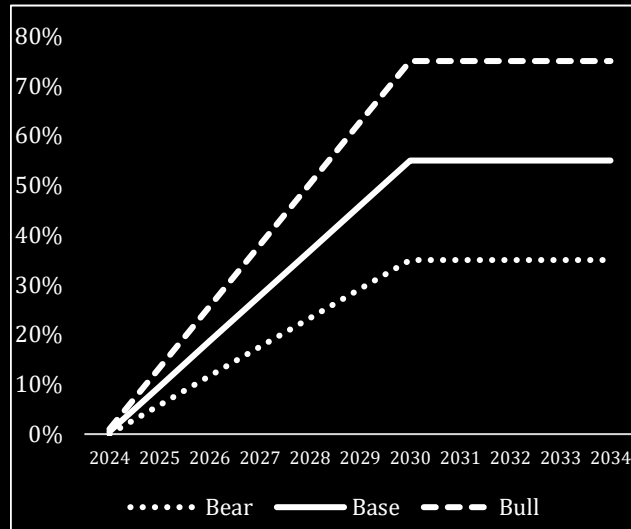
Methodology: Given \$SPRY is pre-revenue and has negative earnings, Comparable Company analysis would not be an effective valuation tactic, so we primarily focused on creating a comprehensive DCF model.

Forecasting TAM: The primary focus of a DCF model on \$SPRY was the modeling of its revenues, given Neffy has not produced any sales yet. We first estimated Neffy's TAM by taking the total number of epinephrine prescriptions, around 6.5 million, factored in population growth rate, and multiplied by the price of Neffy, \$199, to get to the total addressable market. It should be noted that our Bull TAM figure of around one billion USD comes out significantly lower than research provider estimates that put the figure closer to \$4bn or \$5bn – likely due to the higher costs of injectable treatments.

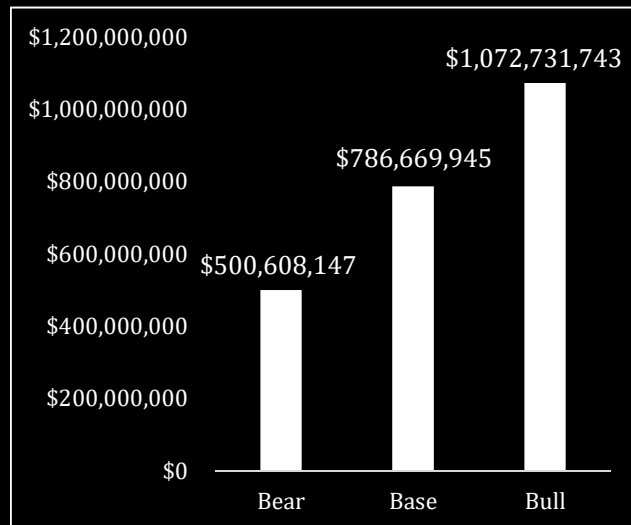
Arriving at Revenue: From there, we looked at market penetration figures from Narcan, Valtoco, and Nayzilam to arrive at the assumption that Neffy will reach its peak market share in six years. We then assumed Neffy maintained this market share until exclusivity runs out in ten years and generics enter the market. We used 35%, 55%, and 75% market share figures as a conservative estimate. Although our Base case is centered around 55% market share, we think that a market share of 80%+ is entirely possible given historical data on nasal alternatives entering the market. For both overdoses (Narcan) and seizures (Valtoco & Nayzilam), previous alternatives required injections. All three have attained closer to 80-90% market share within six years. Hence, there is reason to believe Neffy can achieve much higher than forecasted revenues in the next few years. Given the unpredictability of revenues after exclusivity loss, we did not account for a terminal growth value and only used the present value of projected FCF in this 10-year period.

Costs: For our cost estimates, we looked at historical data from other nasal spray solutions and modeled them accordingly to get a reasonable estimate for FCF. We expect relatively low cash expenses given R&D expenses should be nonexistent and most expenses are tied into COGS and SG&A.

Market Share Penetration



Revenue Estimates at Peak Market Share



Implied Share Prices



Valuation: Using the assumptions above, our DCF estimates a share price of \$12.95 as a bear case, \$19.49 as a Base/ Street case, and \$34.91 as a Bull case, leading us to an Overweight Rating.

About \$SPRY

ARS Pharmaceuticals, the company behind Neffy, is a promising set to disrupt the epinephrine market. Neffy, their flagship product, is an intranasal epinephrine spray designed to treat severe allergic reactions (anaphylaxis). Unlike traditional epinephrine auto-injectors, Neffy offers a needle-free alternative, which could significantly enhance patient compliance and ease of use.

Disclosures & Ratings

Consortium Equity Research does not hold any professional relationships with any reported equities.

Overweight means the analyst team believes the stock price will outperform the coverage industry (TMT, Healthcare, Industrial, Consumer) in the next 6-12 months. **Equal Weight** means the team expects performance in line with the industry. **Underweight** means the team expects underperformance relative to the industry.

Appendix

Revenue Estimate							
		2024	2025	2026	2027	2028	2029
Total # of Prescriptions		6,500,000	6,559,150	6,618,838	6,679,070	6,739,849	6,801,182
Pop growth	0.91%						
Neffy Price	\$199						
TAM		\$1,293,500,000	\$1,318,323,559	\$1,330,320,303	\$1,342,426,218	\$1,354,642,296	\$1,366,969,541
Increased Adopters	1%						
Penetration (%) at Peak							
Bear	35%	0%	5.83%	11.67%	17.50%	23.33%	29.17%
Base	55%	0.50%	9.58%	18.67%	27.75%	36.83%	45.92%
Bull	75%	1%	13.33%	25.67%	38.00%	50.33%	62.67%
Net Revenue							
Bear		\$0	\$76,902,208	\$155,204,035	\$234,924,588	\$316,083,202	\$398,699,449
Base		\$6,467,500	\$126,339,341	\$248,326,457	\$372,523,275	\$498,959,912	\$627,666,848
Bull		\$12,935,000	\$175,776,474	\$341,448,878	\$510,121,963	\$681,836,622	\$856,634,246
Income Statement							
Revenue	\$	6,467,500	\$ 126,339,341	\$ 248,326,457	\$ 372,523,275	\$ 498,959,912	\$ 627,666,848
COGS		\$	35,155,295	\$ 68,289,776	\$ 102,024,393	\$ 136,367,324	\$ 171,326,849
SG&A		\$	17,577,647	\$ 27,315,910	\$ 32,647,806	\$ 34,910,035	\$ 42,831,712
Other Opex		54,360,000.00	52,732,942.34	71,704,264.33	85,700,489.73	91,638,842.05	92,105,314.10
EBIT	\$	(41,425,000)	\$ 20,873,456	\$ 81,016,506	\$ 152,150,588	\$ 236,043,711	\$ 321,402,972
Taxes	14% \$	-	\$ 2,922,284	\$ 11,342,311	\$ 21,301,082	\$ 33,046,120	\$ 44,996,416
Unlevered FCF							
EBIT	\$	(41,425,000)	\$ 20,873,456	\$ 81,016,506	\$ 152,150,588	\$ 236,043,711	\$ 321,402,972
(-) Taxes	\$	-	\$ 2,922,284	\$ 11,342,311	\$ 21,301,082	\$ 33,046,120	\$ 44,996,416
(-) CapEx	\$	300,000	\$ 300,000	\$ 300,000	\$ 300,000	\$ 300,000	\$ 300,000
(+) D&A	\$	15,000	\$ 15,000	\$ 15,000	\$ 15,000	\$ 15,000	\$ 15,000
(-) Changes in WC	\$	-	\$ -	\$ -	\$ -	\$ -	\$ -
Unlevered FCF	\$	(41,710,000)	\$ 17,666,172	\$ 69,389,196	\$ 130,564,505	\$ 202,712,591	\$ 276,121,556
Present Value of FCF	\$	(41,710,000)	\$ 17,666,172	\$ 69,389,196	\$ 130,564,505	\$ 202,712,591	\$ 276,121,556

8/10/2024

Revenue Estimate

		2030	2031	2032	2033	2034
Total # of Patients		6,863,073	6,925,527	6,988,549	7,052,145	7,116,319
Pop growth	0.91%					
Neffy Price	\$199					
TAM		\$1,379,408,964	\$1,391,961,586	\$1,404,628,436	\$1,417,410,555	\$1,430,308,991
Increased Adopters	1%					
Penetration (%) at Peak						
Bear	35%	35%	35%	35%	35%	35%
Base	55%	55%	55%	55%	55%	55%
Bull	75%	75%	75%	75%	75%	75%
Net Revenue						
Bear		\$482,793,137	\$487,186,555	\$491,619,953	\$496,093,694	\$500,608,147
Base		\$758,674,930	\$765,578,872	\$772,545,640	\$779,575,805	\$786,669,945
Bull		\$1,034,556,723	\$1,043,971,189	\$1,053,471,327	\$1,063,057,916	\$1,072,731,743

Income Statement

Revenue		\$ 1,034,556,723	\$ 1,043,971,189	\$ 1,053,471,327	\$ 1,063,057,916	\$ 1,072,731,743
COGS		\$ 206,911,345	\$ 208,794,238	\$ 210,694,265	\$ 212,611,583	\$ 214,546,349
		20%	20%	20%	20%	20%
SG&A		\$ 51,727,836	\$ 52,198,559	\$ 52,673,566	\$ 53,152,896	\$ 53,636,587
incl. Commissions		5%	5%	5%	5%	5%
Other Opex		88,988,431.08	71,838,580.64	72,492,311.73	73,151,991.76	73,817,674.89
		9%	7%	7%	7%	7%
EBIT		\$ 686,929,111	\$ 711,139,811	\$ 717,611,183	\$ 724,141,445	\$ 730,731,132
Taxes	14%	\$ 96,170,076	\$ 99,559,574	\$ 100,465,566	\$ 101,379,802	\$ 102,302,359

Unlevered FCF

EBIT		\$ 686,929,111	\$ 711,139,811	\$ 717,611,183	\$ 724,141,445	\$ 730,731,132
(-) Taxes		\$ 96,170,076	\$ 99,559,574	\$ 100,465,566	\$ 101,379,802	\$ 102,302,359
(-) CapEx		\$ 300,000	\$ 300,000	\$ 300,000	\$ 300,000	\$ 300,000
(+) D&A		\$ 15,000	\$ 15,000	\$ 15,000	\$ 15,000	\$ 15,000
(-) Changes in WC		\$ -	\$ -	\$ -	\$ -	\$ -
Unlevered FCF		\$ 590,474,035.58	\$ 611,295,237.64	\$ 616,860,617.80	\$ 622,476,642.92	\$ 628,143,773.87
Present Value of FCF		\$ 331,242,131.72	\$ 311,424,831.89	\$ 285,395,244.13	\$ 261,541,257.92	\$ 239,681,033.35

8/10/2024

DCF		
Sum of Discounted Cash Flows	\$	2,515,914,739
Cash and Cash Equivalents		222,840,000
Debt		0
Market Value of Common Equity	\$	2,738,754,739.11
Number of Shares Outstanding		96,500,000
Implied Share Price	\$	28.38

WACC		
Market Cap (in Millions)		927
<u>COE</u>		
% of Equity		100.00%
Risk Free Rate		3.95%
Beta		1.56
Market Risk Premium		3.95%
Cost of Equity		10.11%
<u>Debt</u>		0
% of Debt		0.00%
Cost of Debt		3%
Tax Rate		0%
Cost of Debt		0.00%
WACC		10.11%