

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549**

FORM 10-Q

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended June 30, 2025

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission File Number 001-39756

ARS Pharmaceuticals, Inc.

(Exact name of Registrant as specified in its Charter)

Delaware
(State or other jurisdiction of
incorporation or organization)
11682 El Camino Real, Suite 300
San Diego, California
(Address of principal executive offices)

81-1489190
(I.R.S. Employer
Identification No.)

92130
(Zip Code)

Registrant's telephone number, including area code: **(858) 771-9307**

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, par value \$0.0001 per share	SPRY	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act:

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input checked="" type="checkbox"/>

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.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

As of August 11, 2025, there were 98,826,337 shares of registrant's common stock, \$0.0001 par value per share, outstanding.

Table of Contents

	<u>Page</u>
PART I FINANCIAL INFORMATION	
Item 1. Financial Statements	7
Condensed Consolidated Balance Sheets	7
Condensed Consolidated Statements of Operations and Comprehensive Loss	8
Condensed Consolidated Statements of Stockholders' Equity	9
Condensed Consolidated Statements of Cash Flows	10
Notes to Unaudited Condensed Consolidated Financial Statements	11
Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations	36
Item 3. Quantitative and Qualitative Disclosures About Market Risk	49
Item 4. Controls and Procedures	49
PART II OTHER INFORMATION	
Item 1. Legal Proceedings	50
Item 1A. Risk Factors	50
Item 2. Unregistered Sales of Equity Securities and Use of Proceeds	103
Item 5. Other Information	104
Item 6. Exhibits	105

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q (this “Quarterly Report”) contains forward-looking statements that involve risks and uncertainties. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. All statements other than statements of historical facts contained in this Quarterly Report are forward-looking statements. In some cases, you can identify forward-looking statements by words such as “anticipate,” “believe,” “contemplate,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “seek,” “should,” “target,” “will,” “would,” or the negative of these words or other comparable terminology. These forward-looking statements include, but are not limited to, statements about:

- future economic conditions or performance, including *neffy* net product revenues and net product sales;
- research and development plans, including planned clinical trials, for our current or future intranasal epinephrine technology product candidates;
- the expected timing for reporting data;
- our expectations regarding the European Medicines Agency’s (“EMA”) review of our post-approval variation for *neffy* 1 mg;
- our plans to submit regulatory filings for *neffy* in additional geographies in collaboration with our partners and the timing thereof;
- the expected timing for regulatory review decisions for *neffy* and our intranasal epinephrine technology product candidates;
- the commercial potential of and commercialization strategy for *neffy* and our intranasal epinephrine technology product candidates;
- the size of the markets (including annual sales opportunities) for our current and future product candidates, as well as for *neffy*, for its currently approved indications in the United States and the European Union (“EU”), the projected growth thereof, and our, and our collaboration and marketing partners’, ability to capture and grow those markets;
- the rate and degree of market acceptance of *neffy* and any future product candidates;
- our expected competitive position;
- our potential to become the standard in treatment and transform the treatment of allergic reactions;
- the likelihood of *neffy* attaining and maintaining favorable coverage;
- the expected intellectual property protection for *neffy*;
- legislative and regulatory developments in the United States and foreign countries;
- estimates regarding anticipated operating losses, capital requirements and needs for additional funds;
- our ability to obtain, maintain and successfully enforce adequate patent and other intellectual property protection for *neffy* or any future product candidate; and
- statements of belief and any statement of assumptions underlying any of the foregoing.

Any forward-looking statements in this Quarterly Report reflect our current views with respect to future events or to our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under Part II, Item 1A, “Risk Factors” of this Quarterly Report. In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this report, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain, and you are cautioned not to unduly rely upon these statements. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

Unless the context otherwise indicates, references in this Quarterly Report to the terms “ARS”, “the Company”, “we”, “our” and “us” refer to ARS Pharmaceuticals, Inc. and its consolidated subsidiaries, and references to our “common stock” refers to our voting common stock.

neffy is a trademark of ours that we use in this Quarterly Report. This Quarterly Report also includes trademarks, trade names, and service marks that are the property of other organizations. Solely for convenience, our trademarks and trade names referred to in this Quarterly Report appear without the ® or ™ symbols, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights, or the right of the applicable licensor, to our trademark and trade names. The use or display of other companies’ trade names or trademarks do not suggest or imply a relationship or affiliation with, or endorsement or sponsorship of us by, any other companies.

SUMMARY OF RISKS ASSOCIATED WITH OUR BUSINESS

An investment in shares of our common stock involves a high degree of risk. Below is a list of the more significant risks associated with our business. This summary does not address all of the risks that we face. Additional discussion of the risks listed in this summary, as well as other risks that we face, are set forth under Part II, Item 1A, “Risk Factors” in this Quarterly Report. Some of the material risks associated with our business include the following:

- We are highly dependent on the successful commercialization of *neffy* in the United States and in the EU for its currently approved indications in those jurisdictions. To the extent *neffy* is not commercially successful, our business, financial condition and results of operations would be materially adversely affected, and the price of our common stock would likely decline.
- *neffy* and our current and future intranasal epinephrine technology product candidates may fail to achieve the degree of market acceptance by allergists, pediatricians and other physicians, patients, caregivers, third-party payors and others in the medical community necessary for commercial success, in which case we may not generate significant revenues or profits.
- If we are unable to achieve and maintain adequate levels of third-party payor coverage and reimbursement for *neffy* on reasonable pricing terms, its commercial success may be severely hindered.
- Competitive products may reduce or eliminate the commercial opportunity for *neffy* or our current and future intranasal epinephrine technology product candidates. If our competitors develop technologies or product candidates more rapidly than us, or their technologies or product candidates are more effective or safer than ours, our ability to develop and successfully commercialize *neffy* and our current and future intranasal epinephrine technology product candidates may be adversely affected.
- If we are unable to successfully develop our current or future intranasal epinephrine technology product candidates, or *neffy* for additional indications, or experience significant delays in doing so, the commercial potential of our current or future intranasal epinephrine technology product candidates or *neffy* will be more limited.
- If the U.S. Food and Drug Administration (“FDA”) does not conclude that our current or future intranasal epinephrine technology product candidates, or *neffy* for additional indications, satisfy the requirements for the Section 505(b)(2) regulatory approval pathway, or if the requirements for such product candidates or additional indications under Section 505(b)(2) are not as we expect, the approval pathway for those product candidates or additional indications will likely take significantly longer, cost significantly more and entail significantly greater complications and risks than anticipated, and in either case may not be successful.
- Product liability lawsuits against us or any of our current and future licensing and collaboration partners could divert our resources and attention, cause us to incur substantial liabilities and limit commercialization of *neffy* or our current or future intranasal epinephrine technology product candidates.
- If our information technology systems or data, or those of third parties with whom we work, are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse consequences.
- We rely completely on third parties to manufacture and warehouse both our domestic and international supply of *neffy* and our current and future intranasal epinephrine technology product candidates.
- We are dependent on international third-party licensees and assignees for the development and commercialization of *neffy* and our current and future intranasal epinephrine technology product candidates outside the United States. If these third parties are not successful in their development and commercialization efforts or if these third parties fail to meet their contractual, regulatory or other obligations, our business and results of operations could be adversely affected.
- International trade policies, including tariffs, sanctions and trade barriers may adversely affect our business, financial condition, results of operations and prospects.
- We expect that our timing of sales and results of operations will fluctuate for the foreseeable future, which may make it difficult to predict our future performance from period to period.
- We have incurred significant losses since our inception.
- We may need additional funding, and if we are unable to raise capital when needed, we could be forced to delay, reduce or eliminate our product development activities or commercialization efforts.

- Our commercial success depends on our ability to obtain and maintain sufficient intellectual property protection for *neffy*, our current and future intranasal epinephrine technology product candidates and other proprietary technologies.
- Our success is highly dependent on our ability to attract and retain highly skilled executive officers and employees.

PART I – FINANCIAL INFORMATION
Item 1. Financial Statements

ARS Pharmaceuticals, Inc.
Condensed Consolidated Balance Sheets
(in thousands, except par value and share amounts)

	<u>June 30, 2025</u>	<u>December 31, 2024</u>
	<u>(unaudited)</u>	
Assets		
Current assets:		
Cash and cash equivalents	\$ 51,540	\$ 50,817
Short-term investments	188,590	263,205
Accounts receivable, net	25,126	8,175
Inventories	8,738	5,212
Prepaid expenses and other current assets	7,442	6,886
Total current assets	281,436	334,295
Long-term inventories	13,374	5,307
Right-of-use asset	1,564	37
Fixed assets, net	1,075	1,029
Intangible assets, net	12,972	7,371
Other assets	3,051	3,114
Total assets	<u>\$ 313,472</u>	<u>\$ 351,153</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued liabilities (including related party amounts of \$1,091 and \$656, respectively)	\$ 44,264	\$ 22,841
Contract liability, current	746	557
Lease liability, current	589	42
Total current liabilities	45,599	23,440
Financing liability	71,959	69,383
Contract liability, net of current portion	1,103	1,532
Lease liability, net of current portion	1,072	—
Other accrued liabilities	1,418	—
Total liabilities	121,151	94,355
Commitments and contingencies (Note 9)		
Stockholders' equity		
Preferred stock, \$0.0001 par value per share; 10,000,000 shares authorized at June 30, 2025 and December 31, 2024; no shares issued and outstanding at June 30, 2025 and December 31, 2024	—	—
Common stock, \$0.0001 par value per share; 200,000,000 shares authorized at June 30, 2025 and December 31, 2024; 98,697,658 and 97,954,172 shares issued and outstanding at June 30, 2025 and December 31, 2024, respectively	10	10
Additional paid-in capital	394,485	379,873
Accumulated other comprehensive (loss) gain, net	(46)	220
Accumulated deficit	(202,128)	(123,305)
Total stockholders' equity	192,321	256,798
Total liabilities and stockholders' equity	<u>\$ 313,472</u>	<u>\$ 351,153</u>

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

ARS Pharmaceuticals, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share data)
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Revenue:				
Product revenue, net	\$ 12,800	\$ —	\$ 20,563	\$ —
Revenue under collaboration agreements	2,594	500	2,804	500
Revenue under supply agreements	323	—	323	—
Total revenue	15,717	500	23,690	500
Operating expenses:				
Cost of goods sold (including related party amounts of \$866, \$0, \$1,354, and \$0, respectively)	4,984	—	6,078	—
Research and development (including related party amounts of \$582, \$518, \$1,245, and \$1,245, respectively)	4,035	6,896	6,987	12,130
Selling, general and administrative (including related party amounts of \$107, \$114, \$231, and \$208, respectively)	54,312	8,944	95,416	16,902
Total operating expenses	63,331	15,840	108,481	29,032
Loss from operations	(47,614)	(15,340)	(84,791)	(28,532)
Other income, net	2,731	2,824	5,968	5,724
Net loss	\$ (44,883)	\$ (12,516)	\$ (78,823)	\$ (22,808)
Change in unrealized gains and losses on available-for-sale securities	(118)	(21)	(266)	(194)
Comprehensive loss	\$ (45,001)	\$ (12,537)	\$ (79,089)	\$ (23,002)
Net loss per share, basic and diluted	\$ (0.46)	\$ (0.13)	\$ (0.80)	\$ (0.24)
Weighted-average shares outstanding used in computing net loss per share, basic and diluted	98,361,771	96,827,687	98,212,035	96,656,690

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

ARS Pharmaceuticals, Inc.
Condensed Consolidated Statements of Stockholders' Equity
(in thousands, except share data)
(unaudited)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Gain (Loss), Net	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2024	97,954,172	\$ 10	\$ 379,873	\$ 220	\$ (123,305)	\$ 256,798
Exercise of common stock options and release of restricted stock units	175,632	—	725	—	—	725
Stock-based compensation	—	—	5,539	—	—	5,539
Net loss and comprehensive loss	—	—	—	(148)	(33,940)	(34,088)
Balance at March 31, 2025	98,129,804	10	386,137	72	(157,245)	228,974
Exercise of common stock options and issuance of common stock under the employee stock purchase plan	567,854	—	2,697	—	—	2,697
Stock-based compensation	—	—	5,651	—	—	5,651
Net loss and comprehensive loss	—	—	—	(118)	(44,883)	(45,001)
Balance at June 30, 2025	98,697,658	\$ 10	\$ 394,485	\$ (46)	\$ (202,128)	\$ 192,321
	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Gain (Loss), Net	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2023	96,414,963	\$ 10	\$ 362,004	\$ 49	\$ (131,303)	\$ 230,760
Exercise of common stock options and release of restricted stock units	159,086	—	258	—	—	258
Stock-based compensation	—	—	3,315	—	—	3,315
Net loss and comprehensive loss	—	—	—	(173)	(10,292)	(10,465)
Balance at March 31, 2024	96,574,049	10	365,577	(124)	(141,595)	223,868
Exercise of common stock options, shares issued under the employee stock purchase plan, and release of restricted stock units	365,748	—	545	—	—	545
Stock-based compensation	—	—	3,365	—	—	3,365
Net loss and comprehensive loss	—	—	—	(21)	(12,516)	(12,537)
Balance at June 30, 2024	96,939,797	\$ 10	\$ 369,487	\$ (145)	\$ (154,111)	\$ 215,241

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

ARS Pharmaceuticals, Inc.
Condensed Consolidated Statements of Cash Flows
(in thousands)
(unaudited)

	<u>Six Months Ended June 30,</u>	
	<u>2025</u>	<u>2024</u>
Cash flows from operating activities:		
Net loss	\$ (78,823)	\$ (22,808)
Non-cash adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	10,669	6,680
Depreciation and amortization expense	559	29
Accretion on investments, net of amortization	(3,428)	(3,884)
Provision for inventory reserve	2,160	—
Changes in operating assets and liabilities:		
Accounts receivable	(14,375)	—
Inventories	(13,232)	—
Prepaid expenses and other assets	(697)	1,564
Donation of equipment	—	30
Accounts payable and accrued liabilities	16,981	4,410
Operating lease right-of-use asset and lease liability, net	92	(10)
Contract liability	(240)	—
Net cash and cash equivalents used in operating activities	(80,334)	(13,989)
Cash flows from investing activities:		
Purchases of short-term investments, available-for-sale	(65,723)	(151,038)
Maturities of short-term investments, available-for-sale	143,500	130,000
Purchases of property and equipment	(142)	(121)
Net cash and cash equivalents provided by (used in) investing activities	77,635	(21,159)
Cash flows from financing activities:		
Proceeds from exercise of common stock options and issuance of common stock under the employee stock purchase plan	3,422	803
Net cash and cash equivalents provided by financing activities	3,422	803
Net increase (decrease) in cash and cash equivalents	723	(34,345)
Cash and cash equivalents at beginning of period	50,817	70,971
Cash and cash equivalents at end of period	<u>\$ 51,540</u>	<u>\$ 36,626</u>
Supplemental cash flow information:		
Intangible assets included in accounts payable and accrued liabilities	\$ 5,860	\$ —
Financing liability included in accounts receivable	\$ 2,576	\$ —
Right-of-use asset obtained in exchange for operating lease obligations	\$ 1,630	\$ —

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

ARS Pharmaceuticals, Inc.
Notes to Unaudited Condensed Consolidated Financial Statements

1. Nature of Business

Description of Business

ARS Pharmaceuticals, Inc. (“ARS”, “ARS Pharma” or the “Company”) is a biopharmaceutical company focused on the commercialization and development of *neffy* (currently identified in the EU by the trade name *EURneffy*) for the needle-free intranasal delivery of epinephrine for the emergency treatment of Type I allergic reactions, including anaphylaxis. *neffy* is the first and only FDA and European Commission-approved needle-free epinephrine product, and the first new delivery method for epinephrine in more than 35 years.

The Company incorporated in Delaware in January 2016 and is located in San Diego, California. The Company has a wholly owned subsidiary, ARS Pharmaceuticals Operations, Inc., incorporated in Delaware in August 2015, through which it conducts substantially all its operations. ARS Pharmaceuticals Operations, Inc. has a wholly owned subsidiary in Ireland, ARS Pharmaceuticals IRL, Limited, to facilitate the filing of regulatory approval for *neffy* in European countries.

Liquidity and Capital Resources

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. The Company has incurred net operating losses in most years since its inception and had an accumulated deficit of \$202.1 million as of June 30, 2025. The Company had cash, cash equivalents, and short-term investments of \$240.1 million as of June 30, 2025 and has not generated positive cash flows from operations in most years. To date, the Company has funded its operations primarily with proceeds from the merger with Silverback in November 2022 (the “Merger”), private placement of convertible preferred stock, issuance of common stock, licensing, supply and distribution agreements, bank debt, and net product sales. The Company’s currently available cash, cash equivalents, and short-term investments as of June 30, 2025 are sufficient to meet its anticipated cash requirements for at least the 12 months following the date these financial statements are issued.

From August 5, 2015 (inception) through June 30, 2025, the Company has devoted substantially all of its efforts to developing intellectual property, conducting product development and clinical trials, organizing and staffing the Company, business planning, raising capital, building infrastructure, pre-commercial and commercial activities, and providing general and administrative support for these operations. The Company has a limited operating history, and the sales and income potential of the Company’s business and market are unproven. Management expects operating expenses to increase for the foreseeable future, and there can be no assurance that the Company will achieve profitability in the future, or if achieved, that it will be sustained on a continuing basis.

2. Summary of Significant Accounting Policies

Basis of Presentation and Principles of Consolidation

The financial statements have been prepared in conformity with U.S. generally accepted accounting principles (“U.S. GAAP”). Any reference in these notes to applicable guidance is meant to refer to the authoritative U.S. GAAP as found in the Accounting Standards Codification (“ASC”), and Accounting Standards Update (“ASU”), of the Financial Accounting Standards Board (“FASB”). The Company’s financial statements are presented on a condensed consolidated basis, which include the accounts of ARS Pharmaceuticals, Inc., ARS Pharmaceuticals Operations, Inc. and ARS Pharmaceuticals IRL, Limited. All intercompany accounts and transactions have been eliminated in consolidation. The Company’s functional and reporting currency is the U.S. dollar. Assets and liabilities that are not denominated in the functional currency are remeasured into U.S. dollars at foreign currency exchange rates in effect at the balance sheet date except for nonmonetary assets, which are remeasured at historical foreign currency exchange rates in effect at the date of transaction. Net realized and unrealized gains and losses from foreign currency transactions and remeasurement are reported in other income in the condensed consolidated statements of operations and comprehensive loss. All adjustments considered necessary for a fair presentation have been included.

Unaudited Interim Condensed Consolidated Financial Statements

The accompanying condensed consolidated balance sheet as of June 30, 2025, the condensed consolidated statements of operations and comprehensive loss for the three and six months ended June 30, 2025 and 2024, the condensed consolidated statements of stockholders' equity for the three and six months ended June 30, 2025 and 2024, and the condensed consolidated statements of cash flows for the six months ended June 30, 2025 and 2024, are unaudited. The balance sheet as of December 31, 2024 was derived from the audited financial statements as of and for the year ended December 31, 2024. The unaudited interim condensed consolidated financial statements have been prepared on a basis consistent with the audited annual financial statements as of and for the year ended December 31, 2024, and, in the opinion of management, reflect all adjustments, consisting solely of normal recurring adjustments, necessary for the fair presentation of the Company's financial position as of June 30, 2025, the condensed consolidated results of its operations for the three and six months ended June 30, 2025 and 2024, and its cash flows for the six months ended June 30, 2025 and 2024. The financial data and other information disclosed in these notes related to the three and six months ended June 30, 2025 and 2024 are also unaudited. The condensed consolidated results of operations for the three and six months ended June 30, 2025 are not necessarily indicative of the results to be expected for the full year ending December 31, 2025 or any other period.

Use of Estimates

The preparation of the Company's condensed consolidated financial statements requires it to make estimates and assumptions that impact the reported amounts of assets, liabilities, revenues and expenses and the disclosure of contingent assets and liabilities in the Company's condensed consolidated financial statements and accompanying notes. The most significant estimates in the Company's condensed consolidated financial statements are revenue recognized under collaboration agreements, accruals for variable components of product revenue, accruals for research and development expenses, and valuation of equity awards. These estimates and assumptions are based on current facts, historical experience and various other factors believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities and the recording of revenue and expenses that are not readily apparent from other sources. Actual results may differ materially and adversely from these estimates. To the extent there are material differences between the estimates and actual results, the Company's future results of operations will be affected.

Cash and Cash Equivalents

Cash and cash equivalents include cash readily available in checking, money market mutual funds, and short-term investments with remaining maturities when purchased of 90 days or less. The Company considers all highly liquid investments with remaining maturities when purchased of 90 days or less to be cash equivalents.

Accounts Receivable and Allowance for Credit Losses

Accounts receivable includes trade accounts receivable from product sales to customers, partner receivables for reimbursable research and development costs, royalties, license fees, and milestone payments under the Company's collaboration agreements, and partner receivables for supply of *neffy* under the Company's supply agreements. Trade accounts receivable are recorded at wholesale acquisition cost ("WAC"), less purchase price discounts, prompt pay discounts, chargebacks, and an allowance for credit losses, if any. The allowance for credit losses is the Company's estimate of losses over the life of the receivables. The Company determines the allowance for credit losses for accounts receivable based on each customer's or partner's accounts receivable balance and age, their financial condition, and the general economic environment. The Company must also use professional judgment for its allowance for credit losses on trade accounts receivable as *neffy* was commercially launched in September 2024 and historical data is limited. The Company is currently operating under the Title Agreement (as defined in [Note 3 – Revenue](#)) with its Title Agent (as defined in [Note 3 – Revenue](#)) and the Title Agent retains all credit and collection risk on product sales to the Company's wholesale distributors and pharmacy customers.

When the collectability of an invoice is no longer probable, the Company will create a reserve for that specific receivable. If a receivable is determined to be uncollectible, it is charged against the general credit loss reserve or the reserve for the specific receivable, if one exists. No allowance for credit losses was deemed necessary at June 30, 2025 or December 31, 2024.

Investments

The Company invests excess cash in investment grade fixed income securities. These investments are included in short-term investments on the condensed consolidated balance sheets, classified as available-for-sale, and reported at fair value with unrealized gains and losses included in accumulated other comprehensive (loss) gain, net. Realized gains and losses on the sale of securities are recognized in net loss.

Fair Value of Financial Instruments

Cash, cash equivalents, and short-term investments are carried at fair value. The carrying amounts of all accounts receivable, prepaid expenses and other current assets, accounts payable, accrued liabilities, and contract liability are considered to be representative of their respective fair values because of the short-term nature of those instruments.

Concentrations of Credit Risk

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash, cash equivalents, and short-term investments. The Company maintains deposits in federally insured financial institutions in excess of federally insured limits and limits its exposure to cash risk by placing its cash with high credit quality financial institutions.

The Company reviews its financial instruments portfolio on a quarterly basis to determine if any unrealized losses have resulted from a credit loss or other factors. As part of the review, management considers factors such as historical experience, market data, issuer-specific factors, and current economic conditions. This review is subjective, as it requires management to evaluate whether an event or change in circumstances has occurred in that period that may be related to credit issues.

The Company is also subject to credit risk related to its accounts receivable from product sales and revenue under collaboration and supply agreements. *neffy* is distributed primarily through wholesale distributors and pharmacies. These entities are not obligated to purchase any set number of units and they distribute *neffy* on demand as orders are received. The Company enters into collaboration and supply agreements with pharmaceutical companies under which the Company is entitled to receive payments for royalties, license fees, milestone achievements, reimbursable costs for research and development services, and supply of *neffy*. The Company extends credit to its customers and partners in the normal course of business after evaluating their overall financial condition. As stated above, the Company is currently operating under the Title Agreement with its Title Agent and the Title Agent retains all credit and collection risk on sales to the Company's wholesale distributors and pharmacy customers. The Company's Title Agent accounts for 76% and 93% of the Company's accounts receivable balance as of June 30, 2025 and December 31, 2024, respectively. One additional customer accounted for 22% of accounts receivable as of June 30, 2025. For the three and six months ended June 30, 2025, four and six customers accounted for 82% and 96% of the Company's gross product sales, with each individual customer ranging from 15% to 23% and 10% to 25% of the Company's gross product sales, respectively. For the three and six months ended June 30, 2025, one customer accounted for all revenue under collaboration agreements and supply agreements. For the three and six months ended June 30, 2024, one customer accounted for all revenue under collaboration agreements, and there was no product sales or revenue under supply agreements. Historically, the Company has not experienced any credit losses.

Inventories

Inventories consist of finished goods held for sale and distribution, raw materials and work in process, and include labor and overhead. Inventories are stated at the lower of cost or net realizable value, and are determined on a first-in, first-out basis. Net realizable value is the estimated selling price in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. The Company periodically reviews its inventory to identify obsolete, slow-moving, or otherwise unsalable inventories, and establishes allowances for situations in which the cost of the inventory is not expected to be recovered. Such impairment charges, if any, are recorded in cost of goods sold on the condensed consolidated statements of operations.

The Company capitalizes inventory costs after regulatory approval, when future commercialization is considered probable, and a future economic benefit is expected to be realized. Prior to regulatory approval, the Company records inventory costs as research and development expenses. As such, when regulatory approval is received, this may result in zero-cost inventory which does not have a carrying value. This inventory is available to the Company to utilize for commercial operations as well as ongoing research and development activities.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation. Depreciation is calculated using the straight-line method over the estimated useful lives of the assets, generally five years. Repair and maintenance costs are charged to expense as incurred.

Impairment of Long-Lived Assets

Long-lived assets consist primarily of property and equipment and intangible assets. The Company reviews its long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. Recoverability is measured by comparison of the carrying amount to the future undiscounted net cash flows which the asset or asset group are expected to generate, including its eventual residual value. If such assets are considered to be impaired, the impairment to be recognized is measured as the amount by which the carrying amount of the assets exceeds its fair value. The Company has not recognized any impairment losses from inception through June 30, 2025.

Leases

The Company determines the initial classification and measurement of its right-of-use (“ROU”) asset and lease liabilities at the lease commencement date and thereafter, if modified. The Company recognizes a ROU asset for its operating leases with lease terms greater than 12 months. The lease term includes any renewal options and termination options that the Company is reasonably assured to exercise. The lease liability is calculated by using the present value of all lease payments, with the present value determined by using the incremental borrowing rate for operating leases determined by using the incremental borrowing rate of interest that the Company would pay to borrow on a collateralized basis an amount equal to the lease payments in a similar economic environment as well as a review of peer companies. Variable charges for common area maintenance and other variable costs are recognized as expense as incurred. Rent expense for operating leases is recognized on a straight-line basis over the reasonably assured lease term based on the total lease payments and is included in research and development and general and administrative expenses in the condensed consolidated statements of operations and comprehensive loss.

Intangible Assets

Intangible assets are measured at fair value as of the acquisition date or, in the case of commercial milestone payments, the date they become due. The evaluation of intangible assets includes assessing the amortization period for which the asset is expected to contribute to the future cash flows of the Company. Intangible assets with finite useful lives are amortized over their estimated useful lives, primarily on a straight-line basis when the Company is unable to reliably estimate the pattern of cash flow.

Revenue Recognition

The Company’s revenues consist of product sales of *neffy* and revenue derived from its collaboration, out-licensing, and supply agreements. See [Note 3 – Revenue](#) for more detail on product revenue, and [Note 8 – Collaboration and Out-Licensing](#) for more detail on revenue from collaboration agreements, out-licensing agreements, and supply agreements.

The Company recognizes revenue in accordance with ASC Topic 606, Revenue from Contracts with Customers (“ASC 606”). The provisions of ASC 606 require the following steps to determine revenue recognition: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations based on estimated selling prices; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation. At contract inception, the Company assesses the goods or services promised within each contract, determines whether each promised good or service is distinct and identifies those that are performance obligations. The Company recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

Cost of Goods Sold

Cost of goods sold primarily consists of direct and indirect costs related to the manufacture of *neffy* for commercial sale, including salaries and related expenses for personnel, stock-based compensation, third-party manufacturing costs, raw material and component costs, packaging services, freight, storage costs, distribution fees, amortization of capitalized in-licensed costs, supply agreement fees, and royalties on product sales. Prior to the FDA approval of *neffy* in August 2024, costs incurred for the manufacture of *neffy* were recorded as research and development expenses, which resulted in zero-cost inventory. As a result, the cost of goods sold related to *neffy* initially reflects a lower average per unit cost of materials, as previously expensed zero-cost inventory is utilized for commercial production and sold to customers.

Research and Development Costs

Research and development costs are expensed in the period incurred. Research and development costs primarily consist of salaries and related expenses for personnel, stock-based compensation expense, external research and development costs incurred under agreements with contract research organizations, investigative sites and consultants to conduct clinical studies, costs related to compliance with regulatory requirements, costs related to manufacturing the Company's product candidates (including *neffy* prior to FDA approval in August 2024) for clinical trials, and other allocated expenses.

Payments for research and development activities are based on the terms of the individual agreements, which may differ from the pattern of costs incurred, and payments made in advance of performance are reflected in the accompanying condensed consolidated balance sheets as prepaid expenses. The Company records accruals for estimated costs incurred for ongoing research and development activities. When evaluating the adequacy of the accrued liabilities, the Company analyzes progress of the services, including the phase or completion of events, invoices received and contracted costs. The Company uses judgments and estimates to determine the prepaid or accrued balances at the end of any reporting period. Actual results could differ from the Company's estimates.

Selling, General and Administrative Costs

Selling, general and administrative costs are expensed in the period incurred. Selling, general and administrative costs primarily consist of marketing-related expenses, salaries and related expenses for personnel, including meals and travel-related expenses incurred by the sales team, stock-based compensation, legal fees incurred relating to corporate and patent matters, professional fees incurred for accounting, auditing, tax, and other consulting services, and insurance costs.

Advertising

Costs for producing advertising are expensed when incurred. Costs for communicating advertising, such as search engine marketing, banner advertisements, social media advertisements, and print advertisements, are recorded as prepaid expenses and then expensed when the advertisement occurs. For the three and six months ended June 30, 2025, advertising costs were \$20.9 million and \$31.9 million, respectively. No advertising costs were incurred for the three and six months ended June 30, 2024.

Patent Costs

Costs related to filing and pursuing patent applications are recorded as general and administrative expenses in the statements of operations and expensed as incurred since recoverability of such expenditures is uncertain.

License Fees

Costs incurred to acquire technology licenses and milestone payments made on existing agreements are expensed or capitalized based upon the asset achieving technological feasibility in accordance with management's assessment regarding the ultimate recoverability of the amounts paid and the potential for alternative future use.

Stock-Based Compensation

Stock-based compensation expense represents the cost of the grant date fair value of stock option grants recognized over the requisite service period of the awards (usually the vesting period) on a straight-line basis. The Company recognizes expense for awards subject to performance-based milestones over the remaining service period when management determines that achievement of the milestone is probable. Management evaluates when the achievement of a performance-based milestone is probable based on the expected satisfaction of the performance conditions at each reporting date. The Company estimates the fair value of stock option grants using the Black-Scholes option pricing model and recognizes forfeitures as they occur. In the event that stock-based awards are granted in contemplation of or shortly before a planned release of material non-public information, and such information is expected to result in a material increase in the share price of the Company's common stock, the Company may consider whether an adjustment to the observable market price is required when estimating the grant date fair value.

Comprehensive Loss

Comprehensive loss is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources. The Company's comprehensive loss typically consists of the change in unrealized gains and losses on available-for-sale securities.

Segment Reporting

Operating segments are components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision-maker for purposes of making decisions regarding resource allocation and assessing performance. The Company views its operations and manages its business as one operating segment.

Net Loss Per Share

Basic net loss per share attributable to common stockholders is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding for the period, without consideration of potentially dilutive securities. Diluted net loss per share attributable to common stockholders is the same as basic net loss per share attributable to common stockholders since the effect of potentially dilutive securities is anti-dilutive given the net loss of the Company. For purposes of this calculation, stock options, warrants, and unvested restricted stock units, are considered to be common stock equivalents but are not included in the calculations of diluted net loss per share for the periods presented as their effect would be antidilutive.

The following securities are excluded from the calculation of weighted-average dilutive common shares because their inclusion would have been anti-dilutive:

	As of June 30,	
	2025	2024
Warrants to purchase common stock	45,456	45,456
Common stock options granted and outstanding	17,271,990	14,436,432
Unvested restricted stock units	1,382	2,763
Total	17,318,828	14,484,651

Recently Adopted Accounting Pronouncements

In November 2023, the FASB issued ASU No. 2023-07, *Segment Reporting (Topic 280)—Improvements to Reportable Segment Disclosures* ("ASU 2023-07"), which requires issuers to make additional disclosures with respect to segment expenses, including required disclosure on an annual and interim basis for significant segment expenses and other segment items. ASU 2023-07 also permits the disclosure of more than one measure of a segment's profit or loss. ASU 2023-07 was effective for the Company on January 1, 2024 for annual periods and on January 1, 2025 for interim periods. The adoption of ASU 2023-07 resulted in enhanced disclosures as included in [Note 15 – Segment Information](#) and did not impact the Company's condensed consolidated financial statements.

Recently Issued Accounting Pronouncements — Not Yet Adopted

From time to time, new accounting pronouncements are issued by the FASB or other standards setting bodies that are adopted as of the specified effective date. The Company believes the impact of recently issued standards, other than those noted below, and any issued but not yet effective standards will not have a material impact on our financial statements upon adoption.

In December 2023, the FASB issued ASU No. 2023-09, *Income Taxes (Topic 740)–Improvements to Income Tax Disclosures* (“ASU 2023-09”). The new standard requires a company to expand its existing income tax disclosures, specifically related to the rate reconciliation and income taxes paid. The amendments in this update are effective for annual periods beginning after December 15, 2024, with early adoption permitted. The Company does not expect to early adopt the new standard. The new standard is expected to be applied prospectively, but retrospective application is permitted. The Company is currently evaluating the impact of ASU 2023-09 on the financial statements and related disclosures.

In November 2024, the FASB issued ASU No. 2024-03, *Income Statement–Reporting Comprehensive Income–Expense Disaggregation Disclosures (Subtopic 220-40)* (“ASU 2024-03”). The amendments in this update require disclosure, in the notes to the financial statements, of specific expense categories present within expense captions presented on the face of the income statement within continuing operations of public business entities. The amendments in this update are effective for annual periods beginning after December 15, 2026 and interim periods beginning after December 15, 2027. Early adoption is permitted. The amendments should be applied either prospectively to financial statements issued for reporting periods after the effective date of this ASU or retrospectively to any and all prior periods presented in the financial statements. The impact of adoption of this ASU on the Company’s disclosures is currently being evaluated.

3. Revenue

The Company’s revenues consist primarily of product sales of *neffy*, revenue derived from its collaboration and out-licensing agreements, and revenue from its supply agreements. See [Note 8 – Collaboration and Out-Licensing](#) for further discussion related to revenue from collaboration, out-licensing, and supply agreements.

Product Revenue

neffy was approved by the FDA in August 2024, and the Company began generating product revenue from sales of *neffy* in September 2024. The Company uses a third-party logistics provider (“3PL Agent”) to fulfill orders of *neffy* to the Company’s customers. The 3PL Agent provides services to the Company that include warehousing, distribution, order and accounts receivable management, and data management.

The Company entered into a title model agreement (“Title Agreement”) with an affiliate of the 3PL Agent (the “Title Agent”) so that the Title Agent may purchase and take title to *neffy* and then sell it to the Company’s wholesale distributors and pharmacy customers that have contracted to make a purchase. Under the Title Agreement, the economic substance of the transaction is such that the Company does not recognize revenue until *neffy* is sold and title has transferred from the Title Agent to a wholesale distributor or pharmacy.

The Company also entered into sales agreements with pharmacies that are not subject to the Title Agreement. Under these agreements, the pharmacy holds *neffy* under consignment. Under the consignment model, the Company recognizes revenue when *neffy* is sold to a patient, at which point title transfers from the Company directly to the patient.

Product revenue is recorded with each sale at the transaction price, net of reserves for variable components, including but not limited to distribution service fees, prompt pay discounts, product returns, chargebacks, rebates, and co-payment assistance, which are collectively referred to as “Gross-to-Net Adjustments.” Estimates for Gross-to-Net Adjustments are reassessed each reporting period, and adjustments are recorded on a cumulative catch-up basis, which would affect product revenue and net loss in the period of adjustment. Trade accounts receivable due to the Company from contracts with its customers are stated in the condensed consolidated balance sheet, net of various allowances as described in the Accounts Receivable and Allowance for Credit Losses policy in [Note 2 – Summary of Significant Accounting Policies](#).

The Company utilizes the expected value method when estimating the amount of variable consideration to include in the transaction price with respect to each of the foregoing variable components. Variable consideration is included in the transaction price only to the extent it is probable that a significant revenue reversal will not occur when the uncertainty associated with the variable consideration is resolved.

In accordance with ASC 606, the Company must make significant judgments to determine the estimate for certain Gross-to-Net Adjustments. The specific considerations that the Company uses in estimating the amounts related to Gross-to-Net Adjustments are as follows:

Distribution Service Fees. The Company pays distribution service fees to its wholesale distributors. These fees are a contractually fixed percentage of WAC and are calculated at the time of sale based on the purchased amount. These fees are recorded as other current liabilities on the condensed consolidated balance sheets.

Commercial Pharmacy Discounts. The Company provides discounts to its pharmacy customers. These discounts are a contractually fixed percentage of WAC and are a direct reduction from the WAC price they are charged. They are calculated at the time of sale based on the purchased amount. These discounts are recorded as contra trade accounts receivable on the condensed consolidated balance sheets.

Prompt Pay Discounts. The Company incentivizes on time invoice payments through prompt pay discounts. Prompt pay discounts are typically taken by customers, so an estimate of the discount is recorded at the time of sale based on the purchased amount. Prompt pay discount estimates are recorded as contra trade accounts receivable on the condensed consolidated balance sheets.

Chargebacks. Certain government entities and covered entities (e.g. Veterans Administration, 340B covered entities) can purchase the product at a price discounted below WAC. The difference between the government or covered entity purchase price and WAC will be charged back to the Company. The Company estimates the amount of chargebacks based on the expected number of claims and the related cost that is associated with the revenue being recognized for product that remains in the distribution channel at the end of each reporting period. Estimated chargebacks are recorded as contra trade accounts receivable on the condensed consolidated balance sheets.

Rebates. The Company provides commercial rebates to pharmacy benefit managers and managed care organizations and is subject to mandatory discount obligations under the Medicare, Medicaid, and Tricare programs. The rebate amounts for these programs are determined by contractual arrangements or statutory requirements. Rebates are owed after the product has been dispensed to a patient and the Company has been invoiced. The Company estimates the amount in rebates based on the expected number of claims and the related cost that is associated with the revenue being recognized for product that remains in the distribution channel at the end of each reporting period. Rebate estimates are recorded as other current liabilities on the condensed consolidated balance sheets.

Co-payment Program. The Company offers co-payment assistance programs to commercially insured patients whose insurance requires a co-payment to be made when filling their prescription. The Company estimates the amount of co-payment assistance based on the expected volume and the average buy down rate associated with the revenue being recognized for product that remains in the distribution channel at the end of each reporting period. Co-payment programs estimates are recorded as other current liabilities on the condensed consolidated balance sheets.

Product Returns. Customers have the right to return damaged product, product that is within six months or less of the labeled expiration date, or product that is past the expiration date by no more than twelve months. *neffy* was commercially launched in September 2024 and due to the lack of historical sales and returns data, the Company used professional judgment and industry data to estimate returns. As time passes and historical data becomes available, the Company will use historical sales and returns data to estimate future product returns. A reserve for potential product returns is recorded as other current liabilities on the condensed consolidated balance sheets.

4. Inventories

The Company began to capitalize the inventory costs associated with *neffy* upon FDA approval in August 2024 when future commercialization was considered probable, and it was determined that the inventory had a probable future economic benefit. These inventory costs consist primarily of purchased materials, third-party manufacturing costs, and packaging and serialization services. Noncurrent inventory consists of inventory anticipated to remain on hand for more than one year from the balance sheet date.

Capitalized inventories consisted of the following (in thousands):

	June 30, 2025	December 31, 2024
Raw materials	\$ 17,784	\$ 4,674
Work in process	—	19
Finished goods	6,488	5,826
Inventory reserve	(2,160)	—
Total inventories, net	<u>\$ 22,112</u>	<u>\$ 10,519</u>
Reported as:		
Inventories	\$ 8,738	\$ 5,212
Long-term inventories	13,374	5,307
Total inventories, net	<u>\$ 22,112</u>	<u>\$ 10,519</u>

Prior to FDA approval in August 2024, costs incurred for the manufacturing of *neffy* were recorded as research and development expenses, which upon approval resulted in zero-cost inventory. The Company held \$9.8 million and \$11.7 million in zero-cost inventory as of June 30, 2025 and December 31, 2024, respectively, none of which was determined to be obsolete as of each period end. The Company expects to fully utilize its zero-cost inventory in future periods.

5. Fair Value Measurements

The Company categorizes its assets and liabilities measured at fair value in accordance with the authoritative accounting guidance that establishes a consistent framework for measuring fair value and expands disclosures for each major asset and liability category measured at fair value on either a recurring or nonrecurring basis. Fair value is defined as the exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, the guidance establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

- Level 1 – Quoted prices (unadjusted) in active markets for identical assets or liabilities;
- Level 2 – Inputs other than quoted prices included within Level 1 that are either directly or indirectly observable; and
- Level 3 – Unobservable inputs in which little or no market activity exists, therefore requiring an entity to develop its own assumptions about the assumptions that market participants would use in pricing.

The following table identifies the Company's assets that were measured at fair value on a recurring basis (in thousands):

	Level	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
June 30, 2025					
Cash and cash equivalents - Money market mutual funds	1	\$ 51,248	\$ —	\$ —	\$ 51,248
Cash and cash equivalents - U.S. Treasury securities	2	—	—	—	—
Short-term investments - U.S. Treasury securities	2	188,636	6	(52)	188,590
Total		<u>\$ 239,884</u>	<u>\$ 6</u>	<u>\$ (52)</u>	<u>\$ 239,838</u>
December 31, 2024					
Cash and cash equivalents - Money market mutual funds	1	\$ 6,506	\$ —	\$ —	\$ 6,506
Cash and cash equivalents - U.S. Treasury securities	2	42,382	5	—	42,387
Short-term investments - U.S. Treasury securities	2	262,990	223	(8)	263,205
Total		<u>\$ 311,878</u>	<u>\$ 228</u>	<u>\$ (8)</u>	<u>\$ 312,098</u>

There were no transfers between the Level 1 and Level 2 categories or into or out of the Level 3 category during the periods presented. During the three and six months ended June 30, 2025, the Company purchased \$31.4 million and \$65.7 million, respectively, in short-term investments and there were \$80.0 million and \$143.5 million, respectively, in maturities of short-term investments. During the three and six months ended June 30, 2024, the Company purchased \$87.6 million and \$151.0 million, respectively, in short-term investments and there were \$75.0 million and \$130.0 million, respectively, in maturities of short-term investments.

The Company's short-term investments portfolio contains investments in U.S. Treasury securities that have an effective maturity date that is less than one year from the respective balance sheet date. The Company's money market mutual fund holdings are highly liquid and invest primarily in cash and U.S. Treasury securities.

There was a \$0.1 million and \$0.3 million net unrealized loss on available-for-sale securities for the three and six months ended June 30, 2025, respectively, and an immaterial and \$0.2 million unrealized loss on available-for-sale securities for the three and six months ended June 30, 2024, respectively. Management determined that the gross unrealized losses on the Company's available-for-sale securities as of June 30, 2025 were primarily attributable to current economic and market conditions and not credit risk. As of June 30, 2025 and December 31, 2024, no allowance for credit losses was recorded. It is neither management's intention to sell nor is it more likely than not that the Company will be required to sell any investments prior to recovery of its amortized cost basis, which is expected to be at maturity.

Accrued interest on the Company's available-for-sale securities was \$1.0 million as of June 30, 2025 and is included in prepaid expenses and other current assets in the accompanying condensed consolidated balance sheet.

As of June 30, 2025 and December 31, 2024, the Company did not have any liabilities that were measured at fair value on a recurring basis.

6. Balance Sheet Details

Prepaid expenses and other current assets consisted of the following (in thousands):

	June 30, 2025	December 31, 2024
Prepaid marketing	\$ 3,447	\$ 3,169
Prepaid insurance	1,012	1,261
Interest receivable	956	987
Other	2,027	1,469
Total	\$ 7,442	\$ 6,886

Other long-term assets consisted of the following (in thousands):

	June 30, 2025	December 31, 2024
Prepaid supply agreement fee	\$ 2,863	\$ 2,800
Capitalized software implementation costs	188	314
Total	\$ 3,051	\$ 3,114

Accounts payable and accrued liabilities consisted of the following (in thousands):

	June 30, 2025	December 31, 2024
Accounts payable	\$ 15,559	\$ 9,870
Accrued gross-to-net adjustments	11,341	2,179
Accrued marketing related expenses	6,374	1,855
Accrued compensation	4,306	2,293
Accrued inventory	539	4,255
Other	6,145	2,389
Total	\$ 44,264	\$ 22,841

7. Intangible assets, net

As described in [Note 10 – In-Licensing and Supply](#), under the Aegis Agreement the Company capitalized a \$2.5 million milestone payment in August 2024 and a \$5.0 million milestone payment in September 2024. Capitalized milestone payments are amortized on a straight-line basis over the estimated life of the intellectual property of 14.5 years, beginning from the first commercial sale of *neffy* in September 2024.

As described in [Note 8 – Collaboration and Out-Licensing](#), under the Recordati Termination Agreement the Company capitalized the achievement of a €5.0 million (\$5.9 million in U.S. dollars) milestone in June 2025. Capitalized milestone payments are amortized on a straight-line basis over the estimated life of the intellectual property of 13.5 years, beginning from the first commercial sale of *EURneffy* in June 2025.

Intangible assets, net, all of which are finite-lived, consisted of the following (in thousands):

	June 30, 2025	December 31, 2024
Capitalized milestone payments	\$ 13,360	\$ 7,500
Less accumulated depreciation	(388)	(129)
Total	\$ 12,972	\$ 7,371

The amortization expense for the three and six months ended June 30, 2025 was \$0.1 million and \$0.3 million, respectively. No intangible assets were held as of June 30, 2024, and there was no amortization expense recognized for the three and six months ended June 30, 2024.

As of June 30, 2025, estimated future amortization expense for capitalized intangible assets for the next five years is as follows (in thousands):

Year Ended December 31,	Amount
2025 (remaining six months)	\$ 476
2026	517
2027	517
2028	517
2029	517
Total	\$ 2,544

8. Collaboration, Out-Licensing and Related Agreements

The Company has entered into collaboration and licensing agreements, including supply and distribution, to license certain rights to *neffy* to third parties. The terms of these arrangements typically include payment to the Company of one or more of the following: non-refundable, upfront license fees; clinical, regulatory, and/or commercial milestone payments; payment for clinical and commercial supply; and royalties or a transfer price on the net sales of licensed products.

Licenses of Intellectual Property. If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, revenue is recognized from non-refundable, upfront payments allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. If the license is subject to repurchase by the Company, at its option, control of the license is not considered transferred to the customer, and in such case, the Company would account for the proceeds allocated to such license as either a financing obligation or a lease in accordance with ASC 606. Future amounts received related to the license which is subject to the Company's repurchase, such as royalties or milestone payments, would be accounted for as additional financing proceeds and would increase the financing obligation on the Company's condensed consolidated balance sheet. The Company would record such financing obligation as revenue when the right to repurchase has lapsed or was exercised.

If the license is not a distinct performance obligation, the Company evaluates the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, upfront fees. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

Milestone Payments. At the inception of each arrangement that includes clinical, regulatory or commercial milestone payments, the Company evaluates whether achieving the milestones is considered probable and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the value of the associated milestone is included in the transaction price. Milestone payments that are not within the Company's control, such as approvals from regulators or where attainment of the specified event is dependent on the development activities of a third party, are not considered probable of being achieved until those approvals are received or the specified event occurs. Revenue is recognized when the underlying performance obligation has been met.

Transaction Price Allocation. At the inception of each arrangement, the Company identifies its distinct performance obligations and allocates the transaction price to the performance obligations based upon their relative standalone selling prices. Standalone selling price is the price at which an entity would sell a promised good or service separately to a customer. The best evidence of standalone selling price is an observable price of a good or service when sold separately by an entity in similar circumstances to similar customers. Since the Company typically does not have such evidence, the Company estimates standalone selling price so that the amount that is allocated to each performance obligation equals the amount that the Company expects to receive for transferring the promised goods or services. The methods that the Company uses to make such estimates include (1) the adjusted market assessment approach, under which the Company forecasts product sales in the appropriate market, considers probability of commercialization success, and estimates discount rates; and (2) the expected cost of satisfying the performance obligations inclusive of a reasonable margin, also known as the expected cost plus margin approach.

Research and Development Revenues. For arrangements that contain research and development commitments, any arrangement consideration allocated to the research and development work is recognized as the underlying services are performed over the research and development term, if the criteria for over time recognition are met. If the over time recognition criteria are not met, research and development performance obligations are recognized at a point in time, when the research and development work is completed.

Clinical and Commercial Supply. Arrangements that include a promise for the future supply of drug product for either clinical development or commercial supply at the licensee's discretion are generally considered customer options. The Company assesses if these options provide a material right to the licensee and if so, they are accounted for as separate performance obligations. Revenue from product sales to the Company's collaboration partners is recognized at the point in time that the collaboration partner obtains control, which is typically based upon the terms of delivery of the product.

Royalty/Transfer Price Revenues. For arrangements that include sales-based royalties or transfer price, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

Alfresa Agreement

In March 2020, the Company signed a Letter of Intent ("LOI") with Alfresa Pharma Corporation ("Alfresa") for the right to negotiate a definitive agreement for the exclusive license and sublicenseable right to develop, register, import, manufacture and commercialize *neffy* in Japan in exchange for an upfront payment of \$2.0 million. In April 2020, the Company entered into a Collaboration and License Agreement for the rights pursuant to the LOI. Under the agreement, the Company delivered a license to *neffy* technology, completed a required clinical study, and remains obligated to use commercially reasonable efforts to develop and commercialize *neffy* in Japan. The parties agreed to share the cost of any additional clinical studies required for approval of *neffy* in Japan. Alfresa is solely responsible for regulatory and commercialization activities and may elect to assume responsibility for manufacturing and supplying drug product for commercial use in Japan. Either party may terminate the agreement for certain breaches of the agreement. Unless terminated earlier by either or both parties, the term of the agreement will continue until the later of (i) expiration of the last-to-expire patent in Japan; or (ii) 10 years after the first commercial sale of *neffy* in Japan.

In addition to the \$2.0 million received under the LOI, the Company was initially eligible to receive up to \$13.0 million in milestone payments upon achievement of certain clinical and regulatory milestones. Further, the Company is eligible to receive a negotiable transfer price expected to be in the low double-digit percentage on net sales subject to the regulatory approval to commercialize *neffy* in Japan.

At the commencement of this collaboration, the Company identified the following performance obligations: the license for *neffy* and research and development services, both of which have been completed. The Company determined the initial transaction price to be \$7.0 million, which includes a clinical milestone as it was deemed not probable of significant reversal at the inception of the agreement. Due to the uncertainty in the achievement of the regulatory and commercial milestones, the variable consideration associated with these future milestone payments has been fully constrained and is excluded from the transaction price until such time that the Company concludes that it is probable that a significant reversal of previously recognized revenue will not occur. These estimates will be reassessed at each reporting period. The transaction price was allocated to the performance obligations based on the estimated stand-alone selling price of each performance obligation.

In July 2020, the Company earned a \$5.0 million milestone payment upon the completion of a clinical milestone in Japan. In November 2024, the Company earned a \$6.0 million milestone payment upon the completion of a regulatory milestone in Japan. Of the \$13.0 million in milestone payments that the Company was eligible to earn, \$11.0 million in milestone payments has been earned and a final \$2.0 million regulatory milestone remains. For the three and six months ended June 30, 2025 and 2024, the Company recognized no revenue related to the Alfresa Agreement. As of both June 30, 2025 and December 31, 2024, there was no contract liability recorded for the final regulatory milestone.

Recordati Agreement

In September 2020, the Company entered into a License and Supply Agreement (the “Recordati Agreement”) with Recordati Ireland, Ltd. (“Recordati”) for the exclusive license and sublicensable right to develop, import, manufacture or have manufactured commercial product, file and hold regulatory approvals and commercialize *neffy* in Europe and certain European Free Trade Association, Russia/the Commonwealth of Independent States, Middle East and African countries (the “Recordati Territory”).

Under the terms of the Recordati Agreement, the Company received an upfront payment of \$11.8 million and a regulatory milestone payment of \$6.0 million during 2020.

At the commencement of this collaboration, the Company identified the following performance obligations: the license for *neffy* in the Recordati Territory and the research and development services. The Company determined the initial transaction price to be the \$11.8 million upfront payment. Due to the uncertainty in the achievement of all the developmental and commercial milestones, at inception of the contract, the variable consideration associated with future milestone payments was fully constrained and excluded from the transaction price until such time that the Company concludes that it is probable that a significant reversal of previously recognized revenue will not occur. The transaction price was allocated to the performance obligations based on the estimated stand-alone selling price of each performance obligation. In November 2020, the Company earned a regulatory milestone of \$6.0 million.

On February 22, 2023, the Company and Recordati entered into a termination agreement (the “Recordati Termination Agreement”), pursuant to which, among other things, the Company and Recordati agreed to terminate the Recordati Agreement. Pursuant to the Recordati Termination Agreement, the Company reacquired all of the Recordati Rights, paid Recordati a one-time upfront payment of €3.0 million (\$3.3 million in U.S. dollars), and has agreed to pay additional payments upon achievement of certain milestones including: (i) an EMA regulatory milestone payment of €2.0 million, (ii) a milestone payment of €5.0 million upon first commercial sale of *neffy* in the Recordati Territory, and (iii) royalty payments of up to €5.0 million in the aggregate from sales of *neffy* in the Recordati Territory (collectively, the “Recordati Rights”).

The Company determined that the Recordati Rights at the time of entering into the Recordati Termination Agreement had no alternative future use and therefore recorded the €3.0 million upfront payment to Recordati as an in-process research and development (“IPR&D”) expense presented within research and development expense. The Recordati Termination Agreement ended the Company’s performance obligations pursuant to the Recordati Agreement and consequently the existing contract liability of \$3.1 million previously received from Recordati was recorded against IPR&D expense presented within research and development expense in the accompanying condensed consolidated statements of operations and comprehensive loss. Accordingly, no revenue has been recognized subsequent to the Recordati Termination Agreement.

In June 2024, the EMA regulatory milestone was met and a €2.0 million (\$2.1 million in U.S. dollars) expense was recorded in research and development expense in the accompanying condensed consolidated statements of operations and comprehensive loss. The Company paid the EMA regulatory milestone to Recordati in July 2024. In June 2025, the first commercial sale milestone was met for the first commercial sale of *neffy* in the Recordati Territory. As a result, the Company capitalized the €5.0 million (\$5.9 million in U.S. dollars) milestone for the first commercial sale of *neffy* in the Recordati Territory to intangible assets in the accompanying condensed consolidated balance sheets. The Company paid the first commercial sale milestone to Recordati in July 2025. The intangible assets will be amortized through the cost of goods sold in the accompanying condensed consolidated statements of operations and comprehensive loss on a straight-line basis over the estimated life of the intellectual property of 13.5 years.

For each of the three and six months ended June 30, 2025, the Company recognized \$0.1 million in royalty expense from the sale of *neffy* in the Recordati Territory as cost of goods sold in the accompanying consolidated statements of operations and comprehensive loss.

Pediatrix Agreement

In March 2021, the Company entered into a Collaboration and Distribution Agreement with Pediatrix Therapeutics, Inc. (“Pediatrix”) for the exclusive license and sublicensable right to develop, import, manufacture or have manufactured commercial product, file and hold regulatory approvals and commercialize *neffy* in the People’s Republic of China, Taiwan, Macau, and Hong Kong (the “Pediatrix Territory”). Under the agreement, Pediatrix is responsible, at its sole cost and expense, for all ongoing development work that is necessary for or otherwise supports regulatory approval in the Pediatrix Territory, including all clinical trials, and activities related to post-approval commitments and commercialization tests. In addition, Pediatrix is responsible for commercialization activities and may elect to assume responsibility for manufacturing and supplying drug product for commercial use. The Company is responsible for the manufacturing of product for clinical studies as well as commercial supply, all at a negotiated transfer price. Either party may terminate the agreement for certain breaches of the agreement. Unless terminated earlier by either or both parties, the term of the agreement will continue until the later of (i) expiration of the last-to-expire patent in the Pediatrix Territory, (ii) the expiration of all regulatory exclusivities that cover *neffy* in the Pediatrix Territory, or (iii) 10 years after the first commercial sale of *neffy* in the Pediatrix Territory.

Under the terms of the agreement, the Company received an upfront payment of \$3.0 million. In addition, the Company is eligible to receive up to \$84.0 million in milestone payments upon achievement of certain regulatory and commercial sales milestones. The next eligible milestone is a \$4.0 million regulatory milestone. Subject to regulatory approval, the Company will earn tiered royalties in the low double-digits on annual net sales in the region and will receive a per unit supply price for the sale of commercial supply to Pediatrix.

At the commencement of this collaboration, the Company identified performance obligations related to the delivery of the license for *neffy* in the Pediatrix Territory and manufacturing of product for clinical studies and commercial supply. The Company concluded that the license was distinct from potential supply obligation. The supply provisions are effectively options granted to Pediatrix to purchase future goods and did not contain a material right. The Company determined the initial transaction price to be the \$3.0 million upfront payment. Due to the uncertainty in the achievement of all the developmental and commercial milestones, the variable consideration associated with these future milestone payments has been fully constrained and is excluded from the transaction price until such time that the Company concludes that it is probable that a significant reversal of previously recognized revenue will not occur. These estimates will be reassessed at each reporting period. The Company recognized revenue of the full \$3.0 million during the year ended December 31, 2021.

Seqirus Agreement

In March 2024, the Company entered into a License and Distribution Agreement (the “Seqirus Agreement”) with Seqirus Pty, Ltd. (“Seqirus”) for the exclusive license to commercialize *neffy* in Australia and New Zealand (the “Seqirus Territory”). Under the Seqirus Agreement, the Company is responsible for the transfer of know-how, which includes regulatory materials, regulatory data, and commercialization data, and also for the manufacturing of product for commercial supply which is available to Seqirus at a negotiated price. Seqirus is solely responsible for all regulatory and commercialization activities in the Seqirus Territory. Either party may terminate the Seqirus Agreement for certain breaches. Unless terminated earlier by either or both parties, the initial term of the Seqirus Agreement is 15 years from the first commercial sale of *neffy* in the Seqirus Territory. The Seqirus Agreement will automatically renew for two-year periods unless either party gives a notice to terminate at least 12 months prior to the end of the initial or any renewal term.

Under the terms of the Seqirus Agreement, the Company received an upfront payment of \$0.5 million in May 2024. In addition, the Company was eligible to receive up to \$4.5 million in milestone payments upon achievement of certain event milestones. Subject to regulatory approval in Australia and New Zealand, the Company will also receive a per unit supply price for the sale of commercial supply to Seqirus.

At the commencement of this collaboration, the Company identified one performance obligation which is the delivery of the license for *neffy* in the Seqirus Territory in combination with the transfer of know-how. The Company determined that the option to purchase the commercial supply does not represent a material right. The Company determined the initial transaction price to be the \$0.5 million upfront payment. Due to the uncertainty in the achievement of all the regulatory milestones, the variable consideration associated with these future milestone payments has been fully constrained and is excluded from the transaction price until such time that the Company concludes that it is probable that a significant reversal of previously recognized revenue will not occur. The variable consideration will be reassessed at each reporting period. In May 2024, the Company delivered the license for *neffy* in the Seqirus Territory in combination with the transfer of know-how and recognized \$0.5 million in revenue. In August 2024, the first milestone event was met and the Company recognized \$1.5 million in revenue.

ALK Collaboration Agreement

In November 2024, the Company entered into a Collaboration, License and Distribution Agreement (the “ALK Collaboration Agreement”) with ALK-Abelló A/S (“ALK”). Pursuant to the ALK 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) (“ALK Territory”), exclusive license under certain of the Company’s patents and know-how to develop, manufacture and commercialize products containing epinephrine administered intranasally, including *EURneffy* (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 (“New Product”), upon ALK’s request such New Product will be included as a Product under the ALK Collaboration Agreement, subject to ALK bearing the costs of development of such New Product for its licensed territory.

Under the ALK Collaboration Agreement, the Company is obligated to transfer to ALK the existing marketing authorizations for the Products in the ALK 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 the ALK 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 the ALK Territory. Following such approval for a Product in each indication within specified countries within the ALK 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 ALK Collaboration Agreement.

Under the ALK Collaboration Agreement, ALK made a \$145.0 million upfront payment to the Company in November 2024, and the Company earned \$5.0 million for the first commercial sale of *EURneffy* in the ALK Territory in June 2025. The Company is eligible to receive additional outstanding regulatory milestone payments of up to \$15.0 million and sales-based milestone payments 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 the first commercial sale of such Product in such country, or expiration of regulatory exclusivity for such Product in such country.

The contract will expire upon the expiration of the last-to-expire royalty term for all Products in the ALK Territory, unless terminated earlier. Either the Company or ALK may terminate the ALK 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 ALK Collaboration Agreement for ALK’s material breach of its commercial diligence obligations. ALK may terminate the ALK Collaboration Agreement for convenience upon 12 months’ prior written notice or for a safety or regulatory concern. The Company may terminate the ALK Collaboration Agreement in the event ALK makes certain challenges to certain of the Company’s patents. Prior to a change of control and outside of a set period of time after which the Company commences change of control negotiations, the Company may terminate the ALK Collaboration Agreement with respect to all countries in the European Economic Area (“EEA”) 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 EEA at the time of such termination (the “Repurchase Option”). The Company may also terminate the ALK Collaboration Agreement if ALK commercializes a non-injectable epinephrine product or manufactures such a product in the United States.

In connection with the ALK Collaboration Agreement, the Company and ALK also entered into a commercial supply agreement (the “ALK Supply Agreement”) in November 2024, 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. The contract term for the ALK Supply Agreement is coterminous with the ALK Collaboration Agreement. Either the Company or ALK may terminate the ALK Supply Agreement in the event of an uncured material breach of the other party.

Accounting Assessment

The Company concluded that the ALK Collaboration Agreement and the ALK Supply Agreement qualify as a contract with a customer under ASC 606 as one combined arrangement. The Company identified the following performance obligations: (i) exclusive commercialization license in the European Economic Area (the “EEA License”); (ii) exclusive commercialization license in the rest of the ALK Territory (the “ROW License”) and; (iii) five separate development and regulatory services performance obligations. The Company also evaluated the (i) promise to add a New Product and new indications to the ALK Collaboration Agreement, and (ii) the promises under the ALK Supply Agreement, and concluded that these promises did not meet the definition of a performance obligation nor did these promises convey a material right to ALK.

The Company determined that the non-refundable upfront payment of \$145.0 million is the estimated transaction price at contract inception. The outstanding regulatory milestone payments (totaling \$15.0 million) were fully constrained at contract inception and as of June 30, 2025 as a result of the uncertainty of whether any of the milestones will be achieved. In making the assessment of the constraint utilizing the most likely amount method, the Company considered the stage of development, and the risks associated with the remaining development required to achieve the milestones, as well as whether the achievement of the milestone is outside the control of the Company or ALK. The Company determined that the commercial milestone (\$5.0 million) and the sales-based milestones and royalties will be recognized on the later of when the related sales occur or when control of the associated license has been transferred, as the Company determined that such sales-based consideration relates predominantly to the licenses granted to ALK. The Company reevaluates the transaction price at the end of each reporting period and as uncertain events are resolved or other changes in circumstances occur and will include regulatory milestones in the transaction price if it is probable that a significant revenue reversal will not occur in future periods.

At contract inception, the Company determined the estimated standalone selling prices for each performance obligation in order to allocate the transaction price among the performance obligations. The standalone selling price for the licenses was estimated using the adjusted market assessment approach. Under this method, the Company forecasted future cash flows expected in the ALK Territory, the probability of commercialization success, and a market discount rate. To estimate the standalone selling prices of the development and regulatory services, the Company forecasted its expected costs of satisfying each performance obligation inclusive of an appropriate margin for that service.

The Company allocated the total transaction price to each performance obligation on a relative standalone selling price basis and determined whether revenue should be recognized at a point in time or over time. The Company allocated \$69.4 million to the EEA License performance obligation; \$73.1 million to the ROW License performance obligation; and \$2.6 million to the development and regulatory services performance obligations.

Revenue should be recognized when, or as, an entity satisfies a performance obligation by transferring a promised good or service to a customer, i.e., when the customer obtains control of the good or service. The licenses granted to ALK are being accounted for as distinct performance obligations. The licenses relate to functional intellectual property for which revenue is recognized at a point in time. In the case of the EEA License, the Company evaluated the impact of the Company’s Repurchase Option, and determined that, as a result of the Company’s ability to repurchase the license, control of the EEA License has not been transferred to ALK under ASC 606. The Company determined that the transaction price allocated to the EEA License should be accounted for as a financing liability, due to the repurchase price being greater than the original selling price of this performance obligation. Control of the EEA License will not be considered transferred to ALK until such time that the Repurchase Option lapses, which under the terms of the ALK Collaboration Agreement, will occur upon the expiration of the contract, or exercise by the Company of the Repurchase Option. In November 2024, the Company recognized the transaction price allocated to the EEA License of \$69.4 million as a financing liability.

In the case of the ROW License, the point in time for recognition of revenue was shortly after the inception of the contract because the customer obtained control of the license and was able to use and benefit from its right to use the intellectual property at that point. In November 2024, the Company recognized \$73.1 million in revenue for the transaction price allocated to the ROW License.

The development and regulatory services performance obligations under the ALK Collaboration Agreement each represent a separate performance obligation. The development and regulatory services, which are transferred to the customer over time, were provided to ALK from inception of the agreement and are expected to continue through 2028. Revenue related to the development and regulatory services performance obligations was initially recorded as contract liability and is being recognized as services are performed based on the costs incurred through the end of each reporting period, as a percentage of the estimated total costs to be incurred for these performance obligations. In November 2024, the Company recognized \$0.5 million of revenue related to the development and regulatory services performance obligations. For the three and six months ended June 30, 2025, the Company recognized less than \$0.1 million and \$0.2 million of revenue related to the development and regulatory services performance obligations, respectively, which is recorded as revenue under collaboration agreements in the accompanying condensed consolidated statement of operations and comprehensive loss. As of June 30, 2025, the accompanying consolidated balance sheet includes a contract liability of \$0.7 million classified as current and \$1.1 million classified as noncurrent associated with these performance obligations and based on the expected period of performance for the development and regulatory services.

In June 2025, ALK completed the first commercial sale of *EURneffy* in the ALK Territory, and the Company began generating revenue from product sales to ALK, earned royalties from the use of the EEA License, and also earned the \$5.0 million commercial milestone. Of the \$5.0 million commercial milestone, \$2.6 million was recognized as revenue under collaboration agreements for the three and six months ended June 30, 2025 in the accompanying condensed consolidated statement of operations and comprehensive loss. The remaining \$2.4 million was allocated to the EEA license and recognized as an increase to the financing liability, along with \$0.1 million related to royalties earned in the EEA.

As of June 30, 2025, the Company had accounts receivable and contract liability balances of \$5.5 million and \$1.8 million, respectively, associated with the ALK Collaboration Agreement.

ALK Contract Liability

A reconciliation of the contract liability from the ALK Collaboration Agreement is as follows (in thousands):

Balance at December 31, 2024	\$ 2,089
Revenue recognized under the ALK Collaboration Agreement	(240)
Balance at June 30, 2025	<u>\$ 1,849</u>

ALK Financing Liability

A reconciliation of the financing liability from the ALK Collaboration Agreement is as follows (in thousands):

Balance at December 31, 2024	\$ 69,383
Commercial milestone allocated to the EEA License	2,435
Sales-based royalties earned in the EEA	141
Balance at June 30, 2025	<u>\$ 71,959</u>

ALK Co-Promotion Agreement

In May 2025, the Company and ALK-Abelló, Inc. (“ALK U.S.”, an affiliate of ALK) entered into a co-promotion agreement (the “ALK Co-Promotion Agreement”) to co-promote *neffy* to up to 9,000 specified pediatricians and other prescribers in the U.S. Accordingly, the Company granted ALK U.S. a non-exclusive, royalty-free license to use the *neffy* trademarks and copyrights and the ARS house marks in the U.S. solely in connection with promoting *neffy* pursuant to the terms of the ALK Co-Promotion Agreement.

Under the ALK Co-Promotion Agreement, ALK U.S. was obligated to start its promotion activities in May 2025 and meet specified ramp-up milestones and minimum detail requirements, using sales representatives that meet specific qualifications. In addition, during the term of the ALK Co-Promotion Agreement and for 180 days thereafter, ALK U.S. will not market, sell or manufacture any injection product containing epinephrine in the U.S.

The Company is the principal of all sales transactions of *neffy* in the U.S. and, subject to the terms of the ALK Co-Promotion Agreement, continues to have sole responsibility for all U.S. commercialization activities, including marketing, medical affairs, market access, production, distribution, pharmacovigilance, quality and safety.

The Company will pay ALK U.S. a base fee to compensate ALK U.S. for its promotion activities. Payments to ALK U.S. for the services performed during the first year of the arrangement will be deferred and paid in the second year of the arrangement. In addition to the base fee, ALK U.S. will be eligible to receive performance-based bonus payments from the Company starting in the second year of the arrangement equal to 30% of the portion of *neffy* net sales generated from the ALK U.S.-targeted prescribers in excess of a specified initial market share threshold in year two or a 50% market share threshold during years three and four of the arrangement.

The ALK Co-Promotion Agreement expires on the fourth anniversary of the commencement of promotion activities thereunder. Either party may terminate the ALK Co-Promotion Agreement in the event of an uncured material breach of the other party or for either party's change of control. The Company may terminate the ALK Co-Promotion Agreement in the case of ALK U.S.'s insolvency, if ALK U.S. fails to meet specified ramp-up timelines, or if ALK U.S. markets, sells or commercializes any non-injection product containing epinephrine in the U.S. After the first six months, the Company may terminate the ALK Co-Promotion Agreement if minimum detail requirements are not met for a consecutive three-month period. After the first year, the Company may terminate the ALK Co-Promotion agreement for any reason or no reason for a fee (as described below). After the first year, ALK U.S. may terminate the ALK Co-Promotion Agreement for any reason or no reason, and the Company may terminate the agreement in the event ALK U.S. restructures its sales force.

Upon termination of the ALK Co-Promotion Agreement by the Company for convenience, so long as ALK U.S. has met specified performance thresholds during the term, the Company is obligated to pay ALK U.S. a specified mid-to-low double-digit percentage of the portion of *neffy* net sales generated from the ALK U.S.-targeted prescribers in excess of a specified mid-quartile market share threshold that increases over time up to 50% for a specified period after termination, which period decreases in duration the later that the termination occurs. Upon termination of the ALK Co-Promotion Agreement by the Company in connection with a change of control of the Company, the Company is obligated to pay ALK U.S. a one-time mid-seven digit to low eight-digit termination fee in an amount that increases the later that the termination occurs.

The Company evaluated the terms of the ALK Co-Promotion Agreement and determined that it is a vendor arrangement with ALK U.S. During the three and six months ended June 30, 2025, the Company has recognized \$1.4 million in ALK-related selling, general, and administrative expense in the accompanying condensed consolidated statements of operations and comprehensive loss, and the corresponding liability was recorded in other accrued liabilities in the accompanying condensed consolidated balance sheet as of June 30, 2025.

9. Commitments and Contingencies

Leases

In October 2021, the Company entered into a 38-month noncancelable office space lease for its current headquarters location in San Diego, California. Under the terms of the agreement, there is no option to extend the lease, and the Company is subject to additional charges for common area maintenance and other costs. Monthly rental payments due under the lease commenced on December 6, 2021 and escalate through the lease term. The Company prepaid the first month's rent upon execution of the lease, and the lease agreement provided full rent abatement for the second and third months of the rental term. As there was not an implicit rate within the lease, the discount rate was determined by using a set of peer companies incremental borrowing rates.

In January 2025, the Company entered into a lease amendment to its headquarters location lease (the "Headquarters Amendment"), pursuant to which the Company will relocate to a new office space located in the same building. In May 2025, the Company took possession of the new office space upon substantial completion of the landlord's work. As of June 30, 2025, the remaining lease term of the new office space is 36 months. Monthly lease payments increased when the Company took possession of the new office space and will escalate through the lease term, resulting in an annualized payment of \$0.6 million. The Company remains subject to additional charges for common area maintenance and other costs. The Company has one option to extend the lease for an additional term of three years, and the monthly payment amounts would be determined by the landlord at the then-prevailing rate.

Upon entering into the Headquarters Amendment, the Company remeasured the right-of-use asset and lease liability pertaining to its current headquarters, and as a result recorded an additional \$0.1 million to both its right-of-use asset and lease liability on its condensed consolidated balance sheet. Upon possession of the new office space, the Company recognized a right-of-use asset and lease liability of \$1.6 million on its condensed consolidated balance sheet. As there was not an implicit rate within the lease amendment, a discount rate of 8% was determined using a set of peer companies' incremental borrowing rates.

The following table summarizes supplemental lease information (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Lease expense ⁽¹⁾	\$ 159	\$ 57	\$ 219	\$ 113
Cash paid for leases	\$ 63	\$ 61	\$ 126	\$ 122

⁽¹⁾ Variable lease costs in each of the three and six months ended June 30, 2025 and 2024 were immaterial.

As of June 30, 2025, future minimum non-cancelable operating lease payments are as follows (in thousands):

Year Ended December 31,	Amount
2025 (remaining six months)	\$ 310
2026	609
2027	627
2028	318
Total lease payments	1,864
Less imputed interest	(203)
Lease liability	1,661
Less lease liability, current portion	589
Lease liability, net of current portion	\$ 1,072

Contingencies

From time to time, the Company may be involved in various legal proceedings and subject to claims that arise in the ordinary course of business.

On July 24, 2023, Aera A/S, an IP consultancy firm in Denmark representing an unidentified opponent, filed a notice of opposition with the European Patent Office (the "EPO") in respect of EP 3678649 (the "EP '649 Patent"), which is a patent directed to a nasal spray formulation of epinephrine, and uses thereof. The Company filed a response to the notice of opposition on December 15, 2023. The EPO scheduled oral proceedings on October 7, 2025, and the Company will continue to vigorously defend the EP '649 Patent. The results of any notice of opposition are inherently unpredictable and uncertain and could result in the EPO finding the patent to be invalid or unenforceable.

On March 25, 2025, Aptargroup, Inc. and Aptar France SAS (collectively, "Aptar") filed a suit against ARS Pharmaceuticals, Inc. and ARS Pharmaceuticals Operations, Inc. in the United States District Court for the Southern District of New York. Aptar alleges the Company violated the Defend Trade Secrets Act (18 USC § 1836), misappropriated trade secrets under New York state law, and committed various breaches of contract. The complaint was served to the Company, and the Company filed a motion to dismiss on June 12, 2025. Aptar subsequently filed opposition to the motion to dismiss on July 28, 2025. The Company intends to vigorously defend itself in this matter.

Regardless of the outcome, involvement in legal proceedings may have an adverse impact on the Company because of defense and settlement costs, diversion of management resources, and other factors. The Company cannot predict the outcome of these suits, and failure by the Company to obtain favorable resolutions could have a material adverse effect on its business, results of operations, and financial condition. The Company's chances of success on the merits of these suits are still uncertain and any possible loss or range of loss cannot be reasonably estimated and as such the Company has not recorded a liability as of June 30, 2025.

Except as described above, there is no action, suit, proceeding, inquiry or investigation before or by any court, public board, government agency, self-regulatory organization or other body pending or, to the knowledge of the Company's executive officers, threatened against or affecting the Company, the Company's common stock, any of its subsidiaries or its subsidiaries' officers or directors in their capacities as such, in which an adverse decision could have a material adverse effect.

Unconditional Purchase Obligations and Commitments

Unconditional purchase obligations and commitments are defined as agreements to purchase goods or services that are enforceable and legally binding (non-cancelable, or cancelable only in certain circumstances). In the normal course of business, the Company enters into arrangements with suppliers, manufacturers, and various other companies that supply goods or services. These arrangements can include unconditional purchase obligations and commitments.

The total amount of unconditional purchase obligations related to the supply of raw materials is \$57.6 million as of June 30, 2025. Payment obligations by year are as follows: 2025 (\$0.9 million), 2026 (\$10.5 million), 2027 (\$11.8 million), 2028 (\$13.8 million), and \$2.9 million per year thereafter through 2035. During the three and six months ended June 30, 2025, the Company made \$3.0 million and \$7.3 million in payments under these agreements, respectively. No payments were made under these agreements during the three and six months ended June 30, 2024.

The total amount of commitments related to the ALK Co-Promotion Agreement is \$26.8 million as of June 30, 2025. Payment obligations by year are as follows: 2025 (\$0), 2026 (\$4.4 million), 2027 (\$14.2 million), 2028 (\$4.6 million), and 2029 (\$3.6 million). No payments were made under this agreement during the three and six months ended June 30, 2025 and 2024.

The total amount of commitments related to a corporate sponsorship agreement with Food Allergy Research and Education, Inc. is \$10.0 million as of June 30, 2025. Payments by year are as follows: 2025 (\$4.0 million), 2026 (\$5.0 million) and 2027 (\$1.0 million). During the three and six months ended June 30, 2025, the Company made zero and \$2.0 million in payments under this agreement, respectively. No payments were made under this agreement during the three and six months ended June 30, 2024.

The total amount of unconditional purchase obligations related to hosted software license subscription fees is \$2.5 million as of June 30, 2025. Payments by year are as follows: 2025 (\$0.6 million), 2026 (\$1.5 million), and 2027 (\$0.4 million). During the three and six months ended June 30, 2025, the Company made \$0.5 million and \$0.8 million in payments under this agreement, respectively. No payments were made under this agreement during the three and six months ended June 30, 2024.

The amounts above do not represent the entire anticipated spend in the future but represent only those items for which the Company is contractually obligated. For this reason, these amounts do not provide an indication of the Company's expected future cash outflows related to purchases and commitments.

10. In-Licensing and Supply

License Agreement with Aegis

In June 2018, the Company entered into a License Agreement (the "Aegis Agreement") with Aegis Therapeutics, LLC ("Aegis"), a wholly owned subsidiary of Neurelis, Inc. Under the Aegis Agreement, the Company licensed the exclusive, worldwide, royalty-bearing, sublicensable, rights to certain proprietary Aegis technology, patent rights and know-how to develop and commercialize epinephrine products. The Company utilizes this technology in its sole commercial product, *neffy*. As consideration for the license, the Company paid an upfront license fee of \$50,000, which was recorded in research and development expenses in the condensed consolidated statement of operations.

The Company is required to make aggregate milestone payments of up to \$20.0 million upon achievement of certain regulatory and commercial milestones. Regulatory milestone payments under the Aegis Agreement are recorded upon completion of the required events, as the triggering events are not considered to be probable until they are achieved. Prior to the FDA approval of *neffy* in August 2024, regulatory milestone payments were recorded as research and development expenses in the condensed consolidated statement of operations. The Company made a \$0.5 million milestone payment to Aegis upon the achievement of a regulatory milestone during 2019, and a \$1.0 million milestone payment to Aegis upon the FDA's acceptance of the Company's new drug application submission for *neffy*, which occurred in the third quarter of 2022. Since the approval of *neffy* in August 2024, regulatory milestone payments have been capitalized as intangible assets in the accompanying condensed consolidated balance sheets. Amortization expense has been recorded to cost of goods sold, in the accompanying condensed consolidated statements of operations and comprehensive loss, on a straight-line basis over the estimated life of the intellectual property of 14.5 years. In August 2024, a \$2.5 million milestone was met for achieving FDA approval of *neffy*. In September 2024, a \$5.0 million milestone was met for the first commercial sale of *neffy*. As a result, the Company capitalized \$7.5 million as intangible assets in the accompanying condensed consolidated balance sheets in the third quarter of 2024. The Company paid the \$2.5 million milestone for achieving FDA approval of *neffy* in September 2024 and paid the \$5.0 million milestone for the first commercial sale of *neffy* in October 2024. The next milestone payment of \$2.0 million is due upon the achievement of certain annual net product sales.

The Company also pays royalties based on a mid-single-digit percentage of net product sales on its or its sublicensees' net sales of the Licensed Products (as defined in the Aegis Agreement) on a product-by-product basis. Royalties are recorded to cost of goods sold in the period the related product revenue is recognized.

In November 2024, OrbiMed Advisors LLC ("OrbiMed") entered into an agreement with Aegis, to purchase the rights, royalty interests, and related sales milestone payments on net product sales of *neffy*. The Company will make all future payments under the Aegis Agreement to OrbiMed. As described in [Note 14 – Related Party Transactions](#), a member of the Company's Board of Directors is a General Partner at OrbiMed.

The Company is responsible for reimbursing Aegis for patent costs incurred in connection with prosecuting and maintaining patent rights that are specific to epinephrine or epinephrine products. No expenses were recognized in connection with legal patent fees for each of the three and six months ended June 30, 2025 and 2024.

The Company may terminate the Aegis Agreement with 30 days written notice or either party may terminate the Aegis Agreement for certain breaches of the Aegis Agreement. Unless terminated earlier by either or both parties, the term of the Aegis Agreement will continue until the final expiration of all royalty obligations under the Aegis Agreement.

In conjunction with the Aegis Agreement, the Company also entered into a supply agreement (the "Aegis Supply Agreement") with Aegis that allows the Company to purchase materials for preclinical, development and commercial use at predetermined prices. The Company may elect to have Aegis supply minimum quantities but there are no minimum or maximum purchase obligations under the Aegis Supply Agreement unless this election is made. The parties may terminate the Aegis Supply Agreement at any time by mutual agreement. In addition, the parties may terminate the Aegis Supply Agreement in the event of certain breaches of the Aegis Supply Agreement or upon the expiration or termination of the Aegis Agreement or June 2028. The Aegis Supply Agreement term may be extended by mutual written agreement. Under the Aegis Supply Agreement, no payments were made to Aegis in each of the three and six months ended June 30, 2025 and 2024.

Manufacturing Agreement with Renaissance

In September 2020, the Company entered into a manufacturing agreement with Renaissance Lakewood, LLC ("Renaissance"), which was subsequently amended in July 2023, September 2024, and July 2025 (the "Renaissance Agreement"). Pursuant to the Renaissance Agreement, Renaissance agreed to manufacture for, and provide to the Company, *neffy* nasal unit dose sprays ("Renaissance Products"). The Company is obligated to provide Renaissance with certain supplies to manufacture the Renaissance Products and to purchase from Renaissance a mid-double-digit percentage of the Company's annual aggregate Renaissance Product requirements in the EU, and a high double-digit percentage of the Company's annual aggregate Renaissance Product requirements in the U.S. The Renaissance Agreement contains conventional commercial pharmaceutical manufacturing provisions including certain minimum purchase amounts to be determined in the future based on forecast needs and minimum batch size projections. The Company may also request Renaissance to perform certain services related to the Renaissance Product, for which the Company will pay reasonable compensation to Renaissance.

Pursuant to the amendment in September 2024, the amended initial term of the Renaissance Agreement commenced on September 17, 2024, and will terminate (a) for Renaissance Product designated for commercial sale in the U.S., on December 31 immediately following the fifth anniversary of the initial U.S. launch date ("U.S. Initial Term"), and (b) for Renaissance Product designated for commercial sale in the EU, on December 31 immediately following the fifth anniversary of the initial EU launch date ("EU Initial Term"), in each case unless earlier terminated by one of the parties. The U.S. Initial Term and EU Initial Term automatically renew for successive two-year terms ("Renewal Term"). Either party may elect not to renew the U.S. Renewal Term and/or the EU Renewal Term by providing the requisite prior notice to the other party, with the initial terms automatically renewing for successive two-year terms, unless either party gives notice pursuant to the Renaissance Agreement. Either party may terminate the Renaissance Agreement (1) for uncured material breach of the other party, (2) upon notice for insolvency-related events of the other party that are not discharged within a defined time period, (3) on a product-by-product basis if the manufacture, distribution or sale would materially contravene any applicable law, (4) by providing the requisite notice if (a) the authorization and approval to distribute or sell Renaissance Product in the U.S. is not granted on or before a specified date, (b) the authorization and approval representing more than a certain number of units of Renaissance Product sold in the U.S. during the last calendar year is withdrawn by the FDA, or (c) the Company decided in its sole discretion to cease commercializing the Renaissance Product in the U.S., (5) in the case of a force majeure event that continues for six months or more, or (6) a violation by the other party of trade control or anti-corruption laws.

Supply Agreement with Ompi

In October 2024, the Company entered into a supply agreement (the "Ompi Supply Agreement") with Nuova Ompi S.r.l. ("Ompi"), pursuant to which Ompi has agreed to supply glass microvials to support the Company's manufacture and commercialization of *neffy*. Under the Ompi Supply Agreement, the Company has committed to purchase, and Ompi has committed to supply, specified annual minimum quantities of glass microvials, which may be increased with prior notice by the Company or through the rolling forecast process, subject to a specified annual cap. Ompi is obligated to establish the relevant manufacturing force, assets and capabilities needed to comply with its supply obligations.

In December 2024, as partial consideration for the supply arrangement, the Company made an upfront payment of €3.0 million (approximately \$3.2 million in U.S. dollars) to Ompi. The supply price for the glass microvials is specified in the Ompi Supply Agreement, subject to an annual adjustment that is capped at a specified percentage except in the case of material and extraordinary increase in Ompi's cost of manufacturing the glass microvials.

The Ompi Supply Agreement will expire on December 31, 2035, and may be terminated (i) upon the parties' mutual written consent, (ii) by the Company for any reasonable business reasons (in which case the termination will become effective at the end of the following calendar year), or (iii) by the non-breaching party if the other party is in material breach of the Ompi Supply Agreement and fails to cure such breach within 90 days after receipt of notice thereof from the non-breaching party.

11. Common Stock and Stockholders' Equity

Authorized Shares

The Company's current Amended and Restated Certificate of Incorporation authorizes 200,000,000 shares of common stock, par value \$0.0001 per share, and 10,000,000 shares of preferred stock, par value \$0.0001 per share.

Common Stock Reserved for Future Issuance

Common stock reserved for future issuance consisted of the following:

	<u>June 30, 2025</u>	<u>December 31, 2024</u>
Common stock options granted and outstanding	17,271,990	15,161,180
Restricted stock units granted and outstanding	1,382	2,763
Common stock reserved for future awards or option grants	8,062,484	5,905,773
Common stock reserved for future employee stock purchase plan issuances	2,811,182	2,223,100
Warrants to purchase common stock	45,456	45,456
Total	<u>28,192,494</u>	<u>23,338,272</u>

Equity Offerings

In January 2025, the Company filed an automatic shelf registration statement on Form S-3ASR with the Securities and Exchange Commission which became effective upon filing (the "Shelf Registration Statement"). The Shelf Registration Statement allows the Company, from time to time, to offer and sell any combination of shares of the Company's common stock and preferred stock, various series of debt securities, and/or warrants to purchase any of such securities, either individually or in combination with other securities, in one or more offerings. The Company simultaneously entered into a Controlled Equity OfferingSM sales agreement (the "Equity Sales Agreement") with Cantor Fitzgerald & Co. ("Cantor") to allow the Company to offer, sell and issue shares of the Company's common stock from time to time through Cantor acting as sales agent and up to a maximum aggregate offering price of \$200.0 million. As of June 30, 2025, no securities have been sold pursuant to the Shelf Registration Statement or Equity Sales Agreement.

12. Stock-Based Compensation

Stock-based compensation expense recognized for all equity awards has been reported in the condensed consolidated statements of operations and comprehensive loss as follows (in thousands):

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2025</u>	<u>2024</u>	<u>2025</u>	<u>2024</u>
Research and development expense	\$ 664	\$ 913	\$ 1,327	\$ 1,824
Selling, general and administrative expense	4,707	2,452	9,342	4,856
Total	<u>\$ 5,371</u>	<u>\$ 3,365</u>	<u>\$ 10,669</u>	<u>\$ 6,680</u>

During the three and six months ended June 30, 2025, \$0.3 million and \$0.5 million of stock compensation expense was capitalized into inventory, respectively. No stock-based compensation expense was capitalized into inventory during the three and six months ended June 30, 2024.

As of June 30, 2025, the total unrecognized stock-based compensation expense related to outstanding employee options was \$53.9 million, which is expected to be recognized over a remaining weighted-average period of approximately 2.6 years.

As of June 30, 2025 and December 31, 2024, there were 1,382 and 2,763 restricted stock units outstanding, respectively.

Equity Incentive Plans

In September 2018, ARS Pharma adopted the 2018 Equity Incentive Plan. As a result of the Merger, on November 8, 2022 ARS Pharma assumed Silverback's 2016 and 2020 Equity Incentive Plans, and Employee Stock Purchase Plan ("ESPP"). There were 111,918 shares and 43,679 shares of common stock purchased under the ESPP during the six months ended June 30, 2025 and 2024, respectively.

As of June 30, 2025, 25,737,116 shares were authorized under the 2016 and 2020 Equity Incentive Plans, of which 7,765,139 shares were available for future grant, and 13,033,358 shares were outstanding. As of June 30, 2025, 6,634,333 shares were authorized under the 2018 Equity Incentive Plan, of which 297,345 shares were available for future grant, and 4,240,014 shares were outstanding. The Company does not intend to grant future stock options or other equity awards under the 2016 or 2018 Equity Incentive Plans.

Stock Options

Stock options granted under the Company's equity incentive plans expire no later than 10 years from the date of grant and generally vest over a four-year period, with vesting either occurring at a rate of 25% at the end of the first year and thereafter in 36 equal monthly installments or on a monthly basis. In the case of awards granted to the Company's non-employee board members, vesting generally occurs on a monthly basis over three years or in full on an annual basis. The Company issues new shares of common stock upon the exercise of stock options.

A summary of the Company's stock option activity for the six months ended June 30, 2025 is as follows:

	Shares Subject to Options Outstanding	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2024	15,161,180	\$ 6.63		
Granted	3,158,150	\$ 11.54		
Exercised	(630,187)	\$ 4.07		
Forfeited	(417,153)	\$ 11.23		
Outstanding at June 30, 2025	17,271,990	\$ 7.51	7.7	\$ 174,541
Exercisable at June 30, 2025	9,540,712	\$ 5.72	6.8	\$ 114,815

The exercisable shares subject to options outstanding at June 30, 2025 in the table above include vested and early exercisable awards. The aggregate intrinsic value in the table above is calculated as the difference between the exercise price of the underlying options and the estimated fair value of the Company's common stock for all options that were in-the-money at June 30, 2025. The aggregate intrinsic value of options exercised during the six months ended June 30, 2025 and 2024 was \$5.9 million and \$3.4 million, respectively.

The weighted-average grant date fair value per share of option grants for the six months ended June 30, 2025 and 2024 was \$8.60 and \$4.52, respectively. The total fair value of shares vested during the six months ended June 30, 2025 and 2024 was \$12.2 million and \$9.9 million, respectively.

The fair value of stock options granted was estimated using a Black-Scholes option-pricing model ("Black-Scholes") with the following weighted-average assumptions:

	Six Months Ended June 30,	
	2025	2024
Expected term (in years)	6.0	6.0
Expected volatility	86.7%	94.0%
Risk-free interest rate	4.3%	4.0%
Expected dividend yield	—	—

The fair value of stock options was determined using the Black-Scholes assumptions below. Each of these inputs is subjective and generally requires significant judgment.

Fair Value of Common Stock. The fair market value of the Company's common stock is based on its closing price as reported on the date of grant on the primary stock exchange on which the Company's common stock is traded.

Expected Term. The expected term represents the period that the options granted are expected to be outstanding. The expected term of stock options issued is determined using the simplified method (based on the mid-point between the vesting date and the end of the contractual term) as the Company has concluded that its stock option exercise history does not provide a reasonable basis upon which to estimate expected term.

Expected Volatility. Given the Company's limited historical stock price volatility data, the Company derived the expected volatility from the average historical volatilities over a period approximately equal to the expected term of comparable publicly traded companies within its peer group that were deemed to be representative of future stock price trends as the Company has limited trading history for its common stock. The Company will continue to apply this process until a sufficient amount of historical information regarding the volatility of its own stock price becomes available.

Risk-free Interest Rate. The risk-free interest rate is based on the U.S. Treasury rate, with maturities similar to the expected term of the stock options.

Expected Dividend Yield. The Company has never paid dividends on its common stock and does not anticipate paying any dividends in the foreseeable future. Therefore, the Company uses an expected dividend yield of zero.

13. Employee Benefit Plans

In June 2022, the Company adopted a retirement plan, which is qualified under section 401(k) of the Internal Revenue Code of 1986, as amended, for the Company's U.S. employees. The plan allows eligible employees to defer, at the employee's discretion, pretax compensation up to the Internal Revenue Service (the "IRS") annual limits. The Company matches up to 5% of an employee's pay that they contribute to the plan, subject to IRS limitations. Expenses associated with the Company's matching contribution totaled \$0.4 million and \$0.8 million for the three and six months ended June 30, 2025, respectively. Expenses associated with the Company's matching contribution totaled \$0.1 million and \$0.2 million for the three and six months ended June 30, 2024, respectively.

14. Related-Party Transactions

In September 2015, the Company entered into a consulting agreement, superseded in July 2022, for regulatory and development services with Pacific-Link Regulatory Consulting, Inc., an entity owned by the President/Chief Executive Officer/director and his spouse, the Chief Medical Officer of the Company. The Company incurred consulting expenses related to this agreement totaling \$0.6 million and \$1.3 million for the three and six months ended June 30, 2025, respectively, and \$0.5 million and \$1.3 million for the three and six months ended June 30, 2024, respectively.

In September 2018, the Company entered into a consulting agreement with Marlinspike Group, LLC ("Marlinspike Group") to provide management, business consulting services and business development support. The managing member of Marlinspike Group is the Chair of the Board of Directors of the Company and one of its stockholders. The Company incurred expenses related to this agreement of \$0.1 million for each of the three and six months ended June 30, 2025 and 2024.

In April 2021, the Company entered into a consulting agreement, as amended in April 2022, with a member of the Board of Directors of the Company for general advice and assistance with the development of *neffy* and any future product candidates. As compensation for the consulting services the Company granted the member of the Board of Directors 590,950 stock options that vest over a four-year period. The Company incurred less than \$0.1 million in stock-based compensation expense related to this agreement in each of the three and six months ended June 30, 2025 and 2024.

As described in [Note 10 – In-Licensing and Supply](#), the Company is required to make milestone payments to Aegis upon achievement of certain regulatory and commercial milestones, and royalty payments to Aegis based on net product sales of *neffy*. In November 2024, OrbiMed entered into an agreement with Aegis to purchase the rights, royalty interests, and related sales milestone payments on net product sales of *neffy*. A member of the Company's Board of Directors is a General Partner at OrbiMed. The Company incurred \$0.9 million and \$1.4 million in royalty expense payable to OrbiMed during the three and six months ended June 30, 2025, respectively.

15. Segment Information

The Company reports segment information using the management approach and views its operations and manages its business as a single operating segment. The Company's Chief Operating Decision Maker ("CODM"), who is the Chief Executive Officer, allocates resources and evaluates the performance of the operating segment based on historical and projected product sales, segment operating expenses, and condensed consolidated net loss, as reflected in the accompanying condensed consolidated statements of operations and comprehensive loss, which is the segment measure of loss.

The segment reports that are provided to the CODM are tracked against the Company's internally budgeted expenses. The segment operating expense categories consist primarily of the Company's functional departments: Clinical, Development, Medical Affairs, Sales and Marketing, and General and Administrative. The CODM does not review assets when evaluating the operating segment's performance; therefore, this information is not presented.

Segment reporting for the three and six months ended June 30, 2025 and 2024 (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Revenue:				
Product revenue, net	\$ 12,800	\$ —	\$ 20,563	\$ —
Revenue under collaboration agreements	2,594	500	2,804	500
Revenue under supply agreements	323	—	323	—
Total revenue	15,717	500	23,690	500
Segment operating expenses:				
Cost of goods sold	4,984	—	6,078	—
Clinical	1,250	1,226	2,454	4,042
Development	2,151	2,591	3,252	4,099
Medical affairs	1,073	421	2,018	754
Sales and marketing	40,925	2,694	67,682	4,145
General and administrative	7,118	5,505	15,837	9,195
Stock-based compensation	5,371	3,365	10,669	6,680
Other	459	38	491	117
Total segment operating expenses	63,331	15,840	108,481	29,032
Loss from operations	(47,614)	(15,340)	(84,791)	(28,532)
Other income, net	2,731	2,824	5,968	5,724
Net loss	\$ (44,883)	\$ (12,516)	\$ (78,823)	\$ (22,808)

16. Subsequent Events

On July 4, 2025, the One Big Beautiful Bill Act ("OBBA") was signed into law, which includes significant changes to federal tax law and other regulatory provisions that may impact the Company. The legislation has multiple effective dates, with certain provisions effective in 2025 and others implemented through 2027. The Company is currently evaluating the provisions of the new law and the potential effects on its financial position, results of operations, and cash flows. As of the date of these financial statements, the Company has not completed its assessment, and therefore no adjustments have been made.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

You should read the following discussion and analysis together with our unaudited condensed consolidated financial statements and related notes thereto included in "Item 1. Financial Statements (Unaudited)" of this Quarterly Report on Form 10-Q and the audited financial statements and related notes thereto as of and for the year ended December 31, 2024 included in our Annual Report on Form 10-K, filed with the Securities and Exchange Commission ("SEC"), on March 20, 2025. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. For a complete discussion of forward-looking statements, see the section above entitled "Forward Looking Statements." As a result of many factors, including those factors set forth in the under the caption "Item 1A. Risk Factors" of this Quarterly Report, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis. You should carefully read the "Risk Factors" section of this Quarterly Report to gain an understanding of the various factors that could cause actual results to differ materially from our forward-looking statements.

Overview

We are a biopharmaceutical company focused on the commercialization and development of *neffy* (currently identified in the European Union ("EU") by the tradename *EU Rneffy*) for the needle-free intranasal delivery of epinephrine for the emergency treatment of Type I allergic reactions, including anaphylaxis. *neffy* is the first and only U.S. Food and Drug Administration ("FDA") and European Commission-approved needle-free epinephrine product, and the first new delivery method for epinephrine in more than 35 years. *neffy* is a proprietary composition of epinephrine with an innovative absorption enhancer called Intravail, which allows *neffy* to safely provide intranasal delivery of epinephrine at a low dose within the exposures of approved injectable products across a range of dosing conditions (including repeat dosing and allergen challenge). We believe the market opportunity for *neffy* in the United States alone is significant. At the current list price for a two-pack of *neffy* and our target total gross-to-net yield, the estimated 6.5 million patients currently prescribed an epinephrine autoinjector in the United States represents an initial addressable market opportunity of approximately \$3 billion in annual net sales, while the remaining 13.5 million diagnosed patients that have not been prescribed an epinephrine product represent an additional addressable market opportunity of approximately \$7 billion in annual net sales.

We believe *neffy*'s "no needle, no injection" approach addresses a significant unmet need in the use of epinephrine, which, except for *neffy*, is currently approved only in injectable formulations for the emergency treatment of Type I allergic reactions. There are approximately 40 million people in the United States who experience Type I allergic reactions. Of this group, approximately 20 million people have been diagnosed and experienced severe Type I allergic reactions that may lead to anaphylaxis, and approximately 6.5 million were prescribed an epinephrine autoinjector. However (in 2023, for example), only 3.2 million filled their active epinephrine autoinjector prescription, and of those, only half consistently carry their prescribed autoinjector with them due to the many drawbacks of these devices.

These drawbacks include the use of needles, which can result in patient and caregiver injury as well as hesitation and delays in administration due principally to apprehension and pain of needles, allowing the allergic reaction to progress in severity leading to symptoms that seriously impact patient quality of life, to potential need for emergency services and/or hospitalizations, and to life-threatening symptoms or events. In particular, intra-muscular injections are subject to dosing errors and risk of accidental blood vessel injections, which can cause a significant spike in the intravascular delivery of epinephrine potentially leading to serious cardiovascular complications or events. In aggregate, we estimate that up to 90% of patients prescribed an epinephrine device are not achieving an optimal treatment outcome today.

We believe *neffy*'s and our intranasal epinephrine technology product candidates' design, particularly the compact size and "no needle, no injection" delivery, eliminates needle-related apprehension and pain, improves portability and ease of use, is highly reliable, and will increase prescriptions for epinephrine, making it more likely that patients and caregivers will administer epinephrine sooner, achieve more rapid symptom relief, and prevent the allergic reaction from progressing to a level of severity that could lead to hospitalization or even death.

Data from our studies of *neffy* and our intranasal epinephrine technology product candidates demonstrated nasally delivered epinephrine reached blood levels comparable to those of already approved epinephrine injectable products across single dosing, repeat dosing, self-administration or allergen challenge conditions, and produced statistically significant responses compared to injection on pharmacodynamic surrogates for efficacy even one minute after dosing with *neffy* and our intranasal epinephrine technology product candidates.

On August 9, 2024, the FDA approved *neffy* 2 mg for the emergency treatment of Type I allergic reactions, including anaphylaxis, in adults and children who weigh 30 kg or greater. As a result, we initiated commercial launch of *neffy* 2 mg in the United States, with product becoming available for shipment on September 23, 2024. This commercialization effort currently includes a direct sales force of approximately 108 individuals targeting high-volume epinephrine prescribers that is supported by branded direct-to-consumer marketing, disease awareness campaigns with advocacy groups and non-personal promotion including continuing medical education programs in collaboration with allergist societies, speaker bureaus, peer-to-peer programs and participation in regional and national medical conferences. On March 5, 2025, the FDA approved *neffy* 1 mg for the emergency treatment of Type I allergic reactions, including anaphylaxis, in patients who are four years of age and older and weigh 15 kg to less than 30 kg. As a result, we initiated commercial launch of *neffy* 1 mg in the United States, with product becoming available on May 7, 2025.

***neffy* U.S. Commercial Launch Initiated in September 2024**



Our launch strategy for *neffy* in the United States involves direct outreach to high-volume prescribers of epinephrine accounting for approximately 55% of prescriptions in the last year through an efficient sales force. As of June 30, 2025, our sales force is comprised of approximately 108 ARS Pharma employees, who serve as sales reps, area sales managers, and national sales directors that began field operations as early as October 2024, as well as 10 virtual sales reps, and approximately 60 sales reps via our co-promotion partner, ALK-Abelló, Inc. (“ALK U.S.”, an affiliate of ALK-Abelló A/S (“ALK”)), who began field operations in early June 2025 and will target up to 9,000 specified pediatricians and other prescribers in the U.S. Our launch strategy is also supported by active participation since November 2024 of approximately 2,800 healthcare professionals in our *neffy* experience program that allows healthcare professionals to use *neffy* firsthand as rescue therapy for anaphylaxis during in-clinic allergen challenge; extensive non-personal promotion including continuing medical education programs in collaboration with allergist societies, speaker bureaus, peer-to-peer programs and participation in regional and national medical conferences; engagement and contracting with payors to obtain timely coverage with favorable gross-to-net discounting; our *neffyconnect* program that provides support to physicians and patients including our \$25 co-pay savings card, \$199 cash price and patient assistance programs; a telemedicine service to conveniently obtain a prescription online; partnerships with patient advocacy organizations including disease awareness campaigns in 2025; and multi-channel branded direct to consumer advertising including connected television, linear television, point of care, endemic and programmatic display, social media, and paid search that initiated on May 15, 2025. We also initiated a U.S. post-marketing registry-based study for *neffy* for the treatment of anaphylaxis in oral food challenge or allergen immunotherapy clinics in the second quarter of 2025.

On August 22, 2024, the EC granted marketing authorization in the EU for *EURneffy* (the trade name for *neffy* 2 mg in the EU), for the emergency treatment of allergic reactions (anaphylaxis), in adults and children who weigh 30 kg or greater. The 1 mg dose of *EURneffy* for children who weigh 15 to 30 kg is currently under review by the European Medicines Agency (“EMA”), and a regulatory decision is expected in the first half of 2026. Through our collaboration with ALK (discussed below), *EURneffy* was launched in Germany in June 2025. We received approval of *EURneffy* in the United Kingdom (“U.K.”) in July 2025 for the emergency treatment of allergic reactions (anaphylaxis), in adults and children who weigh 30 kg or greater, and commercial launch in the U.K. is expected late in the second half of 2025. Regulatory review of *neffy* is ongoing in Canada, China, Japan, and Australia with filings submitted by our partners, or by ARS Pharma on behalf of our partners, during the fourth quarter of 2024. *neffy* has been approved or is under regulatory review in countries representing approximately 98% of the current global epinephrine autoinjector sales. Regulatory decisions are anticipated by year-end 2025 in Japan, Canada and Australia, with commercial rollouts planned for the first half of 2026. A regulatory decision is also anticipated in the first half of 2026 in China.

We reported positive topline results demonstrating statistically significant and clinically meaningful improvements in treatment-refractory chronic urticaria patients at the American Academy of Allergy and Immunology medical conference in February 2024. In the second quarter of 2025, we initiated a Phase 2b randomized, placebo-controlled outpatient clinical trial involving chronic spontaneous urticaria patients, on chronic treatment regimens, who still experience flares or exacerbations. Topline data from this clinical trial is anticipated in the first half of 2026, followed by the potential initiation of a single pivotal efficacy study in 2026.

Since our inception in 2015 as ARS Pharmaceuticals, Inc., we have devoted substantially all of our efforts to developing intellectual property, conducting product development and clinical trials, organizing and staffing, business planning, raising capital, building infrastructure, pre-commercial and commercial activities, and providing general and administrative support for these operations. We began commercial operations in September 2024 and therefore have had limited net product sales. We have funded our operations primarily with proceeds from the Merger (see [Note 1 – Nature of Business](#) to the notes to the condensed consolidated financial statements included in this report), private placement of convertible preferred stock, issuance of common stock, licensing, supply and distribution arrangements with our commercialization partners, bank debt, and limited net product sales. As of June 30, 2025, we had cash, cash equivalents, and short-term investments of \$240.1 million.

We have incurred net losses from operations in most years since our inception. Our net loss from operations for the six months ended June 30, 2025 and 2024 was \$47.6 million and \$15.3 million, respectively. As of June 30, 2025, we had an accumulated deficit of \$202.1 million. Until we consistently generate positive net income, if ever, our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our clinical trials, our expenditures on other development activities, the cost for regulatory filings, expenses for commercial activities to establish, maintain and enhance sales, marketing and distribution capabilities for *neffy*, the timing and volume of our product sales, and our ability to earn potential regulatory and commercial milestones under our license and collaboration arrangements.

Until such time, if ever, that we can generate substantial product revenue, we may finance our operations through our existing cash, cash equivalents, short-term investments, equity offerings, debt financings and other capital sources which may include collaborations, strategic alliances, marketing, distribution or licensing arrangements or other arrangements with third parties. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. In addition, any future debt agreements may limit our ability to enter into certain debt financings without the consent of the lenders thereunder. Our failure to raise capital or enter into such other arrangements when needed would have a negative impact on our financial condition and may require us to delay or reduce our marketing and sales efforts, or delay, reduce or terminate our research and development programs or other operations, or grant rights to develop and market products or product candidates that we would otherwise prefer to develop and market ourselves.

We do not own or operate manufacturing facilities. We currently rely on third-party manufacturers and suppliers for *neffy* and our intranasal epinephrine technology product candidates, and we expect to continue to do so to meet our nonclinical, clinical and commercial activities. Our third-party manufacturers are required to manufacture our product under cGMP requirements and other applicable laws and regulations.

ALK Collaboration Agreement

In November 2024, the Company entered into a collaboration, license and distribution agreement (the “ALK Collaboration Agreement”) with ALK. Pursuant to the ALK 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) (“ALK Territory”), exclusive license under certain of the Company’s patents and know-how to develop, manufacture and commercialize products containing epinephrine administered intranasally, including *EURneffy* (the tradename for *neffy* 2 mg in the European Union) (“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 (“New Product”), upon ALK’s request such New Product will be included as a Product under the ALK Collaboration Agreement, subject to ALK bearing the costs of development of such New Product for its licensed territory.

Under the ALK Collaboration Agreement, we are obligated to transfer to ALK the existing marketing authorizations for the Products in the ALK Territory. We are also required to conduct certain development and regulatory activities for Products in support of obtaining further regulatory approval of Products in the ALK 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 the ALK Territory. Following such approval for a Product in each indication within specified countries within the ALK 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 ALK Collaboration Agreement.

Under the ALK Collaboration Agreement, ALK made an upfront payment to us of \$145.0 million in November 2024, and we earned \$5.0 million for the first commercial sale of *EURneffy* in the ALK Territory in June 2025. We are eligible to receive additional outstanding regulatory and commercialization milestone payments of up to \$15.0 million and sales-based milestone payments of up to \$300.0 million, provided that \$55.0 million of such sales-based milestones are contingent upon us obtaining regulatory approval for the Product in Canada by a specified time. We are 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 the first commercial sale of such Product in such country, or expiration of regulatory exclusivity for such Product in such country.

The contract will expire upon the expiration of the last-to-expire royalty term for all Products in the ALK Territory, unless terminated earlier. Either we or ALK may terminate the ALK 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 we may not terminate the ALK Collaboration Agreement for ALK’s material breach of its commercial diligence obligations. ALK may terminate the ALK Collaboration Agreement for convenience upon 12 months’ prior written notice or for a safety or regulatory concern. We may terminate the ALK Collaboration Agreement in the event ALK makes certain challenges to certain of our patents. Prior to a change of control and outside of a set period of time after which we commence change of control negotiations, we may terminate the ALK Collaboration Agreement with respect to all countries in the European Economic Area (“EEA”) 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 EEA at the time of such termination. Except with respect to ALK’s activities pursuant to and in accordance with the ALK Co-Promotion Agreement (as defined below), we may also terminate the ALK Collaboration Agreement if ALK commercializes a non-injectable epinephrine product or manufactures such a product in the United States.

ALK Supply Agreement

In November 2024, in connection with the ALK Collaboration Agreement, ARS and ALK also entered into a commercial supply agreement (the “ALK Supply Agreement”), under which ARS will supply ALK’s requirements (and ALK will purchase from ARS 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. Either the Company or ALK may terminate the ALK Supply Agreement in the event of an uncured material breach of the other party.

ALK Co-Promotion Agreement

In May 2025, the Company and ALK U.S. entered into a co-promotion agreement (the “ALK Co-Promotion Agreement”) to co-promote *neffy* to up to 9,000 specified pediatricians and other prescribers in the U.S. Accordingly, we granted ALK U.S. a non-exclusive, royalty-free license to use the *neffy* trademarks and copyrights and the ARS house marks in the U.S. solely in connection with promoting *neffy* pursuant to the terms of the ALK Co-Promotion Agreement.

Under the ALK Co-Promotion Agreement, ALK U.S. was obligated to start its promotion activities in May 2025 and meet specified ramp-up milestones and minimum detail requirements, using sales representatives that meet specific qualifications. In addition, during the term of the ALK Co-Promotion Agreement and for 180 days thereafter, ALK U.S. will not market, sell or manufacture any injection product containing epinephrine in the U.S.

We record all sales of *neffy* in the U.S. and, subject to the terms of the ALK Co-Promotion Agreement, continue to have sole responsibility for all U.S. commercialization activities, including marketing, medical affairs, market access, production, distribution, pharmacovigilance, quality and safety.

We will pay ALK U.S. a base fee to compensate ALK U.S. for its promotion activities. Payments for the first year of the partnership will be deferred and paid in the second year of the partnership. In addition to the base fee, ALK U.S. will be eligible to receive performance-based bonus payments from us starting in the second year of the partnership equal to 30% of the portion of *neffy* net sales generated from the ALK U.S.-targeted prescribers in excess of a specified initial market share threshold in year two or a 50% market share threshold during years three and four of the partnership.

The ALK Co-Promotion Agreement expires on the fourth anniversary of the commencement of promotion activities thereunder. Either party may terminate the ALK Co-Promotion Agreement in the event of an uncured material breach of the other party or for either party's change of control. We may terminate the ALK Co-Promotion Agreement in the case of ALK U.S.'s insolvency, if ALK U.S. fails to meet specified ramp-up timelines, or if ALK U.S. markets, sells or commercializes any non-injection product containing epinephrine in the U.S. After the first six months, we may terminate the ALK Co-Promotion Agreement if minimum detail requirements are not met for a consecutive three-month period. After the first year, we may terminate the ALK Co-Promotion agreement for any reason or no reason for a fee (as described below). After the first year, ALK U.S. may terminate the ALK Co-Promotion Agreement for any reason or no reason, and we may terminate the agreement in the event ALK U.S. restructures its sales force.

Upon termination of the ALK Co-Promotion Agreement by us for convenience, so long as ALK U.S. has met specified performance thresholds during the term, we are obligated to pay ALK U.S. a specified mid-to-low double-digit percentage of the portion of *neffy* net sales generated from the ALK U.S.-targeted prescribers in excess of a specified mid-quartile market share threshold that increases over time up to 50% for a specified period after termination, which period decreases in duration the later that the termination occurs. Upon termination of the ALK Co-Promotion Agreement by us in connection with a change of control of the Company, we are obligated to pay ALK U.S. a one-time mid-seven digit to low eight-digit termination fee in an amount that increases the later that the termination occurs.

Financial Overview

Revenues

We have recognized limited net product sales in the United States since the commercial launch of *neffy* in September 2024. We have signed collaboration and license agreements for *neffy* for all geographies outside of the United States. The terms of these agreements may include payment to us of one or more of the following: non-refundable, upfront license fees; clinical, regulatory, and/or commercial milestone payments; clinical development fees; and royalties or a transfer price on net sales of licensed products if *neffy* receives marketing approval in these regions. We expect product revenues to fluctuate in future periods as we continue with the commercial launch of *neffy*. We expect revenues under collaboration agreements to fluctuate in future periods based on our ability to meet various regulatory milestones, and contingent on successfully obtaining regulatory approval for *neffy* in the licensed regions, commercial milestones, royalties or transfer price earned from our partner's net sales and the supply of commercial product as set forth in the agreements described earlier.

Cost of Goods Sold

Cost of goods sold consists primarily of direct and indirect costs related to the manufacture of *neffy* for commercial sale, including salaries and related expenses for personnel, stock-based compensation, third-party manufacturing costs, raw material and component costs, excess or obsolete inventory adjustment charges, inventory write offs, packaging services, freight, storage costs, distribution fees, amortization of capitalized in-licensed costs, and royalties on product sales. Prior to the FDA approval of *neffy* in August 2024, costs incurred for the manufacture of *neffy* were recorded as research and development expenses, which resulted in zero-cost inventory. As a result, the cost of goods sold related to *neffy* will initially reflect a lower average per unit cost of materials, as previously expensed zero-cost inventory is utilized for commercial production and sold to customers. We expect the cost of goods sold for *neffy* to increase in relation to product revenues as we deplete this inventory. As of June 30, 2025, we had \$9.8 million in zero-cost inventory remaining and based on our current forecast, we expect zero-cost inventory to be depleted by mid-2026.

The Company periodically evaluates zero-cost inventory for obsolescence. This evaluation considers the shelf life of raw materials, work in process, and finished goods as well as estimated sales trends. As of June 30, 2025, no zero-cost inventory was determined to be obsolete.

Research and Development Expenses

To date, our research and development expenses have been related primarily to clinical development, process development, and manufacturing costs of *neffy* and our intranasal epinephrine technology product candidates. Research and development expenses are recognized as incurred and payments made prior to the receipt of goods or services to be used in research and development are capitalized until the goods or services are received.

Research and development expenses include:

- salaries, payroll taxes, benefits and stock-based compensation charges for personnel engaged in research and development efforts;
- external research and development expenses incurred under agreements with contract research organizations (“CROs”), investigative sites and consultants and other third-party organizations to conduct our clinical studies and development activities;
- costs related to manufacturing *neffy* and our intranasal epinephrine technology product candidates for clinical trials and process validation studies, including fees paid to third-party manufacturers;
- costs related to compliance with regulatory requirements and regulatory filings; and
- indirect expenses including insurance and facility-related expenses.

Our external research and development expenses for *neffy* and our intranasal epinephrine technology product candidates consist primarily of fees, materials and other costs paid to CROs, CMOs, consultant and contractors. Our clinical, regulatory, manufacturing, and non-clinical development costs for the periods presented below reflect an allocation of expenses associated with personnel costs, stock-based compensation expense, and indirect costs incurred in support of overall research and development, such as facilities-related costs.

We expect our research and development expenses to remain relatively consistent in 2025 based on our planned clinical development and manufacturing activities. We cannot determine with certainty the timing of initiation, the duration or the completion costs of current or future clinical trials and the manufacturing costs of *neffy* and our intranasal epinephrine technology product candidates due to the inherently unpredictable nature of clinical development and manufacturing activities. Clinical development and manufacturing timelines, the probability of success and development costs can differ materially from expectations. In addition, we cannot forecast to what degree our licensing, supply and distribution arrangements would affect our development plans and capital requirements.

The duration, costs and timing of clinical trials and development of *neffy* and our intranasal epinephrine technology product candidates for the treatment of additional indications will depend on a variety of factors that include:

- per patient trial costs;
- the number of patients that participate in the trials;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- tariffs and international trade relations;
- the length of time required to enroll eligible patients;
- the number of doses that patients receive;
- the drop-out or discontinuation rates of patients;
- potential additional safety monitoring or other studies requested by regulatory agencies;
- the efficacy and safety profile of *neffy* and our current and future intranasal epinephrine technology product candidates;
- the cost to seek regulatory approvals for our intranasal epinephrine technology product candidates in additional indications and any product candidates that successfully complete clinical trials;
- the timing, receipt, and terms of any approvals from applicable regulatory authorities including the FDA and non-U.S. regulators;
- maintaining a continued acceptable safety profile of *neffy* and our intranasal epinephrine technology product candidates;
- establishing or maintaining commercial manufacturing capabilities or making arrangements with third-party manufacturers in order to ensure that we or our third-party manufacturers are able to make product successfully;
- significant and changing government regulation and regulatory guidance;
- the impact of any business interruptions to our operations or to those of the third parties with whom we work; and
- the extent to which we establish additional strategic collaborations or other arrangements.

A change in the outcome of any of these variables with respect to the development of *neffy* and our intranasal epinephrine technology product candidates could significantly change the costs and timing associated with the development of that future product candidate. The process of conducting the necessary clinical research and manufacturing to obtain regulatory approval is costly and time-consuming. The actual probability of success for any future candidates may be affected by a variety of factors. Further, a number of factors, including those outside of our control, could adversely impact the timing and duration of our product's or any future candidates' development, which could increase our research and development expenses.

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist primarily of salaries, benefits, stock-based compensation for personnel in executive, finance, business development, sales and marketing and other corporate administrative functions. Selling, general and administrative expenses also include pre-commercial launch activities prior to product launch, the initiation of commercialization activities in September 2024, legal fees incurred relating to corporate and patent matters, professional fees incurred for accounting, auditing, tax and administrative consulting services, and insurance costs.

We expect our selling, general and administrative expenses to increase substantially in 2025. The increase in expenses is due to our sales force which was established in the third quarter of 2024, the development and commencement of our marketing campaigns and initiatives, the ALK Co-Promotion Agreement, the hiring of additional sales and marketing personnel to support full commercialization activities, and the addition of infrastructure and programs to support commercialization activities. We expect to continue to incur audit, legal, regulatory and tax-related services associated with maintaining compliance with exchange listing and SEC requirements, director and officer insurance premiums, board of director fees, investor relations costs associated with operating as a public company, patent costs and defense, and general and administrative personnel.

Other Income, net

Other income, net consists primarily of interest income from our cash, cash equivalents, and short-term investments, and net amortization and accretion associated with our short-term investments.

Results of Operations

Comparison of the Three Months Ended June 30, 2025 and 2024

The following table summarizes our results of operations for the three months ended June 30, 2025 and 2024 (in thousands, except percentages):

	Three Months Ended June 30,		Dollar Change	% Change
	2025	2024		
Revenue:				
Product revenue, net	\$ 12,800	\$ —	\$ 12,800	*
Revenue under collaboration agreements	2,594	500	2,094	*
Revenue under supply agreements	323	—	323	*
Total revenue	15,717	500	15,217	*
Operating expenses:				
Cost of goods sold	4,984	—	4,984	*
Research and development ⁽¹⁾	4,035	6,896	(2,861)	(41%)
Selling, general and administrative ⁽¹⁾	54,312	8,944	45,368	*
Total operating expenses	63,331	15,840	47,491	*
Loss from operations	(47,614)	(15,340)	(32,274)	*
Other income, net	2,731	2,824	(93)	(3%)
Net loss	\$ (44,883)	\$ (12,516)	(32,367)	*
Change in unrealized gains and losses on available-for-sale securities	(118)	(21)	(97)	*
Comprehensive loss	\$ (45,001)	\$ (12,537)	(32,464)	*

* Not meaningful

⁽¹⁾ Includes stock-based compensation expense as follows (in thousands):

	Three Months Ended June 30,	
	2025	2024
Research and development	\$ 664	\$ 913
Selling, general and administrative	4,707	2,452
Total	\$ 5,371	\$ 3,365

Revenues. Revenue for the three months ended June 30, 2025 was \$15.7 million, as compared to \$0.5 million for the three months ended June 30, 2024. Revenue for the three months ended June 30, 2025 includes \$12.8 million in net product revenues for sales of *neffy*, \$2.6 million in revenue for the achievement of the milestone for the first commercial sale of *EURneffy* and for the performance of development and regulatory services performance obligations under the ALK Collaboration Agreement, and \$0.3 million in revenue under supply agreements. Revenue for the three months ended June 30, 2024 includes the recognition of revenue for the delivery of the license for *neffy* in the Seqirus Territory in combination with the transfer of know-how under our license and distribution agreement with Seqirus.

Cost of Goods Sold. Cost of goods sold for the three months ended June 30, 2025 was \$5.0 million, as compared to zero for the three months ended June 30, 2024. Prior to August 2024, costs incurred to manufacture *neffy* were recorded as research and development expenses, and product sales subsequent to August 2024 primarily utilized zero-cost inventory. Cost of goods sold consisted primarily of product costs, the establishment of an inventory reserve, and royalties.

Research and Development Expenses. Research and development expenses for the three months ended June 30, 2025 was \$4.0 million, as compared to \$6.9 million for the three months ended June 30, 2024. The decrease of \$2.9 million was primarily due to decreases in in-process research and development (“IPR&D”) expense of \$2.1 million, personnel-related expenses of \$0.3 million, stock-based compensation expense of \$0.3 million, and other research and development expenses of \$0.2 million.

The following table summarizes our research and development expenses for the three months ended June 30, 2025 and 2024 (in thousands):

	Three Months Ended June 30,	
	2025	2024
Clinical and regulatory	\$ 1,647	\$ 1,849
Manufacturing and non-clinical development	2,388	5,047
Total	\$ 4,035	\$ 6,896

Selling, General and Administrative Expenses. Selling, general and administrative expenses for the three months ended June 30, 2025 was \$54.3 million, as compared to \$8.9 million for the three months ended June 30, 2024. The increase of \$45.4 million was primarily due to increases in marketing-related expenses of \$28.2 million, personnel-related expenses of \$9.0 million, stock-based compensation expense of \$2.3 million, outside services and consulting fees of \$1.8 million, travel and meals expense of \$1.3 million incurred by our sales personnel, conference and seminar expense of \$1.2 million, legal fees of \$0.9 million, audit, tax and valuation fees of \$0.3 million, and other general operating costs of \$0.4 million.

Other Income, Net. Other income, net for the three months ended June 30, 2025 was \$2.7 million, as compared to \$2.8 million for the three months ended June 30, 2024. The decrease of \$0.1 million was primarily due to a decrease in net accretion of discounts on short-term investments of \$0.5 million, partially offset by an increase in interest income of \$0.4 million from our cash, cash equivalents, and short-term investments.

Results of Operations

Comparison of the Six Months Ended June 30, 2025 and 2024

The following table summarizes our results of operations for the six months ended June 30, 2025 and 2024 (in thousands, except percentages):

	Six Months Ended June 30,		Dollar Change	% Change
	2025	2024		
Revenue:				
Product revenue, net	\$ 20,563	\$ —	\$ 20,563	*
Revenue under collaboration agreements	2,804	500	2,304	*
Revenue under supply agreements	323	—	323	*
Total revenue	23,690	500	23,190	*
Operating expenses:				
Cost of goods sold	6,078	—	6,078	*
Research and development ⁽¹⁾	6,987	12,130	(5,143)	(42%)
Selling, general and administrative ⁽¹⁾	95,416	16,902	78,514	*
Total operating expenses	108,481	29,032	79,449	*
Loss from operations	(84,791)	(28,532)	(56,259)	*
Other income, net	5,968	5,724	244	4%
Net loss	(78,823)	(22,808)	(56,015)	*
Change in unrealized gains and losses on available-for-sale securities	(266)	(194)	(72)	37%
Comprehensive loss	\$ (79,089)	\$ (23,002)	\$ (56,087)	*

* Not meaningful

⁽¹⁾ Includes stock-based compensation expense as follows (in thousands):

	Six Months Ended June 30,	
	2025	2024
Research and development	\$ 1,327	\$ 1,824
Selling, general and administrative	9,342	4,856
Total	\$ 10,669	\$ 6,680

Revenues. Revenue for the six months ended June 30, 2025 was \$23.7 million, as compared to \$0.5 million for the six months ended June 30, 2024. Revenue for the six months ended June 30, 2025 includes \$20.6 million in net product revenues for sales of *neffy*, \$2.8 million in revenue for the achievement of the milestone for the first commercial sale of *EURneffy* and for the performance of development and regulatory services performance obligations under the ALK Collaboration Agreement, and \$0.3 million in revenue under supply agreements. Revenue for the six months ended June 30, 2024 includes the recognition of revenue for the delivery of the license for *neffy* in the Seqirus Territory in combination with the transfer of know-how under our license and distribution agreement with Seqirus.

Cost of Goods Sold. Cost of goods sold for the six months ended June 30, 2025 was \$6.1 million, as compared to zero for the six months ended June 30, 2024. Prior to August 2024, costs incurred to manufacture *neffy* were recorded as research and development expenses, and product sales subsequent to August 2024 primarily utilized zero-cost inventory. Cost of goods sold consisted primarily of product costs, the establishment of an inventory reserve, and royalties.

Research and Development Expenses. Research and development expenses for the six months ended June 30, 2025 was \$7.0 million, as compared to \$12.1 million for the six months ended June 30, 2024. The decrease of \$5.1 million was primarily due to decreases in IPR&D expense of \$2.1 million, clinical trial costs of \$1.7 million, personnel-related expenses of \$0.7 million, stock-based compensation expense of \$0.5 million, and other research and development expenses of \$0.4 million, partially offset by an increase in outside services of \$0.3 million.

The following table summarizes our research and development expenses for the six months ended June 30, 2025 and 2024 (in thousands):

	Six Months Ended June 30,	
	2025	2024
Clinical and regulatory	\$ 3,233	\$ 5,264
Manufacturing and non-clinical development	3,754	6,866
Total	\$ 6,987	\$ 12,130

Selling, General and Administrative Expenses. Selling, general and administrative expenses for the six months ended June 30, 2025 was \$95.4 million, as compared to \$16.9 million for the six months ended June 30, 2024. The increase of \$78.5 million was primarily due to increases in marketing-related expenses of \$45.7 million, personnel-related expenses of \$18.0 million, stock-based compensation expense of \$4.5 million, outside services and consulting fees of \$2.8 million, travel and meals expense of \$2.7 million incurred by our sales personnel, conference and seminar expense of \$1.8 million, legal fees of \$1.3 million, audit, tax and valuation fees of \$1.0 million, and other general operating costs of \$0.7 million.

Other Income, Net. Other income, net for the six months ended June 30, 2025 was \$6.0 million, as compared to \$5.7 million for the six months ended June 30, 2024. The increase of \$0.2 million was primarily due to an increase in interest income from our cash, cash equivalents, and short-term investments of \$0.7 million, partially offset by a decrease in net accretion of discounts on short-term investments of \$0.5 million.

Liquidity and Capital Resources

Sources of Liquidity and Capital

Since our inception, we have incurred significant operating losses and negative cash flows from our operations. We have recognized limited net product sales since the commercial launch of *neffy* in September 2024. We have funded our operations to date primarily with proceeds from the Merger, private placement of convertible preferred stock, issuance of common stock, licensing, supply and distribution arrangements with our commercialization partners, bank debt, and limited net product sales. As of June 30, 2025, we had cash, cash equivalents, and short-term investments of \$240.1 million.

Cash flows

The following table summarizes our cash flows for the six months ended June 30, 2025 and 2024 (in thousands):

	Six Months Ended June 30,	
	2025	2024
Net cash and cash equivalents used in operating activities	\$ (80,334)	\$ (13,989)
Net cash and cash equivalents provided by (used in) investing activities	77,635	(21,159)
Net cash and cash equivalents provided by financing activities	3,422	803
Net increase (decrease) in cash and cash equivalents	\$ 723	\$ (34,345)

Operating Activities

During the six months ended June 30, 2025, net cash used in operating activities was \$80.3 million. This consisted primarily of a net loss of \$78.8 million, an increase in our operating assets and operating liabilities of \$28.3 million and \$16.8 million, respectively, and non-cash charges of \$10.0 million. The increase in our operating assets was due to increases in accounts receivable of \$14.4 million, inventories of \$13.2 million, and prepaid expenses and other assets of \$0.7 million. The increase in our operating liabilities was primarily attributable to an increase in accounts payable and accrued expenses of \$17.0 million, partially offset by a decrease in contract liability of \$0.2 million. The non-cash charges consisted primarily of non-cash stock-based compensation of \$10.7 million, establishment of an inventory reserve of \$2.2 million, and depreciation and amortization expense of \$0.6 million, partially offset by \$3.4 million in net accretion of discounts on short-term investments.

During the six months ended June 30, 2024, net cash used in operating activities was \$14.0 million. This consisted primarily of a net loss of \$22.8 million, an increase in our operating liabilities of \$4.4 million, a decrease in our operating assets of \$1.6 million, and non-cash charges of \$2.8 million. The increase in our operating liabilities was primarily due to an increase in accounts payable and accrued liabilities of \$4.4 million. The decrease in our operating assets was primarily due to a decrease in prepaid and other assets of \$1.6 million. The non-cash charges consisted of non-cash stock-based compensation of \$6.7 million, partially offset by \$3.9 million in net accretion of discounts on short-term investments.

Investing Activities

During the six months ended June 30, 2025, the cash and cash equivalents provided by investing activities was \$77.6 million. This consisted of maturities of short-term investments of \$143.5 million, partially offset by purchases of short-term investments of \$65.7 million and purchases of property and equipment of \$0.1 million. During the six months ended June 30, 2024, the cash and cash equivalents used in investing activities was \$21.2 million. This consisted primarily of purchases of short-term investments of \$151.0 million, maturities of short-term investments of \$130.0 million, and purchases of property and equipment of \$0.1 million.

Financing Activities

During the six months ended June 30, 2025, the \$3.4 million of cash and cash equivalents provided by financing activities was attributable to proceeds from stock option exercises and issuance of common stock under the employee stock purchase plan. During the six months ended June 30, 2024, the cash and cash equivalents provided by financing activities was \$0.8 million, which consisted of proceeds from stock option exercises and issuance of common stock under the employee stock purchase plan.

Future Funding Requirements

Based on our current operating plan, we believe that our existing cash, cash equivalents, short-term investments, and revenues from product sales and cash proceeds from collaboration and out-licensing agreements will be sufficient to meet our anticipated cash requirements through at least the next three years. In particular, we expect our existing cash, cash equivalents, short-term investments, and revenues from net product sales and cash proceeds from collaboration and out-licensing agreements will allow us to fund commercial manufacturing and sales and marketing activities, general operating activities and working capital requirements, and proof of concept clinical trials of *neffy* for additional indications. However, our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially. We have based this estimate on assumptions that may prove to be wrong, and we could deplete our capital resources sooner than we expect. Additionally, the process of testing product candidates in clinical trials is costly, and the timing of progress and expenses in these trials is uncertain.

Our future funding requirements will depend on many factors, including:

- the scope, progress, results and costs of researching and developing our intranasal epinephrine technology for additional indications;
- the scope and costs of clinical and commercial manufacturing of *neffy* and our intranasal epinephrine technology product candidates;
- the timing of, and the costs involved in, obtaining marketing approvals for our intranasal epinephrine technology for additional indications;
- the number of additional indications for our intranasal epinephrine technology that we may pursue and their development requirements;
- the costs of commercialization activities for *neffy* and our intranasal epinephrine technology product candidates, to the extent such costs are not the responsibility of any collaborators, including the costs and timing of building and maintaining product sales, marketing, distribution and manufacturing capabilities;
- revenue received from commercial sales of *neffy*;
- the timing and amount of any milestone and royalty payments under the ALK Collaboration Agreement, ALK Co-Promotion Agreement, Pediatrix Agreement, Aegis Agreement, Alfresa Agreement, Recordati Termination Agreement, and the Seqirus Agreement;
- the extent to which we in-license or acquire rights to other products, product candidates, or technologies;
- our headcount growth and associated costs as we expand our employee headcount and building and maintaining a commercial infrastructure;
- the costs of preparing, filing, and prosecuting patent applications, maintaining and protecting our intellectual property rights, including enforcing and defending intellectual property related claims; and
- the costs of operating as a public company.

Until such time, if ever, as we can generate substantial product revenues to support our cost structure, we expect to finance our cash needs through a combination of our existing cash, cash equivalents, short-term investments, equity offerings, debt financings and other capital sources which may include collaborations, strategic alliances, marketing, distribution or licensing arrangements or other arrangements with third parties. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be or could be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing and equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. In addition, our current or future debt agreements may limit our ability to incur additional debt. If we raise funds through additional collaborations, or other similar arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, development programs or product candidates or grant licenses on terms that may not be favorable to us and/or may reduce the value of our common stock.

Our ability to raise additional funds may be adversely impacted by macroeconomic factors that may result in worsening global economic conditions and disruptions to and volatility in the global credit and financial markets, including due to tariffs, trade wars, inflation, high interest rates, recessionary concerns, recessions, bank failures, geopolitical conflicts, and general economic uncertainty. Because of the numerous risks and uncertainties associated with product development and commercialization, we cannot predict the timing or amount of increased expenses and cannot assure you that we will generate profits or positive cash flows from operating activities in the future.

Material Cash Requirements

The total amount of unconditional purchase obligations related to the supply of raw materials is \$57.6 million as of June 30, 2025. Our estimated remaining payment obligations by year are as follows: 2025 (\$0.9 million), 2026 (\$10.5 million), 2027 (\$11.8 million), 2028 (\$13.8 million), and \$2.9 million per year thereafter through 2035.

The total amount of unconditional purchase obligations related to hosted software license subscription fees is \$2.5 million as of June 30, 2025. Our estimated remaining payment obligations by year are as follows: 2025 (\$0.6 million), 2026 (\$1.5 million), and 2027 (\$0.4 million).

In August 2024, we entered into a corporate sponsorship agreement with Food Allergy Research and Education, Inc., which was subsequently amended in May 2025, pursuant to which we have payment obligations of \$14.0 million over a 43-month period. Our remaining payment obligations as of June 30, 2025 are \$10.0 million. Our estimated remaining payment obligations by year are as follows: 2025 (\$4.0 million), 2026 (\$5.0 million), and 2027 (\$1.0 million).

In June 2018, we entered into a License Agreement (the “Aegis Agreement”) with Aegis Therapeutics, LLC (“Aegis”), a wholly owned subsidiary of Neurelis, Inc. In November 2024, OrbiMed Advisors LLC (“OrbiMed”) entered into an agreement with Aegis, to purchase the rights, royalty interests, and related sales milestone payments on net product sales of *neffy*. Our remaining payment obligations to OrbiMed under the Aegis Agreement are contingent upon our achievement of certain commercial milestones and have been reduced to \$11.0 million as of June 30, 2025. Under the Aegis Agreement, we are also required to make royalty payments to OrbiMed based on a mid-single-digit percentage of net product sales. Future royalty payment amounts are indeterminate since they depend on future revenues, which are uncertain.

In February 2023, we entered into a termination agreement (the “Recordati Termination Agreement”) with Recordati Ireland, Ltd. (“Recordati”) to reacquire the rights to *neffy* in Europe and certain European Free Trade Association, Russia/the Commonwealth of Independent States, Middle East and African countries (the “Recordati Territory”). Pursuant to which, we are obligated to make milestone payments to Recordati that are contingent upon our achievement of certain regulatory and commercial milestones. Our remaining milestone payment obligations to Recordati have been reduced to €5.0 million (approximately \$5.9 million in U.S. dollars) as of June 30, 2025. Under the Recordati Termination Agreement, we are also required to make royalty payments to Recordati of up to €5.0 million (approximately \$5.9 million in U.S. dollars) in the aggregate from sales of Recordati Licensed Product(s) in the Recordati Territory. Future royalty payment amounts are indeterminate since they depend on future revenues, which are uncertain.

In May 2025, we entered into the ALK Co-Promotion Agreement with ALK U.S. to co-promote *neffy* to up to 9,000 specified pediatricians and other prescribers in the U.S. Pursuant to the ALK Co-Promotion Agreement, we will pay ALK U.S. a base fee to compensation ALK U.S. for its promotion activities. Payments for the first year of the partnership will be deferred and paid in the second year of the partnership. The total remaining payment obligations under this agreement are \$26.8 million as of June 30, 2025. Our remaining payment obligations by year are as follows: 2025 (\$0.0 million), 2026 (\$4.4 million), 2027 (\$14.2 million), 2028 (\$4.6 million), and 2029 (\$3.6 million). In addition to the base fee, ALK U.S. will be eligible to receive performance-based payments from us. Future performance-based payment amounts are indeterminate since they depend on future revenues, which are uncertain.

We enter into contracts in the normal course of business with third-party contract organizations and vendors for clinical studies, manufacturing and other services and products. These contracts generally provide for termination after a notice period.

As of June 30, 2025, we have not recognized any reserves related to uncertain tax positions and had no accrued interest or penalties related to uncertain tax positions.

Critical Accounting Policies and Estimates

Our management’s discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles (GAAP). The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and the disclosure of contingent assets and liabilities in our financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to revenue, accrued expenses, stock-based compensation, and valuation allowances for deferred tax assets. We base our estimates on historical experience, known trends and events, and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

During the six months ended June 30, 2025, there were no material changes to our critical accounting policies or estimates. Our critical accounting policies and estimates are described under the heading “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Policies and Significant Judgments and Estimates” in our Annual Report on Form 10-K filed with the SEC on March 20, 2025 and [Note 2 – Summary of Significant Accounting Policies](#) to our unaudited condensed consolidated financial statements appearing in Part I, Item 1 of this Quarterly Report on Form 10-Q.

Recent Accounting Pronouncements

See [Note 2 – Summary of Significant Accounting Policies](#) to our unaudited condensed consolidated financial statements appearing in Part I, Item 1 of this Quarterly Report on Form 10-Q for additional information.

Emerging Growth Company and Smaller Reporting Company Status

We are an emerging growth company, as defined in the JOBS Act. For so long as we remain an emerging growth company, we are permitted and intend to rely on certain exemptions from various public company reporting requirements, including not being required to have our internal control over financial reporting audited by our independent registered public accounting firm pursuant to Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and any golden parachute payments not previously approved.

Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We have elected to use this extended transition period for complying with certain new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

We will remain an emerging growth company until the earlier of: (i) the date on which we have issued more than \$1.0 billion in nonconvertible debt securities during the prior three-year period; and (ii) December 31, 2025.

We are also a “smaller reporting company” as defined in the Exchange Act.

However, on June 30, 2025, the aggregate market value of our common stock held by non-affiliates exceeded \$700 million, based on the closing price of our common stock on The Nasdaq Stock Global Select Market on such date. As a result, effective December 31, 2025, we will be considered a “large accelerated filer”, as defined in Rule 12b-2 under the Exchange Act. We will be permitted to continue to comply with the scaled disclosures rules applicable to smaller reporting companies until the filing of our quarterly report on Form 10-Q for the quarter ending March 31, 2026.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Not required for a “smaller reporting company” as defined under Item 10(f)(1) of Regulation S-K of the Securities Act.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

As required by Rules 13a-15(b) and 15d-15(b) of the Exchange Act, our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2025. The term “disclosure controls and procedures” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of June 30, 2025, our Chief Executive Officer and our Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the quarter ended June 30, 2025 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we may be involved in various claims and legal proceedings relating to claims arising out of our operations. See [Note 9 – Commitments and Contingencies](#) to the unaudited condensed consolidated financial statements in this Form 10-Q, which is incorporated by reference in this Part II, Item 1, for any required disclosure.

Item 1A. Risk Factors

We operate in a dynamic and rapidly changing environment that involves numerous risks and uncertainties. Certain factors may have a material adverse effect on our business, financial condition and results of operations, and you should carefully consider them. Accordingly, in evaluating our business, we encourage you to consider the following discussion of risk factors, in its entirety, in addition to other information contained in this Quarterly Report on Form 10-Q and our other public filings with the SEC. Other events that we do not currently anticipate or that we currently deem immaterial may also affect our results of operations and financial condition. The risk factors set forth below that are marked with an asterisk () did not appear as separate risk factors in, or contain changes to the similarly titled risk factor included in Item 1A. of our Annual Report on Form 10-K, filed with the SEC on March 20, 2025.*

Risks Related to Our Business

We are highly dependent on the successful commercialization of neffy in the United States and in the EU for its currently approved indications in those jurisdictions. To the extent neffy is not commercially successful, our business, financial condition and results of operations would be materially adversely affected, and the price of our common stock would likely decline.

neffy is our only product that has been approved for sale and it has only been approved in the United States for the emergency treatment of Type I allergic reactions, including anaphylaxis, in patients who are four years of age and older and weigh 15 kg to less than 30 kg (in the case of *neffy* 1 mg), and in adults and children who weigh 30 kg or greater (in the case of *neffy* 2 mg), and in the EU (under the trade name *EURneffy*, and only in the 2 mg form) for the emergency treatment of allergic reactions (anaphylaxis) due to insect stings or bites, foods, medicinal products and other allergens as well as idiopathic or exercise induced anaphylaxis, for adults and children with a body weight 30 kg or greater. We are focusing a significant portion of our activities and resources on *neffy*, and we believe our near-term revenues are highly dependent on, and a meaningful portion of the value of our company relates to, our ability to successfully commercialize *neffy* in the United States and the EU (under the trade name *EURneffy*). Successful commercialization of *neffy* is subject to many risks. Prior to *neffy*, we have not, as an organization, commercialized any product, and there is no guarantee that we will be able to do so successfully with *neffy*. There are numerous examples of unsuccessful product launches and failures to meet high expectations of market potential, including by pharmaceutical companies with more experience and resources than we have. The commercial success of *neffy* depends on the extent to which patients and physicians accept and adopt *neffy* as a treatment of Type I allergic reactions, including anaphylaxis, and we do not know whether our or others' estimates in this regard will be accurate. For example, if the population of patients who may suffer a Type I allergic reaction is smaller than we estimate or if physicians are unwilling to prescribe or patients are unwilling to use *neffy* for any reason, the commercial potential of *neffy* will be limited. It is too soon to tell how physicians, patients and payors will respond to the pricing of *neffy*. Physicians may not prescribe *neffy* and patients may be unwilling to use *neffy* if coverage is not provided or reimbursement is inadequate to cover a significant portion of the cost. Additionally, any negative development for *neffy* in post-approval trials or potential additional indications, including urticaria, or in regulatory processes in other jurisdictions, may adversely impact the commercial results and potential of *neffy*. Thus, significant uncertainty remains regarding the commercial potential of *neffy*. If the commercialization of *neffy* is unsuccessful or perceived as disappointing, our stock price could decline significantly and the long-term success of the product and our company could be harmed.

If we are unable to fully develop and maintain our sales, marketing and distribution capabilities on our own or through collaborations with marketing partners, we may not be successful in commercializing neffy.*

We have built a sales force and entered into the ALK Co-Promotion Agreement to commercialize *neffy* in the United States. In order to successfully commercialize *neffy*, we must, among other things, continue to build our sales, marketing, distribution, managerial and other non-technical capabilities. Factors that may hinder our ability to successfully market and commercially distribute our products include:

- inability of sales personnel to obtain access to or educate adequate numbers of physicians on the benefits and safety of prescribing *neffy*;
- inability to recruit, retain and effectively manage adequate numbers of effective sales personnel, including ALK U.S. sales personnel;
- lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies that have more extensive product lines; and
- unforeseen delays, costs and expenses associated with maintaining our sales organization and receive the intended benefits to be provided by the ALK Co-Promotion Agreement.

If we are unable to maintain an effective sales force, including through the ALK Co-Promotion Agreement, for *neffy*, we may not be able to generate significant product revenue in the United States. In addition, until the commencement of our commercial launch in September 2024, no one in our sales force had promoted *neffy*. We are required to expend significant time and resources to train our sales force, including through the ALK Co-Promotion Agreement, to be credible in educating physicians and pharmacists on the benefits of *neffy*. In addition, we must continually train our sales force, including through the ALK Co-Promotion Agreement, to ensure that a consistent and appropriate message about *neffy* is being delivered to our potential customers. We currently have limited resources compared to some of our competitors, and the continued development of our own commercial organization to market *neffy* and any additional products we may develop or acquire will be expensive and time-consuming. We also cannot be certain that we will be able to continue to successfully develop this capability.

We have entered into the ALK Co-Promotion Agreement with ALK U.S. for the co-promotion of *neffy* to up to 9,000 specified pediatricians and other prescribers in the U.S. The commercial success of *neffy* in the United States, will be influenced in part by the efforts and allocation of resources by ALK U.S. Currently, ALK U.S. has limited experience promoting *neffy*, and while we will continue to work with ALK U.S. to optimize their commercialization activities, we cannot guarantee that such efforts will be successful. We also depend on ALK U.S. to comply with all applicable laws relative to the promotion of *neffy*. Because we do not control the individual efforts of ALK U.S., they may take actions or fail to take actions in a manner that is inconsistent with our interests. As a result, we may not realize the full potential benefits from the ALK Co-Promotion Agreement, and such actions or inactions could result in more limited or reduced sales, reputational harm, or regulatory or other adverse legal implications, any of which could adversely affect our business and results of operations.

We entered into exclusive licensing and collaboration agreements for the development and commercialization of *neffy* with Alfresa Pharma Corporation in Japan; Pediatrix Therapeutics, Inc. in China, Macau, Hong Kong and Taiwan; CSL Seqirus in Australia and New Zealand; and ALK in all other unpartnered geographies outside the United States. If these third parties do not effectively engage or maintain their sales force for *neffy* if approved in the applicable territories, our ability to recognize milestone payments and royalties from the sales in such territories will be adversely affected.

We will need to continue to expend significant time and resources to train our sales forces to be credible in discussing *neffy* with the specialists treating the patients indicated under the product's label. In addition, if we are unable to effectively train our sales force and equip them with effective marketing materials our ability to successfully commercialize *neffy* could be diminished, which would have a material adverse effect on our business, results of operations and financial condition.

neffy and our current and future intranasal epinephrine technology product candidates may fail to achieve the degree of market acceptance by allergists, pediatricians and other physicians, patients, caregivers, third-party payors and others in the medical community necessary for commercial success, in which case we may not generate significant revenues or profits.

We have never commercialized a product before our U.S. commercial launch of *neffy* in September 2024, and *neffy* may fail to gain sufficient market acceptance by allergists, pediatricians and other physicians, patients, caregivers, third-party payors and others in the medical community. Physicians may be reluctant to prescribe *neffy* or our current and future intranasal epinephrine technology product candidates in place of well-established epinephrine intra-muscular injectable devices or other available treatments. Further, patients and caregivers may be reluctant to switch unless their physicians recommend switching products or are required to switch due to lack of coverage and adequate reimbursement. In addition, even though *neffy* has been determined to be safe and effective by the FDA and the EMA, safety or efficacy concerns in the medical community may hinder market acceptance.

The degree of market acceptance of *neffy* and any future intranasal epinephrine technology product will depend on a number of factors, including:

- the ability to provide acceptable evidence of safety and efficacy;
- the potential advantages of the product compared to competitive therapies and our ability to successfully publicize these advantages or highlight them in any marketing materials;
- the scope of the approved indication(s) for the product;
- the inclusion of any warnings or contraindications in the product label;
- the relative convenience and ease of administration;
- the willingness of the target patient population to try, and of physicians to prescribe, the product;
- the prevalence and severity of any adverse side effects;
- the availability of alternative treatments and products from our competitors;
- pricing and cost effectiveness, which may be subject to regulatory control;
- changes in the standard of care for the targeted indications for the product;
- effectiveness of our or our collaborators' sales and marketing strategy; and
- our ability to obtain sufficient third-party insurance coverage or adequate reimbursement levels.

The market for neffy and our intranasal epinephrine technology may be smaller than we expect.

We have focused our development of our intranasal epinephrine technology initially for the emergency treatment of Type I allergic reactions. We base our market opportunity estimates on a variety of factors, including our estimates of the number of people who have experienced severe Type I allergic reactions and are at risk of anaphylaxis, the continued growth rate of our patient population, the number of those in our patient population who we expect will fill a prescription for *neffy*, including those that currently do not fill prescriptions for epinephrine intra-muscular injectable devices or whose prescriptions have lapsed, the estimated increase in per patient device acquisition of *neffy* as compared to epinephrine intra-muscular injectable devices and the net sales of epinephrine intra-muscular injectable devices. These estimates are based on many assumptions and may prove incorrect, and new studies or market research may reduce our estimated patient population and potential sales. If our market opportunities are smaller than we expect, our future product revenues may be smaller than anticipated, which would adversely affect our business, financial condition, results of operations and prospects.

If we are unable to achieve and maintain adequate levels of third-party payor coverage and reimbursement for neffy on reasonable pricing terms, its commercial success may be severely hindered.*

Successful sales of any approved products, including *neffy*, depend on the availability of adequate coverage and reimbursement from third-party payors. Patients who are prescribed medicine for the treatment of their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their prescription drugs. Coverage and adequate reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available. Even with coverage for *neffy*, the resulting reimbursement payment rates might not be adequate or may require co-payments that patients find unacceptably high. Patients may not use *neffy* if coverage is not provided or reimbursement is inadequate to cover a significant portion of the cost of those products.

Payors may require documented proof that patients meet certain eligibility criteria in order to be reimbursed for *neffy*. Payors may even require that pre-approval, or prior-authorization, be obtained from the payor for reimbursement of *neffy*. Patients are unlikely to use *neffy* unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of *neffy*.

In addition, the market for *neffy* may depend significantly on access to third-party payors' medical policies, drug formularies, or lists of medications for which third-party payors provide coverage and reimbursement. The industry competition to be included in such formularies often leads to downward pricing pressures on pharmaceutical companies, and we will be required to offer discounted rates to state Medicaid programs to ensure Medicaid coverage of our drugs. Also, third-party payors may refuse to include a particular branded drug in their formularies or otherwise restrict patient access to a branded drug when a less costly generic equivalent or other alternative is available, even if not approved for the indication(s) for which *neffy* is approved.

Third-party payors, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. The current environment is putting pressure on companies to price products below what they may feel is appropriate. Selling *neffy* at less than an optimized price could impact our revenues and overall success as a company. In addition, in the United States, no uniform policy of coverage and reimbursement for drug products exists among third-party payors. Therefore, coverage and reimbursement for *neffy* may differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of *neffy* to each payor separately, with no assurance that coverage will be obtained, or that payment levels will be adequate for *neffy* or any other products we may market. Further, coverage policies and third-party payor reimbursement rates may change at any time. Therefore, even if favorable coverage and reimbursement status is attained for *neffy* or more products for which we receive marketing approval, less favorable coverage policies and reimbursement rates may be implemented in the future. In addition, physicians may limit how much or under what circumstances they will prescribe or administer *neffy*, or any other products we may market, and patients may decline to purchase them. This in turn could affect our ability to successfully commercialize *neffy*, or any other products we may market, and thereby adversely impact our profitability, results of operations, financial condition and future success.

neffy has only been studied in a limited number of patients. neffy is now available to a much larger number of patients, and we do not know whether the results of neffy's use in such larger number of patients will be consistent with the results from our clinical studies.

Prior to commercialization, *neffy* had been administered only to a limited number of patients in clinical studies. While the FDA and European Commission granted approval of *neffy* based on the data included in the NDA and marketing authorization application ("MAA"), respectively, we do not know whether the results when a large number of patients are exposed to *neffy*, including results related to safety and efficacy, will be consistent with the results from earlier clinical studies of *neffy* that served as the basis for the approval of *neffy*. New data relating to *neffy* may result in changes to the product label and may adversely affect sales, or result in withdrawal of *neffy* from the market. The FDA and regulatory authorities in other jurisdictions may also consider the new data in reviewing *neffy*'s marketing applications for additional indications and/or in other jurisdictions, or impose post-approval requirements. If any of these actions were to occur, it could result in significant expense and delay or limit our ability to generate sales revenues.

Competitive products may reduce or eliminate the commercial opportunity for neffy or our current and future intranasal epinephrine technology product candidates. If our competitors develop technologies or product candidates more rapidly than us, or their technologies or product candidates are more effective or safer than ours, our ability to develop and successfully commercialize neffy and our current and future intranasal epinephrine technology product candidates may be adversely affected.*

The clinical and commercial landscape for the emergency treatment of Type I allergic reactions is highly competitive and subject to significant technological change. We face competition with respect to our current indications for our intranasal epinephrine technology, including *neffy*, and will face competition with respect to any future indications of our intranasal epinephrine technology or other product candidates that we may seek to develop or commercialize in the future from large pharmaceutical and biotechnology companies, specialty pharmaceutical and generic drug companies, academic institutions, government agencies and research institutions. Based on the initially approved indications for *neffy*, we anticipate that *neffy* will compete primarily against epinephrine intra-muscular injectable products, for the emergency treatment of Type I allergic reactions including EpiPen and its generics, which is marketed by Viatris, Inc. and Teva Pharmaceuticals, Inc.; Adrenaclick, which is marketed by Amneal Pharmaceuticals, Inc.; Auvi-Q, which is marketed by Kaleo, Inc.; and Symjepi, which is marketed by Sandoz, Inc., a Novartis division. Several other companies are also clinically developing larger dose intranasal epinephrine product candidates that may compete with *neffy*, including Bryn Pharma, Nasus Pharma, Hikma Pharmaceuticals, Inc. (previously INSYS Therapeutics, Inc.), Orexo AB and Belhaven BioPharma. Aquestive Therapeutics is developing a sublingual candidate based on a prodrug of epinephrine. If our current and future intranasal epinephrine technology product candidates are approved for other indications, they would also compete with a range of other therapeutic treatments that are well established such as antihistamines or in development.

Many of our potential competitors have substantially greater financial, technical, commercial and human resources than we do and significantly more experience in the discovery, development and regulatory approval of product candidates and the commercialization of those products. Accordingly, our competitors may be more successful than we may be in obtaining regulatory approval for therapies and achieving widespread market acceptance. Our competitors' products may be more effective, safer, or more effectively marketed and sold, than any product candidate we may commercialize and may render *neffy* or our current and future intranasal epinephrine technology product candidates obsolete or non-competitive before we can recover development and commercialization expenses. In addition, our competitors may succeed in developing, acquiring or licensing technologies and drug products that are more effective or less costly than *neffy* or our current and future intranasal epinephrine technology product candidates, which could render such products or product candidates obsolete and noncompetitive.

We face competition based on many different factors, including the efficacy, safety and tolerability of *neffy* and our current and future intranasal epinephrine technology product candidates, the ease with which *neffy* and our current and future intranasal epinephrine technology product candidates can be administered, the scope of regulatory approval for *neffy* and our current and future intranasal epinephrine technology product candidates, the availability and cost of manufacturing, marketing and sales capabilities, price, reimbursement coverage and patent position. Such competitors could also recruit our employees, which could negatively impact our level of expertise and our ability to execute our business plan.

In addition, our competitors may obtain patent protection, regulatory exclusivities or regulatory approval and commercialize products more rapidly than we do, which may impact future approvals or sales of any of our products that receive regulatory approval. We will also be competing with respect to marketing capabilities and manufacturing efficiency for *neffy* as an early commercial stage product. We expect competition among future products, if any, will be based on product efficacy and safety, the timing and scope of regulatory approvals, availability of supply, marketing and sales capabilities, product price, reimbursement coverage by government and private third-party payors, regulatory exclusivities and patent position. Our profitability and financial position will suffer if our product or future products cannot compete effectively in the marketplace.

Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early commercial stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites, as well as in acquiring technologies complementary to, or necessary for, our activities.

If the FDA, the European Commission or other comparable foreign regulatory authorities approve generic versions of neffy or our current or future intranasal epinephrine technology product candidates that receives regulatory approval, or such authorities do not grant our products appropriate periods of non-patent exclusivity before approving generic versions of such products, the sales of such products could be adversely affected.*

In the United States, once an NDA is approved, the product covered thereby becomes a "reference listed drug" in the FDA's publication, "Approved Drug Products with Therapeutic Equivalence Evaluations," or the Orange Book. Manufacturers may seek approval of generic versions of reference listed drugs through submission of ANDAs in the United States. In support of an ANDA, a generic manufacturer generally must show that its product has the same active ingredient(s), dosage form, strength, route of administration, and adequate labeling as the reference listed drug and that the generic version is bioequivalent to the reference listed drug, meaning, in part, that it is absorbed in the body at the same rate and to the same extent. Generic products may be significantly less costly to bring to market than the reference listed drug and companies that produce generic products are generally able to offer them at lower prices. Moreover, third-party insurers require, and many states allow or require, substitution of therapeutically equivalent generic drugs at the pharmacy level even if the branded drug is prescribed. Thus, following the introduction of a generic drug, a significant percentage of the sales of any branded product or reference listed drug may be lost to the generic product.

The FDA may not finally approve an ANDA for a generic product or a Section 505(b)(2) NDA of a competitor until any applicable period of non-patent exclusivity for the reference listed drug has expired. The FDCA provides a period of five years of non-patent exclusivity for a new drug containing a new chemical entity ("NCE"). For the purposes of this provision, an NCE is a drug that contains no active moiety that has previously been approved by the FDA in any other NDA. An active moiety is the molecule or ion responsible for the physiological or pharmacological action of the drug substance. Specifically, in cases where such exclusivity has been granted, an ANDA may not be filed with the FDA until the expiration of five years unless the submission is accompanied by a Paragraph IV certification that a patent covering the listed drug is invalid, unenforceable or will not be infringed by the generic product. In that case, the applicant may submit its application four years following approval of the listed drug and seek to launch its generic product even if we still have patent protection for our product unless an infringement suit is timely filed by the NDA or patent holder in which case the FDA cannot approve the ANDA or a Section 505(b)(2) NDA for 30 months unless a court decision in favor of the generic manufacturer is issued earlier.

Upon receiving a marketing authorization in the EU from the European Commission, innovative medicinal products are generally entitled to receive eight years of data exclusivity and 10 years of market exclusivity. Data exclusivity, if granted, prevents regulatory authorities in the EU from referencing the innovator's data to assess a generic application or biosimilar application for eight years from the date of authorization of the innovative product, after which a generic or biosimilar MAA can be submitted, and the innovator's data may be referenced. The market exclusivity period prevents a successful generic or biosimilar applicant from commercializing its product in the EU until 10 years have elapsed from the initial MA of the reference product in the EU. The overall ten-year period may, occasionally, be extended for a further year to a maximum of 11 years if, during the first eight years of those 10 years, the MA holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. However, there is no guarantee that a product will be considered by the EU's regulatory authorities to be a new chemical/biological entity, and products may not qualify for data exclusivity. Comparable regimes to those in the US and EU exist in some other major markets, including the United Kingdom.

Obtaining regulatory approval of neffy or our current or future intranasal epinephrine technology product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval in other jurisdictions.*

Even though we have obtained regulatory approval of *neffy* in the United States and the EU, there is no guarantee that we will be able to maintain these regulatory approvals or obtain or maintain regulatory approval in any other jurisdiction. A failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even though the FDA and European Commission have granted marketing approval of *neffy*, comparable regulatory authorities in other foreign jurisdictions must also approve the manufacturing, marketing and promotion of *neffy* before it can be marketed in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States or the EU including additional nonclinical studies or clinical trials, as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States including certain jurisdictions in the EU, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

We have submitted and plan to submit additional or supplemental marketing applications in the United States and in the EU. Regulatory authorities in jurisdictions outside of the United States have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions and such regulatory requirements can vary widely from country to country. Obtaining other regulatory approvals and compliance with other regulatory requirements could result in significant delays, difficulties and costs for us and could require additional nonclinical studies or clinical trials, which could be costly and time-consuming and could delay or prevent the introduction of our products in certain countries. The foreign regulatory approval process involves all of the risks associated with FDA approval. We have one product approved for sale. We have limited experience in obtaining regulatory approval in domestic and international markets. If we or our collaboration partners fail to comply with the regulatory requirements in international markets and/or obtain and maintain applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of *neffy* will be harmed.

If we are unable to successfully develop our current or future intranasal epinephrine technology product candidates, or neffy for additional indications, or experience significant delays in doing so, the commercial potential of our current or future intranasal epinephrine technology product candidates or neffy will be more limited.*

Successful continued development and ultimate regulatory approval of our current or future intranasal epinephrine technology product candidates and *neffy* for additional indications is important to the future success of our business. The future regulatory and commercial success of our current or future intranasal epinephrine technology product candidates and *neffy* for additional indications is subject to a number of risks, including the following:

- successful completion of nonclinical studies and clinical trials;
- successful patient enrollment in clinical trials;
- successful data from our nonclinical studies and clinical trials that support an acceptable risk-benefit profile of our intranasal epinephrine technology in the intended populations and indications;
- satisfaction of applicable regulatory requirements, including to satisfy applicable rules governing combination products;
- potential unforeseen safety issues or adverse side effects;
- receipt and maintenance of marketing approvals from applicable regulatory authorities;
- remaining in compliance with post-marketing regulatory requirements;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our intranasal epinephrine technology;
- making arrangements or maintaining existing arrangements with third-party manufacturers, or establishing manufacturing capabilities, for both clinical and commercial supplies of our intranasal epinephrine technology;
- entry into collaborations to further the development of *neffy* and our current and future intranasal epinephrine technology product candidates in other jurisdictions or for additional indications;
- continuing to grow our sales, marketing and distribution capabilities and commercializing any approved products, whether alone or in collaboration with others;
- successfully commercializing *neffy* and our current and future intranasal epinephrine technology product candidates;
- acceptance by patients, the medical community and third-party payors of *neffy* and our current and future intranasal epinephrine technology product candidates;
- obtaining and maintaining third-party coverage and adequate reimbursement;
- products, following approval, maintaining a continued acceptable safety profile;
- effectively competing with other therapies;
- ensuring that we promote and distribute our products consistent with all applicable healthcare laws; and
- enforcing and defending intellectual property rights and claims.

Many of these risks are beyond our control, including the risks related to clinical development, the regulatory submission and review process, maintaining regulatory approval, potential threats to our intellectual property rights and the manufacturing, marketing and sales efforts of any current or future collaboration partner. If we or a collaboration partner are unable to develop, receive regulatory approval for our intranasal epinephrine technology for the additional indications we are developing it for, including urticaria, or if we experience delays as a result of any of these risks or otherwise, our ability to grow our business will be limited.

If the FDA does not conclude that our current or future intranasal epinephrine technology product candidates, or neffy for additional indications, satisfy the requirements for the Section 505(b)(2) regulatory approval pathway, or if the requirements for such product candidates or additional indications under Section 505(b)(2) are not as we expect, the approval pathway for those product candidates or additional indications will likely take significantly longer, cost significantly more and entail significantly greater complications and risks than anticipated, and in either case may not be successful.*

The Hatch Waxman Act added Section 505(b)(2) to the FDCA. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference. Section 505(b)(2), if available to us, would allow an NDA we submit to the FDA to rely in part on data in the public domain or the FDA's prior conclusions regarding the safety and effectiveness of approved compounds, which could expedite the development program for any additional indications by potentially decreasing the amount of nonclinical and/or clinical data that we would need to generate in order to obtain FDA approval. This pathway does not, however, expedite the FDA review process timelines.

If the FDA does not allow us to proceed under the Section 505(b)(2) regulatory pathway for our current or future intranasal epinephrine technology product candidates, or *neffy* for additional indications, we may need to conduct additional nonclinical studies and/or clinical trials, provide additional data and information, and meet additional standards for regulatory approval. If this were to occur, the time and financial resources required to obtain FDA approval for any such product candidates or additional indications, including for urticaria, and complications and risks associated with such product candidates, would likely substantially increase. Moreover, inability to pursue the Section 505(b)(2) regulatory pathway could result in new competitive products reaching the market more quickly than any product candidates we develop, which could adversely impact our competitive position and prospects. We cannot assure you that our current or future intranasal epinephrine technology product candidates or *neffy* for additional indications will receive the requisite approval for commercialization.

In addition, notwithstanding the approval of a number of products by the FDA under Section 505(b)(2), certain pharmaceutical companies and others have objected to the FDA's interpretation of Section 505(b)(2). If the FDA's interpretation of Section 505(b)(2) is successfully challenged, the FDA may change its Section 505(b)(2) policies and practices, which could delay or even prevent the FDA from approving any NDA that we submit under Section 505(b)(2). In addition, the pharmaceutical industry is highly competitive, and Section 505(b)(2) NDAs are subject to certain requirements designed to protect the patent rights of sponsors of previously approved drugs that are referenced in a Section 505(b)(2) NDA. These requirements may give rise to patent litigation and mandatory delays in approval of our NDAs for up to 30 months or longer depending on the outcome of any litigation. It is not uncommon for a manufacturer of an approved product to file a citizen petition with the FDA seeking to delay approval of, or impose additional approval requirements for, pending competing products. If successful, such petitions can significantly delay, or even prevent, the approval of a new product. Even if the FDA ultimately denies such a petition, the FDA may substantially delay approval while it considers and responds to the petition. Finally, a competitor might receive FDA approval and obtain non-patent market exclusivity before we obtain approval of any such product candidates or additional indications, including urticaria, which could delay approval of potential additional indications, including urticaria, for our intranasal epinephrine technology.

We may incur unexpected costs or experience delays in completing, or ultimately be unable to complete, further development and the commercialization of our current and future intranasal epinephrine technology product candidates.*

To obtain the requisite regulatory approvals to market and commercialize our current and future intranasal epinephrine technology product candidate, including for urticaria, we must demonstrate through extensive nonclinical studies and clinical trials that such product candidates are safe and effective for their intended use in humans. Nonclinical and clinical testing are expensive and can take many years to complete, and their outcome is inherently uncertain. Failure can occur at any time during the clinical trial process and our future clinical trial results may not be successful.

We may experience delays in completing our clinical trials or nonclinical studies and initiating or completing additional studies or clinical trials. We may also experience numerous unforeseen events during our clinical trials that could delay or prevent our ability to receive marketing approval or commercialize for our current and future intranasal epinephrine technology product candidates, including for urticaria, including:

- regulators, IRBs, ethics committees or other reviewing bodies may not authorize or issue positive opinions permitting us or our investigators to commence a clinical trial, or to conduct or continue a clinical trial at a prospective or specific trial site;
- we may not reach an agreement on acceptable terms with prospective contract research organizations (“CROs”) and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- a delay in receiving study or clinical trial material from outside the United States;
- the number of subjects or patients required for clinical trials of our current and future intranasal epinephrine technology product candidates, including for urticaria, may be larger than we anticipate, enrollment in these clinical trials may be insufficient or slower than we anticipate, and the number of clinical trials being conducted at any given time may be high and result in fewer available patients for any given clinical trial, or patients may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors, including those manufacturing *neffy* or conducting clinical trials on our behalf, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we may have to amend clinical trial protocol(s) submitted to regulatory authorities or conduct additional studies to reflect changes in regulatory requirements or guidance, which we may be required to resubmit to an IRB or ethics committee and regulatory authorities for re-examination;
- unforeseen safety events may occur during the course of a clinical trial and these events may result in the temporary suspension or termination of a clinical trial, or require urgent safety measures or restrictions to protect human subjects during the conduct of a clinical trial;
- regulators, IRBs, ethics committees or other reviewing bodies may fail to approve or issue positive opinions or subsequently find fault with the manufacturing processes or facilities of third-party manufacturers with which we have entered and may enter into agreement for clinical and commercial supplies, or the supply or quality of our current and future intranasal epinephrine technology product candidates or other materials necessary to conduct clinical trials of our current and future intranasal epinephrine technology product candidates, including for urticaria, may be insufficient, inadequate or not available at an acceptable cost, or we may experience interruptions in supply; and
- the potential for policies or regulations of the FDA, the EMA, the EU or any other applicable foreign regulatory authorities to significantly change in a manner rendering our clinical data insufficient for approval.

Regulators, IRBs and ethics committees of the institutions in which clinical trials are being conducted, or data monitoring committees may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to appear to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

Negative or inconclusive impressions of the results from our earlier clinical trials of *neffy* for the emergency treatment of Type I allergic reactions or any other clinical trial or nonclinical studies in animals that we have conducted, could mandate repeated or additional nonclinical studies or clinical trials and could delay marketing approvals or result in changes to or delays in nonclinical studies or clinical trials of our current and future intranasal epinephrine technology product candidates, including for urticaria. While data from our studies of our intranasal epinephrine technology product candidates demonstrated nasally delivered epinephrine reached blood levels comparable to those of already approved epinephrine injectable products, we do not know whether any future clinical trials or studies that we may conduct will demonstrate adequate efficacy and safety necessary to result in obtaining regulatory approval to market our current and future intranasal epinephrine technology product candidates, including for urticaria. If later stage clinical trials do not produce favorable results that meet regulatory authority criteria, our ability to obtain regulatory approval for our current and future intranasal epinephrine technology product candidate, including for urticaria, may be adversely impacted.

Our failure to successfully initiate and complete clinical trials of our current and future intranasal epinephrine technology product candidates, including for urticaria, and to demonstrate the efficacy and safety necessary to obtain regulatory approval to market our current and future intranasal epinephrine technology product candidates, including for urticaria, would significantly harm our business. Our product candidate development costs will also increase if we experience delays in testing or regulatory approvals and we may be required to obtain additional funds to complete clinical trials. We cannot assure you that our clinical trials will begin as planned or be completed on schedule, if at all, or that we will not need to restructure our trials after they have begun. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our current and future intranasal epinephrine technology product candidates, including for urticaria, or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize such product candidates, which may harm our business and results of operations. In addition, many of the factors that cause, or lead to, delays of clinical trials may ultimately lead to the denial of regulatory approval of our current and future intranasal epinephrine technology product candidates, including urticaria.

We may not be successful in our efforts to expand our pipeline by identifying additional indications for which to investigate intranasal epinephrine technology in the future or by developing or acquiring new products or product candidates. We may expend our limited resources to pursue a particular indication or formulation for our intranasal epinephrine technology and fail to capitalize on product candidates, indications or formulations that may be more profitable or for which there is a greater likelihood of success.

Although *neffy* is approved in the United States for the emergency treatment of Type I allergic reactions, including anaphylaxis, in patients who are four years of age and older and weigh 15 kg to less than 30 kg (in the case of *neffy* 1 mg), and in adults and children who weigh 30 kg or greater (in the case of *neffy* 2 mg), and in the EU (under the trade name *EURneffy*, and only in the 2 mg form) for the emergency treatment of allergic reactions (anaphylaxis) due to insect stings or bites, foods, medicinal products and other allergens as well as idiopathic or exercise induced anaphylaxis, for adults and children with a body weight 30 kg or greater, as part of our longer-term growth strategy, we are evaluating and plan to continue to evaluate our intranasal epinephrine technology, including *neffy*, for use in other potential indications. We may evaluate opportunities to in-license or acquire other development programs, product candidates, as well as commercial products, including for the treatment of other indications like Type I allergic reactions. Other than our intranasal epinephrine technology, we do not currently have any other programs in development. Our development of our intranasal epinephrine technology for other indications remains at an early clinical development stage and will require significant further investment and regulatory approvals prior to commercialization in such indications. Because we have limited financial and managerial resources, we are focused on specific indications for our intranasal epinephrine technology. As a result, we may fail to generate additional clinical development opportunities for our intranasal epinephrine technology for a number of reasons, including, that our intranasal epinephrine technology may in certain indications, on further study, be shown to have harmful side effects, limited to no efficacy or other characteristics that suggest it is unlikely to receive marketing approval and achieve market acceptance in such additional indications. In addition, we may forgo or delay pursuit of opportunities with other indications that could have had greater commercial potential or likelihood of success. We may not be able to develop our intranasal epinephrine technology for any additional indications based on resource allocation decisions and other reasons. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development activities for specific indications may not yield any commercially viable products.

Research activities to identify additional indications for our intranasal epinephrine technology require substantial technical, financial and human resources. Additionally, any future potential indications for our intranasal epinephrine technology will require the selection of suitable patients for our clinical trials and additional clinical development, management of clinical, preclinical and manufacturing activities, obtaining regulatory approval, obtaining manufacturing supply, continued build out of a commercial organization, substantial investment and significant marketing efforts before we generate any revenues from product sales in such additional indications, if approved. We are not permitted to market or promote any future indications before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approval. By such time, if ever, as we may receive necessary regulatory approvals for any potential additional indications for our intranasal epinephrine technology, including urticaria, the standard of care for such treatments may have evolved such that it would be necessary to modify our plans for full approval and commercial acceptance of such products may be limited by a change in the standard of care. Additionally, if we receive the necessary approval for any additional indications for our intranasal epinephrine technology, we may not realize the full potential benefits from the sale of our intranasal epinephrine technology for such indications due to our existing collaboration and marketing arrangements.

Even if we develop, license, or otherwise acquire potential product candidates or development programs, and obtain the required financing or establish a collaboration to enable us to conduct pre-clinical and clinical development of such product candidates, we cannot be certain that such development would be successful, or that we will obtain regulatory approval or be able to successfully commercialize any other product candidates and generate revenue. Further, even if any product candidate we develop or acquire was to receive marketing approval, we would continue to bear the risks that the FDA or similar foreign regulatory authorities could revoke, vary or suspend approval of our product candidate or that safety, efficacy, manufacturing or supply issues could arise with such product candidate.

The results of early-stage clinical trials and preclinical studies may not be predictive of future results. Initial data in our clinical trials may not be indicative of results obtained when these trials are completed or in later stage trials.

The results of preclinical studies may not be predictive of the results of clinical trials, and the results of any early-stage clinical trials we commence may not be predictive of the results of the later-stage clinical trials. In addition, initial data in clinical trials may not be indicative of results obtained when such trials are completed. There can be no assurance that any of our ongoing, planned or future clinical trials will ultimately be successful or support further clinical development or regulatory approval of our current or future intranasal epinephrine technology product candidates. There is a high failure rate for drugs and biologics candidates proceeding through clinical trials. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in clinical development even after achieving promising results in earlier studies, and any such setbacks in our clinical development could have a material adverse effect on our business and operating results.

Interim topline and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publish interim topline or preliminary data from our clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary or topline results also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Adverse differences between preliminary or interim data and final data could significantly harm our reputation and business prospects.

neffy or our current or future intranasal epinephrine technology product candidates may cause undesirable side effects, adverse events, or have other properties that could delay or prevent its regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following regulatory approval, if obtained.*

Undesirable side effects or adverse events caused by *neffy* or our current or future intranasal epinephrine technology product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay, denial, or withdrawal of regulatory approval by the FDA, the European Commission or comparable foreign regulatory authorities. Although our clinical studies to date have demonstrated that *neffy* is well-tolerated by patients with no serious treatment-related adverse events, and reported adverse events generally no more severe than grade 1 and comparable with injection products, and with no meaningful pain or irritation based on formal scoring, results of our ongoing or future clinical trials for *neffy* or our current or future intranasal epinephrine technology product candidates could reveal a high and unacceptable severity and prevalence of side effects, adverse events, or unexpected characteristics. Many compounds that initially showed promise in clinical or earlier stage testing are later found to cause undesirable or unexpected side effects or adverse events that prevented further development of the compound.

If unacceptable side effects or adverse events are observed following the commercialization of *neffy* or our current or future intranasal epinephrine technology product candidates, including for urticaria, we, the FDA or comparable foreign regulatory authorities, the IRBs, or independent ethics committees at the institutions in which our trials are conducted, or the independent safety monitoring committee could suspend or terminate our clinical trials or regulatory authorities could order us to cease clinical trials, restrict us or *neffy* or our current or future intranasal epinephrine technology product candidates, including withdrawing the marketing approval of *neffy* or our current or future intranasal epinephrine technology product candidates or deny approval for or all targeted indications. Treatment-emergent side effects and adverse events that are deemed to be drug-related could also affect subject recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims, an unwillingness of physicians to prescribe *neffy* or our current or future intranasal epinephrine technology product candidates for approved indications, patients' unwillingness to purchase *neffy* or our current or future intranasal epinephrine technology product candidates, or payors' willingness to cover *neffy* or our current or future intranasal epinephrine technology product candidates. Undesirable side effects or adverse events resulting from the use of *neffy* or our current or future intranasal epinephrine technology product candidates (whether by patients in our clinical studies or through the commercialization of *neffy* or our current or future intranasal epinephrine technology product candidates) could adversely affect enrollment in clinical trials, regulatory approval and commercialization of *neffy* or our current or future intranasal epinephrine technology product candidates. Additionally, there may be negative findings regarding components of *neffy* or our current or future intranasal epinephrine technology product candidates by other parties. Any negative findings by third parties may impact *neffy* for its initially approved indications and labeling, or the future approvability or labeling of our current or future intranasal epinephrine technology product candidates, including for urticaria. In addition, all side effects and adverse events may not be appropriately recognized or managed by the treating medical staff. Inadequate training in recognizing or managing the potential side effects and adverse events of *neffy* or our current or future intranasal epinephrine technology product candidates could result in patient injury or death. Any of these occurrences may harm our business, financial condition, and prospects significantly.

In addition, clinical trials of our intranasal epinephrine technology product candidates are and have been conducted in carefully defined sets of patients who have agreed to enter into clinical trials. Consequently, it is possible that our clinical trials, or those of any future collaborator, may indicate an apparent positive effect of our intranasal epinephrine technology product candidates that is greater than the actual positive effect, if any, or alternatively fail to identify undesirable side effects.

Finally, our intranasal epinephrine technology product candidates are comprised of epinephrine and Intravail that is delivered via an intranasal device. Intra-muscular injection of epinephrine has been approved by the FDA and other regulatory authorities for the emergency treatment of Type I allergic reactions. In addition, Intravail has previously been included in the formulations of FDA approved products such as VALTOCO and TOSYMRA nasal sprays. The intranasal apparatus we use to deliver our intranasal epinephrine technology product candidates has been used to deliver several drugs approved by the FDA and other regulatory authorities, including VALTOCO, TOSYMRA and NARCAN. Even though *neffy* has received marketing approval for its initial indication, we are subject to the risks that the FDA, European Commission or similar regulatory authorities could revoke approval of intra-muscular epinephrine injection products, other drug formulations containing Intravail or utilizing the same intranasal apparatus, or that efficacy, manufacturing or supply issues could arise with epinephrine API, Intravail or our intranasal apparatus. This could result in our own products being removed from the market or being less commercially successful.

We received Fast Track designation for neffy in the United States and may in the future pursue Fast Track designation for other product candidates that we may develop, but we might not receive such future designations, and Fast Track designations may not lead to a faster development or regulatory review or approval process.

If the FDA determines that a product candidate is intended for the treatment of a serious or life-threatening condition and preclinical or clinical data demonstrate the potential to address an unmet medical need for this condition, the FDA may grant a product candidate Fast Track designation. Fast Track designation is intended to expedite or facilitate the process for reviewing new drug products meeting the specified criteria and gives the sponsor of a Fast Track product opportunities for more frequent interactions with the applicable FDA review team during product development and, once an NDA is submitted, the product candidate may be eligible for priority review. We were granted Fast Track designation for *neffy* for the emergency treatment of Type I allergic reactions and may in the future request Fast Track designation for additional indications for our current or future intranasal epinephrine technology product candidates, however, we cannot assume that any such applications will meet the criteria for that designation. The FDA has broad discretion whether or not to grant this designation, so even if we believe a particular product candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it. Even if we do receive Fast Track Designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may rescind the Fast Track designation if it believes that the designation is no longer supported by data from our clinical development activities.

We may seek priority review by the FDA for potential additional indications, including urticaria, for our current or future intranasal epinephrine technology product candidates, and we may be unsuccessful. If we are successful, the designation may not actually lead to a faster development or regulatory review or approval process.

A priority review designation means that the goal for the FDA to review an application is six months, rather than the standard review period of ten months. We may in the future request priority review designation for potential additional indications, including urticaria, for our current or future intranasal epinephrine technology product candidates, however, we cannot assume that any application for priority review will meet the criteria for that designation. A product is eligible for priority review if it is designed to treat a serious condition, and if approved, would provide a significant improvement in the treatment, diagnosis or prevention of a serious condition compared to marketed products. The FDA has broad discretion with respect to whether or not to grant priority review status to a product candidate, so even if we believe a particular product candidate is eligible for such designation or status, the FDA may decide not to grant it. Moreover, a priority review designation does not necessarily mean a faster development or regulatory review or approval process or necessarily confer any advantage with respect to approval compared to standard FDA review and approval. Receiving priority review from the FDA does not guarantee approval within the six-month review cycle or at all.

Product liability lawsuits against us or any of our current and future licensing and collaboration partners could divert our resources and attention, cause us to incur substantial liabilities and limit commercialization of neffy or our current or future intranasal epinephrine technology product candidates.

We are exposed to potential product liability and professional indemnity risks that are inherent in the research, development, manufacturing, marketing, commercialization, and use of pharmaceutical products. Currently, we have one product, *neffy*, that has been approved for commercial sale. The sale of *neffy* and the use of *neffy* by us and any current and future licensing and collaboration partners in clinical trials may expose us to liability claims. Product liability claims may be brought against us or our partners by participants enrolled in our clinical trials, patients, health care providers, pharmaceutical companies, our current and future licensing and collaboration partners or others using, administering, or selling any of our future products, if approved. If we cannot successfully defend ourselves against any such claims, we may incur substantial liabilities or be required to limit commercialization of *neffy* or our current or future intranasal epinephrine technology product candidates. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for *neffy* or our current or future intranasal epinephrine technology product candidates;
- injury to our reputation;
- withdrawal of clinical trial participants;
- termination of clinical trial sites or entire trial programs;
- significant litigation costs, including with respect to potential class action lawsuits;
- substantial monetary awards to, or costly settlements with, patients or other claimants;
- product recalls or a change in the indications for which they may be used;
- loss of revenue;
- diversion of management and scientific resources from our business operations; and
- the inability to successfully commercialize *neffy* or our current or future intranasal epinephrine technology product candidates.

We face an inherent risk of product liability as a result of the commercialization and clinical testing of *neffy* or our current or future intranasal epinephrine technology product candidates. Although the clinical trial process is designed to identify and assess potential side effects and adverse events, clinical development does not always fully characterize the safety and efficacy profile of a new drug, and it is always possible that a drug, even after regulatory approval, may exhibit unforeseen side effects. If *neffy* or our current or future intranasal epinephrine technology product candidates causes adverse events or side effects, we may be exposed to substantial liabilities. Physicians may not prescribe or patients may not use *neffy* or our current or future intranasal epinephrine technology product candidates for its approved indications or in accordance with *neffy*'s our current or future intranasal epinephrine technology product candidates' instructions or any warnings that identify known potential adverse effects, side effects, and patients who should not use *neffy* or our current or future intranasal epinephrine technology product candidates. We are highly dependent upon consumer perceptions of us regarding the safety and efficacy of *neffy* and our current or future intranasal epinephrine technology product candidates. We could be adversely affected if we are subject to negative publicity associated with illness or other adverse effects resulting from patients' use or misuse of our products or any similar products distributed by other companies.

Although we maintain product liability insurance coverage in the amount of up to \$10.0 million in the aggregate, including commercial product liability and clinical trial liability, this insurance may not fully cover potential liabilities that we may incur. The cost of any product liability litigation or other proceeding, even if resolved in our favor, could be substantial. In addition, insurance coverage is becoming increasingly expensive. If we are unable to maintain sufficient insurance coverage at an acceptable cost or to otherwise protect against potential product liability claims, it could prevent or inhibit the development and commercial production and sale of *neffy* or our current or future intranasal epinephrine technology product candidates, which could harm our business, financial condition, results of operations and prospects.

If our information technology systems or data, or those of third parties with whom we work, are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse consequences.*

In the ordinary course of our business, we and the third parties with whom we work collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, “process”) personal data and other sensitive information, including proprietary and confidential business data, trade secrets, intellectual property, data we collect about trial participants in connection with clinical trials, sensitive third-party data, business plans, transactions, and financial information (collectively, “sensitive data”). As a result, we and such third parties face a variety of evolving threats, including but not limited to ransomware attacks, which could cause security incidents. Cyber-attacks, malicious internet-based activity, online and offline fraud, and other similar activities threaten the confidentiality, integrity, and availability of our sensitive data and information technology systems, and those of the third parties with whom we work. Such threats are prevalent and continue to rise, are increasingly difficult to detect, and come from a variety of sources, including traditional computer “hackers,” threat actors, “hacktivists,” organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation-state-supported actors.

Some actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we and the third parties with whom we work may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks, which could materially disrupt our systems and operations, supply chain, and ability to conduct our business.

We and the third parties with whom we work are subject to a variety of evolving threats, including but not limited to social-engineering attacks (including through deep fakes, which may be increasingly more difficult to identify as a fake, and phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks, credential stuffing attacks, credential harvesting, personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, earthquakes, fires, floods, attacks enhanced or facilitated by AI, and other similar threats.

In particular, severe ransomware attacks are becoming increasingly prevalent and can lead to significant interruptions in our operations, loss of sensitive data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments.

It may be difficult and/or costly to detect, investigate, mitigate, contain, and remediate a security incident. Our efforts to do so may not be successful. Actions taken by us or the third parties with whom we work to detect, investigate, mitigate, contain, and remediate a security incident could result in outages, data losses, and disruptions of our business. Threat actors may also gain access to other networks and systems after a compromise of our networks and systems.

Remote work has become more common and has increased risks to our information technology systems and data, as more of our employees utilize network connections, computers, and devices outside our premises or network, including working at home, while in transit and in public locations. Additionally, future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities’ systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

In addition, our reliance on third-party service providers could introduce new cybersecurity risks and vulnerabilities, including supply-chain attacks, and other threats to our business operations. We rely on third-party service providers and technologies to operate critical business systems to process sensitive data in a variety of contexts, including, without limitation, cloud-based infrastructure, data center facilities, encryption and authentication technology, employee email, content delivery to customers, and other functions. We also rely on our licensing and collaboration partners, our CROs, third-party logistics providers, distributors and other contractors and consultants to utilize information technology systems and networks to process, transmit and store electronic information in connection with our business activities, including in connection with our clinical trials.

Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If our third-party service providers experience a security incident or other interruption, we could, and in certain cases have, experienced adverse consequences. While we may be entitled to damages if our third-party service providers fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. In addition, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or that of the third parties with whom we work have not been compromised.

Any of the previously identified or similar threats have in the past and may in the future cause a security incident or other interruption that have in the past and may in the future result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive data or our information technology systems, or those of the third parties with whom we work. For example, we have been the target of unsuccessful phishing attempts in the past, as well as successful phishing attempts that did not have a material adverse effect, and expect such attempts will continue in the future. In addition, we have become aware of certain security incidents whereby vendor email accounts have been hacked and the bad actors impersonate our vendors in email communications with us. None of these incidents have had a material adverse effect on our business. A security incident or other interruption could disrupt our ability (and that of third parties with whom we work) to operate our business.

We may expend significant resources or modify our business activities (including our clinical trial activities) to try to protect against security incidents. Additionally, certain data privacy and security obligations have required us to implement and maintain specific security measures or industry-standard or reasonable security measures to protect our information technology systems and sensitive data.

While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We take steps designed to detect, mitigate and remediate vulnerabilities in our information systems (such as our hardware and/or software, including that of third parties with whom we work). We have not and may not in the future, however, detect and remediate all such vulnerabilities, including on a timely basis. Vulnerabilities could be exploited and result in a security incident. Any unremediated critical or high risk vulnerabilities could pose material risks to our business. Further, we have and may in the future experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities.

Applicable data privacy and security obligations may require us, or we may voluntarily choose, to notify relevant stakeholders, including affected individuals, customers, regulators, and investors, of security incidents, or to take other actions, such as providing credit monitoring and identity theft protection services. Such disclosures and related actions can be costly, and the disclosure or the failure to comply with such applicable requirements could lead to adverse consequences.

If we (or a third party with whom we work) experience a security incident or are perceived to have experienced a security incident, we may experience material adverse consequences, such as government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing sensitive data (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; interruptions in our operations (including availability of data); financial loss; and other similar harms. Security incidents and attendant consequences may negatively impact our ability to operate our business. For example, the loss of clinical trial data from completed, ongoing or future clinical trials for *neffy* could result in delays in our development and regulatory approval efforts and significantly increase our costs to recover or reproduce the data. In addition, we may suffer reputational harm or face litigation or adverse regulatory action as a result of cyber-attacks or other data security breaches and may incur significant additional expense to implement further data protection measures.

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

In addition to experiencing a security incident, third parties may gather, collect, or infer sensitive information about us from public sources, data brokers, or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position.

International trade policies, including tariffs, sanctions and trade barriers may adversely affect our business, financial condition, results of operations and prospects.*

We operate in a global economy, and our business depends on a global supply chain for the development, manufacturing, and distribution of *neffy*, and for the advancement of our clinical development programs. There is inherent risk, based on the complex relationships among the U.S. and the countries in which we conduct our business, that political, diplomatic, and national security factors can lead to global trade restrictions and changes in trade policies and export regulations that may adversely affect our business and operations. The current international trade and regulatory environment is subject to significant ongoing uncertainty.

We source raw materials, active pharmaceutical ingredient (“API”) and other important components related to the manufacture of *neffy* and our intranasal epinephrine technology product candidates, including Intravail and our nasal sprayer apparatus, from international suppliers located in the European Union. Although we anticipate that our current supply of materials for *neffy* and our product candidates will be sufficient for at least the next 18-24 months, tariff policies, particularly those affecting the Europe Union and pharmaceutical products could materially increase our costs and reduce our margins, including as a result of our inability to adjust pricing in formulary-based markets. Recent and potential future changes in international trade policies, particularly regarding pharmaceutical-specific tariffs, present material risks to our operations and financial performance.

Recent policy discussions have included potential targeted tariffs or other trade measures specifically aimed at pharmaceutical products and ingredients as part of broader healthcare cost control or national security initiatives. Unlike consumer goods, pharmaceuticals face unique regulatory constraints that make rapid supply chain adjustments particularly difficult and costly. Should additional tariffs be imposed, including those specifically targeting pharmaceutical imports, our production costs could rise significantly, and it would be difficult and costly to qualify alternative sources within another country with a lower tariff rate or within the United States, as developing and qualifying alternative sources typically requires at least 18-24 months and substantial investment and regulatory approvals. Moreover, the dynamic and unpredictable tariff and trade landscape creates substantial uncertainty and significant planning challenges for our operations. Changes in tariff classifications, country-of-origin requirements, or customs procedures can occur with limited notice. This uncertainty complicates our long-term investment decisions regarding manufacturing facilities, supply chain optimization, and research and development locations.

Unlike many industries, our ability to pass increased costs to customers is limited by the structure of pharmaceutical pricing and reimbursement systems. *neffy* is included in formularies with pricing established through annual or multi-year contracts with commercial, third-party payors and pharmacy benefit managers, and reimbursement methodologies established by government programs, such as Medicare. These arrangements typically include fixed pricing terms that were negotiated prior to the implementation of the recently announced tariffs. As a result, and depending on the timing and scope of the implementation of these tariffs, cost increases due to tariffs may be difficult or impossible to pass through to customers until the next negotiation cycle, which could be up to 36 months away.

Current or future tariffs may also result in increased research and development expenses, including with respect to increased costs associated with raw materials, API, laboratory equipment and research materials and components. Trade restrictions affecting the import of materials necessary for clinical trials could result in delays to our development timelines. Increased development costs and extended development timelines could place us at a competitive disadvantage compared to companies operating in regions with more favorable trade relationships and could reduce investor confidence and negatively impact our business, results of operations, financial condition and growth prospects.

The complexity of announced or future tariffs may also increase the risk that we or our customers or suppliers may be subject to civil or criminal enforcement actions in the United States or foreign jurisdictions related to compliance with trade regulations. Foreign governments may also adopt non-tariff measures, such as procurement preferences or informal disincentives to engage with, purchase from or invest in U.S. entities, which may limit our ability to compete internationally and attract non-U.S. investment, employees, customers and suppliers. Foreign governments may also take other retaliatory actions against U.S. entities, such as decreased intellectual property protection, increased enforcement actions, or delays in regulatory approvals, which may result in heightened international legal and operational risks. In addition, the United States and other governments have imposed and may continue to impose additional sanctions, such as trade restrictions or trade barriers, which could restrict us from doing business directly or indirectly in or with certain countries or parties and may impose additional costs and complexity to our business.

Trade disputes, tariffs, restrictions and other political tensions between the United States and other countries may also exacerbate unfavorable macroeconomic conditions including inflationary pressures, foreign exchange volatility, financial market instability, and economic recessions or downturns. The ultimate impact of current or future tariffs and trade restrictions remains uncertain and could materially and adversely affect our business, financial condition, and prospects. While we actively monitor these risks, any prolonged economic downturn, escalation in trade tensions, or deterioration in international perception of U.S.-based companies could materially and adversely affect our business, ability to access the capital markets or other financing sources, results of operations, financial condition and prospects. In addition, tariffs and other trade developments have and may continue to heighten the risks related to the other risk factors described elsewhere in this report.

A pandemic, epidemic, or outbreak of an infectious disease may materially and adversely affect our business, including our nonclinical studies, clinical trials, third parties on whom we rely, our supply chain, our ability to raise capital, our ability to conduct regular business and our financial results.

We are subject to risks related to public health crisis and any efforts to halt the spread of any public health crises. For example, COVID-19 and policies and regulations implemented by governments in response to its outbreak, such as directing businesses and governmental agencies to cease non-essential operations at physical locations, prohibiting certain nonessential gatherings and ceasing non-essential travel had a significant impact, both direct and indirect, on businesses and commerce, as worker shortages occurred, supply chains were disrupted, facilities and production were suspended, and demand for certain goods and services, such as medical services and supplies, spiked, while demand for other goods and services fell. We experienced certain impacts of COVID-19, including inability to conduct clinical trial site monitoring for certain earlier phase clinical trials and delays in completing clinical trials, bioanalytical sample analysis and study reports. There can be no guarantee we will not experience other impacts from other pandemics, epidemics or infectious disease outbreaks, such as being forced to further delay or pause enrollment, experiencing potential interruptions to our supply chain, facing difficulties or additional costs in enrolling patients in future clinical trials or being able to achieve full enrollment of our studies within the timeframes we anticipate, or at all. Additionally, pandemics, epidemics or other infectious disease outbreaks could have extensive impacts in many aspects of society and could result in significant disruptions to the global economy, as well as businesses and capital markets around the world. Other global health concerns could also result in social, economic, and labor instability in the countries in which we or the third parties with whom we engage operate.

While we have been working closely with our third-party manufacturers, distributors and other partners to manage our supply chain activities and mitigate potential disruptions to the production of *neffy* or our current or future intranasal epinephrine product candidates as a result of pandemics, epidemics or other infectious disease outbreaks, if such a public health crisis were to persist for an extended period of time, there could be significant and material disruptions to our supply chain and operations, and associated delays in the manufacturing and supply of *neffy* or our current or future intranasal epinephrine product candidates. Any such supply disruptions, including disruptions in procuring items that are essential for our development activities and securing manufacturing slots for the products needed for such activities, could adversely impact our ability to initiate and complete nonclinical studies or clinical trials and generate sales of and revenue from *neffy* or our current or future intranasal epinephrine product candidates, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

COVID-19 affected and other public health crises may in the future affect employees of third-party CROs located in affected geographies that we rely upon to carry out our clinical trials. If any future public health crisis is not contained, we may experience disruptions that could severely impact our business and clinical trials, including:

- delays or difficulties in our commercialization efforts;
- delays or difficulties in enrolling patients in our clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of sites or facilities serving as our clinical trial sites and staff supporting the conduct of our clinical trials, including our trained therapists, or absenteeism that reduces site resources;
- interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal, state or national governments, employers and others or interruption of clinical trial subject visits and study procedures, the occurrence of which could affect the integrity of clinical trial data;
- risk that participants enrolled in our clinical trials will acquire a virus or illness while the clinical trial is ongoing, which could impact the results of the clinical trial, including by increasing the number of observed adverse events or patient withdrawals from our trials;
- limitations in employee resources that would otherwise be focused on conducting our clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people;
- delays in receiving authorizations from regulatory authorities to initiate our future clinical trials;
- delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials;
- interruption in global shipping that may affect the transport of clinical trial materials, such as *neffy* used in our clinical trials;
- changes in local regulations as part of a response to the public health crisis which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or the discontinuation of the clinical trials altogether;
- interruptions or delays in nonclinical studies due to restricted or limited operations at research and development laboratory facilities;
- delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees; and
- refusal of the FDA, the EMA or the other regulatory bodies to accept data from clinical trials in affected geographies outside the United States, the EU or other relevant local geographies.

Any negative impact a public health crisis has on patient enrollment or treatment, or the commercialization of *neffy* and the development of any additional indications could cause costly delays to clinical trial activities, which could adversely affect our ability to obtain regulatory approval for potential additional indications, including urticaria, for our current or future intranasal epinephrine technology product candidates, increase our operating expenses, which could have a material adverse effect on our financial results. COVID-19 caused significant volatility in public equity markets and disruptions to the United States and global economies and any future pandemic, epidemic, infectious disease outbreak or similar public health crisis could lead to market dislocation. Any such volatility and economic dislocation may make it more difficult for us to raise capital on favorable terms, or at all. If we or any of the third parties with whom we engage were to experience shutdowns or other business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively affected, which could have a material adverse impact on our business and our results of operations and financial conditions. To the extent a future pandemic, epidemic, infectious disease outbreak or other public health crisis adversely affects our business and financial results, it may also heighten many of the other risks described in this “Risk Factors” section, such as those relating to the timing and completion of our clinical trials and our ability to obtain future financing.

The increasing use of social media platforms presents new risks and challenges.

Social media is increasingly being used to communicate about our clinical development activities and the indications our intranasal epinephrine technology product candidates has been approved to treat and is being developed to treat, and we intend to utilize appropriate social media in connection with our commercialization efforts for *neffy*. Advertising and promotional materials must comply with FDA rules concerning the advertising and promotion of our intranasal epinephrine technology product candidates and are subject to FDA review, in addition to other potentially applicable federal and state laws. Failure to comply with these regulations can result in warning letters and further liability if off-label promotion is involved. The FDA's Office of Prescription Drug Promotion has sent warning letters to sponsors for alleged violative labeling and promotional materials, including those disseminated through social media. Social media practices in the biotechnology and biopharmaceutical industries continue to evolve and regulations and regulatory guidance relating to such use are evolving and not always clear. This evolution creates uncertainty and risk of noncompliance with regulations applicable to our business, resulting in potential regulatory actions against us, along with the potential for litigation related to off-label marketing or other prohibited activities and heightened scrutiny by the FDA, the Federal Trade Commission, the SEC and other regulators. For example, patients may use social media channels to comment on their experience in an ongoing clinical trial or to report an alleged side effect or adverse event. If such disclosures occur, there is a risk that trial enrollment may be adversely impacted, that we may fail to monitor and comply with applicable adverse event reporting obligations or that we may not be able to defend our business or the public's legitimate interests in the face of the political and market pressures generated by social media due to restrictions on what we may say about any potential additional indications. There is also a risk of inappropriate disclosure of sensitive or confidential information or negative or inaccurate posts or comments about us on any social networking website. In addition, we may encounter attacks on social media regarding us, our management or our current or future intranasal epinephrine technology product candidates. Moreover, information communicated on social media must take into consideration applicable rules governing the advertising and promotion of medicinal products. In the EU, the advertising and promotion of medicinal products are subject to both EU and EU Member States' laws governing promotion of medicinal products, interactions with physicians and other healthcare professionals, misleading and comparative advertising and unfair commercial practices. General requirements for advertising and promotion of medicinal products, such as direct-to-consumer advertising of prescription medicinal products are established in EU law. However, the details are governed by regulations in individual EU Member States and can differ from one country to another. For example, applicable laws require that promotional materials and advertising in relation to medicinal products comply with the product's Summary of Product Characteristics ("SmPC"), which may require approval by the competent national authorities in connection with an MA. The SmPC is the document that provides information to physicians concerning the safe and effective use of the product. Promotional activity that does not comply with the SmPC is considered off-label and is prohibited in the EU. If any of these events were to occur or we otherwise fail to comply with applicable regulations, we could incur liability, face regulatory actions or incur other harm to our business.

Risks Related to Our Results of Operations and Financial Position

We expect that our timing of sales and our results of operations will fluctuate for the foreseeable future, which may make it difficult to predict our future performance from period to period.

Our operating results have fluctuated in the past and are likely to do so in future periods, especially in the near term as we continue our ongoing commercial launch of *neffy*. Some of the factors that could cause our operating results to fluctuate from period to period include the factors described elsewhere in the "Risk Factors" section of this report as well as in "Management's Discussion and Analysis of Financial Condition and Results of Operations" section of this report.

We believe that comparisons from period to period of our financial results are not necessarily meaningful and should not be relied upon as indications of our future performance.

We have incurred significant losses since our inception.*

Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval and become commercially viable. We have one product approved for commercial sale and have generated only limited revenue from product sales to date, and we will continue to incur significant expenses related to our commercialization activities, clinical development and ongoing operations. As a result, we have incurred significant losses in most periods since our inception. Since our inception, we have devoted substantially all of our efforts and financial resources to organizing and staffing our company, business planning, raising capital, performing research and development activities, pre-commercialization activities, the commercial launch of *neffy* and providing general and administrative support for these operations. Our financial condition and operating results, including net losses, may fluctuate significantly from quarter to quarter and year to year. Accordingly, you should not rely upon the results of any quarterly or annual periods as indications of future operating performance. Additionally, net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity and working capital. Our net income was \$8.0 million for the year ended December 31, 2024 and our net loss was \$54.4 million for the year ended December 31, 2023. Our net loss was \$44.9 million for the six months ended June 30, 2025. As of June 30, 2025, we had an accumulated deficit of \$202.1 million. We expect to continue to incur significant losses for the foreseeable future.

We anticipate that our expenses will increase substantially if and as we:

- maintain and expand our sales, marketing, distribution, manufacturing, supply chain and other commercial infrastructure to support the commercialization of *neffy* and any other product candidates for which we may obtain regulatory approval;
- continue to develop and conduct nonclinical studies and clinical trials for our current or future intranasal epinephrine technology product candidates and for *neffy* on a post-approval basis;
- seek regulatory approvals in the United States and in other geographic regions for our current or future intranasal epinephrine technology product candidates;
- seek to identify future product candidates;
- experience any delays or encounter any issues with any of the above, including but not limited to failed studies, negative or mixed clinical trial results, safety issues or other regulatory challenges, the risk of which in each case may be exacerbated by tariffs, trade wars, geopolitical conflicts and a health epidemic or pandemic;
- add clinical, scientific, operational, sales, financial and management information systems and personnel, including personnel to support our product candidate development and commercialization efforts and help us comply with our obligations as a public company;
- maintain, expand and protect our intellectual property portfolio; and
- acquire or in-license other product candidates and technologies.

Our expenses could increase beyond our expectations if we are required by the FDA, the EMA or other regulatory authorities to perform clinical trials or conduct nonclinical studies in addition to those that we currently expect, or if there are any delays in completing our clinical trials or the development of our current or future intranasal epinephrine technology product candidates, or if we choose to develop or acquire any future product candidates. Our expenses could also increase significantly as a result of tariffs, trade wars and geopolitical conflicts.

We may need additional funding, and if we are unable to raise capital when needed, we could be forced to delay, reduce or eliminate our product development activities or commercialization efforts.*

Our operations have consumed significant amounts of cash since inception. Based upon our current operating plan, we believe that our cash and cash equivalents will fund our operating and capital expenses for at least three years. We expect to incur significant expenses related to commercialization, such as product sales, medical affairs, marketing, manufacturing and distribution of *neffy*. Further, we expect to incur additional costs associated with operating as a public company. We may require significant additional amounts of cash in order to commercialize *neffy* for its currently approved indications in the United States, or for our current or future intranasal epinephrine technology product candidates which receive regulatory approval. In addition, other unanticipated costs may arise in the course of our continued development and commercialization efforts. Because the outcome of our commercialization efforts and continued development of our current or future intranasal epinephrine technology product candidates is highly uncertain, we cannot reasonably estimate the actual amounts of cash necessary to commercialize *neffy* for its approved indications in the United States, or any other indications we are pursuing.

Our future capital requirements depend on many factors, including:

- the costs of commercialization activities for *neffy* for its approved indications and our current or future intranasal epinephrine technology product candidates that receives regulatory approval, to the extent such costs are not the responsibility of any current or future licensing and collaboration partners, including the costs and timing of establishing product sales, marketing, distribution and manufacturing capabilities;
- revenue received from commercial sales of *neffy* or any current or future intranasal epinephrine technology product candidates that receives regulatory approval;
- the scope, progress, results and costs of researching and developing our intranasal epinephrine technology for potential additional indications, including urticaria;
- the timing of, and the costs involved in, obtaining regulatory approval for the marketing of our current or future intranasal epinephrine technology product candidates and *neffy* for additional indications;
- the amount and timing of potential royalty and milestone payments to our current or future licensing and collaboration partners;
- the receipt of licensing fees, royalties and potential milestone payments under our current or future out-licensing arrangements;
- the extent to which we in-license or acquire rights to other products, product candidates or technologies;
- our headcount growth and associated costs as we expand our personnel, including personnel to support our product development and commercialization efforts and help us comply with our obligations as a public company;
- the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights, including enforcing and defending intellectual property related claims; and
- the ongoing costs of operating as a public company.

We cannot be certain that additional funding will be available on acceptable terms, or at all. The global credit and financial markets have experienced extreme volatility and disruptions and have been adversely impacted, and may continue to be adversely impacted or further adversely impacted, by macroeconomic factors such as tariffs, trade wars, inflation, high interest rates, recessionary concerns, recessions, bank failures, geopolitical conflicts and general economic uncertainty. If the equity and credit markets do not improve or further deteriorate, it may make any necessary debt or equity financing more difficult, more costly or more dilutive.

We believe that our existing cash and cash equivalents will be sufficient to fund our planned operations for at least three years. This estimate may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Further, changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned.

We have no committed source of additional capital other than potential milestone payments and royalties under our collaboration and licensing agreements. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development and commercialization of *neffy*. We may need to seek licensing and collaboration partners for *neffy* for commercialization in additional indications on terms that are less favorable than might otherwise be available or relinquish or license on unfavorable terms our rights to *neffy* in markets where we otherwise would seek to pursue development or commercialization ourselves. Any of the above events could significantly harm our business, prospects, financial condition, and results of operations.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidate.

We expect our expenses to increase in connection with our planned operations. Based upon our current operating plan, we believe that our cash and cash equivalents will fund our operating and capital expenses for at least three years. However, unless and until we can generate a substantial amount of revenue from our current or future intranasal epinephrine technology product candidates, we may seek to finance our future cash needs through public or private equity offerings, royalty-based or debt financings, collaborations, licensing arrangements or other sources, or any combination of the foregoing. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans. On January 31, 2025, we entered into a Controlled Equity OfferingSM Sales Agreement (the “ATM Sales Agreement”) pursuant to which we may from time to time offer and sell our common stock to or through Cantor Fitzgerald & Co., acting as sales agent, in any manner deemed to be an “at-the market offering”. We have filed a sales agreement prospectus with the SEC pursuant to which we may offer and sell up to \$200.0 million of our common stock pursuant to the ATM Sales Agreement. To the extent that we raise additional capital through the sale of common stock, convertible securities or other equity securities, stockholders’ interests may be diluted, and the terms of these securities could include liquidation or other preferences and anti-dilution protections that could adversely affect our stockholders’ rights. In addition, new debt financing, if available, may result in fixed payment obligations and may involve agreements that include restrictive covenants that further limit our ability to take specific actions, such as incurring additional debt, making capital expenditures, creating liens, redeeming stock or declaring dividends, which could adversely impact our ability to conduct our business. In addition, securing financing could require a substantial amount of time and attention from our management and may divert a disproportionate amount of their attention away from day-to-day activities, which may adversely affect their ability to oversee the commercialization of *neffy* and the development and potential future commercialization of *neffy* or our intranasal epinephrine technology product candidates for additional indications.

If we raise additional funds through collaborations or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams or product candidates or grant licenses on terms that may not be favorable to us.

Changes in tax law could adversely affect our business and financial condition.*

The rules dealing with U.S. federal, state and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service, the U.S. Treasury Department, and state and local taxing authorities. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our common stock. In recent years, many such changes have been made and changes are likely to continue to occur in the future. For example, legislation informally titled the One Big Beautiful Bill Act and the Inflation Reduction Act of 2022 (“IRA”) enacted many significant changes to the U.S. tax laws. Future guidance from the Internal Revenue Service and other tax authorities with respect to new and existing legislation may affect us, and certain aspects of such legislation could be repealed or modified in future legislation. Future changes in tax laws could have a material adverse effect on our business, cash flow, financial condition, realization of tax assets or results of operations.

Our ability to use net operating loss carryforwards and certain other tax attributes may be limited.

We have incurred substantial losses during our history. Unused federal net operating losses (“NOLs”) for the tax years beginning before January 1, 2018, will carry forward to offset future taxable income, if any, until such unused losses expire. Unused federal NOLs generated in tax years beginning after December 31, 2017, will not expire and may be carried forward indefinitely, but the deductibility of such federal NOL carryforwards is limited to 80% of taxable income. In addition, both current and future unused losses and other tax attributes may be subject to limitation under Sections 382 and 383 of the Code if we undergo an “ownership change,” generally defined as a greater than 50 percentage point change (by value) in our equity ownership by certain stockholders over a three-year period. The Merger resulted in an ownership change of our company. The NOL carryforwards of pre-Merger, privately-held ARS Pharma may also be subject to limitation as a result of prior shifts in equity ownership and/or the Merger. Additional ownership changes in the future could result in additional limitations on our NOL carryforwards. Similar provisions of state tax law may also apply to limit our use of accumulated state tax attributes. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. For example, California recently imposed limits on the usability of California state NOL carryforwards and certain state tax credits in tax years beginning after 2023 and before 2027. Consequently, even if we achieve profitability in the future, we may not be able to utilize a material portion of our NOL carryforwards and other tax attributes, which could adversely affect our business, cash flow, financial condition or results of operations.

Risks Related to our Legal and Regulatory Environment

neffy and our current or future intranasal epinephrine technology product candidates are subject to ongoing obligations and continued regulatory review, which may result in significant additional expense. *neffy* and our current or future intranasal epinephrine technology product candidates could be subject to post-marketing restrictions or withdrawal from the market and we, or any current or future licensing and collaboration partners, may be subject to substantial penalties if we, or they, fail to comply with regulatory requirements or if we, or they, experience unanticipated problems with our products following approval.

neffy and our current or future intranasal epinephrine technology product candidates, as well as, among other things, the manufacturing processes, post-approval studies, labeling, post-approval pharmacovigilance monitoring, advertising and promotional activities for *neffy*, is subject to ongoing requirements of and review by the FDA, the EMA and other applicable regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping. For certain commercial prescription drug products, manufacturers and other parties involved in the supply chain must also meet chain of distribution requirements and build electronic, interoperable systems for product tracking and tracing and for notifying the FDA and comparable foreign regulatory authorities of counterfeit, diverted, stolen and intentionally adulterated products or other products that are otherwise unfit for distribution in the United States or relevant territory. We and our contract manufacturers will also be subject to user fees and periodic inspection by regulatory authorities to monitor compliance with these requirements and the terms of any product approval we may obtain. Even if regulatory approval of a product candidate is granted, the approval may be subject to limitations on the indications or uses for which the product may be marketed or to the conditions of approval, including the requirement in the United States to implement a Risk Evaluation and Mitigation Strategy or the inclusion of a Boxed Warning, which highlights a specific life-threatening safety risk, or comparable foreign strategies and requirements.

The FDA or other regulatory authorities may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of a product. For example, the FDA and other agencies, including the Department of Justice, closely regulate and monitor the post-approval marketing and promotion of products to ensure that they are manufactured, marketed and distributed only for the approved indications and in accordance with the provisions of the approved labeling. Regulatory authorities impose stringent restrictions on manufacturers' communications regarding off-label use. However, companies generally may share truthful and not misleading information that is otherwise consistent with a product's approved labeling. If we, or any current or future licensing and collaboration partners, do not market *neffy* or our current or future intranasal epinephrine technology product candidates, for only its approved indications, we, or they, may be subject to warnings or enforcement action for off-label marketing if it is alleged that we are doing so. Violation of laws and regulations relating to the promotion and advertising of prescription drugs may lead to investigations or allegations of violations of federal and state health care fraud and abuse laws and state consumer protection laws, including the False Claims Act and any comparable foreign laws. In the EU, the direct-to-consumer advertising of prescription-only medicinal products is prohibited. Violations of the rules governing the promotion of medicinal products in the EU could be penalized by administrative measures, fines and imprisonment. These laws may further limit or restrict the advertising and promotion of our products to the general public, and may also impose limitations on our promotional activities with health care professionals.

In addition, later discovery of previously unknown side effects, adverse events or other problems with our products or their manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including:

- restrictions on the manufacturing of such products;
- restrictions on the labeling or marketing of such products;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning letters or untitled letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- restrictions on coverage by third-party payors;
- fines, restitution or disgorgement of profits or revenues;
- exclusion from federal health care programs such as Medicare and Medicaid or comparable foreign programs;
- suspension, variation or withdrawal of regulatory approvals;
- refusal to permit the import or export of products;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

Recently enacted and future legislation may increase the difficulty and cost for us to commercialize neffy or our current or future intranasal epinephrine technology product candidates and affect the prices we may obtain.*

In the United States and some foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes and proposed changes regarding the healthcare system, including cost-containment measures, that could reduce or limit coverage and reimbursement for newly approved drugs, prevent or delay marketing approval of *neffy* or our current or future intranasal epinephrine technology product candidates for potential additional indications, including urticaria, restrict or regulate post-approval activities and affect our ability to profitably sell *neffy* or our current or future intranasal epinephrine technology product candidates for which we obtain marketing approval.

For example, in 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the “ACA”), was signed into law. The ACA was intended, among other things, to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. The ACA and subsequent regulations increased the Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program for both branded and generic drugs and revised the definition of “average manufacturer price” for reporting purposes, which could further increase the amount of Medicaid drug rebates to states. However, on March 11, 2021, the American Rescue Plan Act of 2021 was signed into law, which eliminated the statutory Medicaid drug rebate cap for single source and innovator multiple source drugs, effective January 1, 2024. Further, the ACA imposed a significant annual fee on companies that manufacture or import branded prescription drug products, increased the number of entities eligible for discounts under the 340B program and included a discount on brand name drugs for Medicare Part D beneficiaries in the coverage gap, or “donut hole.” Substantial provisions affecting compliance have also been enacted, which may require us to modify our business practices with healthcare practitioners.

Since its enactment, there have been amendments and judicial, executive and Congressional challenges to certain aspects of the ACA. For example, on August 16, 2022, the IRA was signed into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the “donut hole” under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges, and the healthcare reform measures of the second Trump administration will impact the ACA and our business.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers of up to two percent per fiscal year pursuant to the Budget Control Act of 2011, which went into effect on April 1, 2013, and due to subsequent legislative amendments, will remain in effect until 2032, unless additional Congressional action is taken.

Recently there has also been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U.S. Presidential executive orders, congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. At the federal level, the IRA, among other things, (i) directs the U.S. Department of Health and Human Services (“HHS”) to negotiate the price of certain high-expenditure, single-source drugs that have been on the market for at least 7 years covered under Medicare (the “Medicare Drug Price Negotiation Program”), and subject drug manufacturers to civil monetary penalties and a potential excise tax by offering a price that is not equal to or less than the negotiated “maximum fair price” for such drugs under the law, and (ii) imposes rebates with respect to certain drugs covered under Medicare Part B or Medicare Part D to penalize price increases that outpace inflation. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has and will continue to issue and update guidance as these programs as implemented. These provisions took effect progressively starting in fiscal year 2023. On August 15, 2024, HHS announced the price of the first ten drugs that were subject to price negotiations, although the Medicare Drug Price Negotiation Program is currently subject to legal challenges. On January 17, 2025, HHS selected fifteen additional products covered under Part D for price negotiation in 2025. Each year thereafter more Part B and Part D products will become subject to the Medicare Drug Price Negotiation Program. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework.

The current administration is pursuing policies to reduce regulations and expenditures across government including at HHS, the FDA, the Centers for Medicare & Medicaid Services (“CMS”) and related agencies. These actions, presently directed by executive orders or memoranda from the Office of Management and Budget, may propose policy changes that create additional uncertainty for our business. These actions include, for example: (1) directives to reduce agency workforce and cut programs; (2) rescinding a Biden administration executive order tasking the Center for Medicare and Medicaid Innovation to consider new payment and healthcare models to limit drug spending; (3) eliminating the Biden administration’s executive order that directed HHS to establishing an AI task force and developing a strategic plan; (4) directing HHS and other agencies to lower prescription drug costs through a variety of initiatives, including by improving upon the Medicare Drug Price Negotiation Program and establishing “Most-Favored-Nation” pricing for pharmaceutical products; and (5) directing certain federal agencies to enforce existing law regarding hospital and price plan transparency and by standardizing prices across hospitals and health plans. If implemented, a “Most-Favored-Nation” pricing policy that is determined to apply to us and *neffy* based on a reference to the lowest ex-U.S. list price for our intranasal epinephrine product could significantly reduce the U.S. list price for *neffy* and likewise reduce our annual market opportunity for *neffy* in the United States. Additionally, in its June 2024 decision in *Loper Bright Enterprises v. Raimondo*, the U.S. Supreme Court overturned the longstanding *Chevron* doctrine, under which courts were required to give deference to regulatory agencies’ reasonable interpretations of ambiguous federal statutes. The *Loper Bright* decision could result in additional legal challenges to current regulations and guidance issued by federal agencies applicable to our operations, including those issued by the FDA. Congress may introduce and ultimately pass health care related legislation that could, among others, impact the drug approval process, modify the Medicare Drug Price Negotiation Program, expand the orphan drug exclusion in the IRA, and reduce Medicaid enrollment and funding.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. As an example, the regulatory landscape related to clinical trials in the EU has evolved. The EU Clinical Trials Regulation (“CTR”), which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. The CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each EU Member State, leading to a single decision for each EU Member State. The assessment procedure for the authorization of clinical trials has been harmonized as well, including a joint assessment by all EU Member States concerned, and a separate assessment by each EU Member State with respect to specific requirements related to its own territory, including ethics rules. Each EU Member State’s decision is communicated to the sponsor via the centralized EU portal. Once the clinical trial approved, clinical study development may proceed. The CTR foresaw a three-year transition period which ended on January 31, 2025. Since this date, all new or ongoing trials are subject to the provisions of the CTR. Compliance with the CTR requirements by us and our third-party service providers, such as CROs, may impact our developments plans.

In addition, on April 26, 2023, the European Commission adopted a proposal for a new Directive and Regulation to revise the existing pharmaceutical legislation and on April 10, 2024, the Parliament adopted its related position. The proposed revisions remain to be agreed and adopted by the European Council. Moreover, on December 1, 2024, a new European Commission took office. The proposal could, therefore, still be subject to revisions. If adopted in the form proposed, the recent European Commission proposals to revise the existing EU laws governing authorization of medicinal products may result in a decrease in data and market exclusivity opportunities for our current or future intranasal epinephrine technology product candidates in the EU and make them open to generic or biosimilar competition earlier than is currently the case with a related reduction in reimbursement status.

Following Brexit, the UK and the EU signed an EU-UK Trade and Cooperation Agreement (“TCA”) which became provisionally applicable on January 1, 2021 and entered into force on May 1, 2021. This agreement sets out some aspects of the UK and EU’s relationship post-Brexit. The TCA primarily focuses on ensuring free trade between the EU and the UK in relation to goods, including medicinal products. Among the changes that have occurred are that the UK is treated as a “third country”, a country that is not a member of the EU and whose citizens do not enjoy the EU right to free movement (Northern Ireland continues to follow certain limited EU regulatory rules, including in relation to medical devices, but not in relation to medicinal products). As part of the TCA, the EU and the UK recognize GMP inspections carried out by the other party and the acceptance of official GMP documents issued by the other party. The TCA also encourages, although it does not oblige, the parties to consult one another on proposals to introduce significant changes to technical regulations or inspection procedures. Among the areas of absence of mutual recognition are batch testing and batch release. The UK has unilaterally agreed to accept EU batch testing and batch release. However, the EU continues to apply EU laws that require batch testing and batch release to take place in the EU territory. This means that medicinal products that are tested and released in the UK must be retested and re-released when entering the EU market for commercial use.

On February 27, 2023, the UK Government and the European Commission reached a political agreement on the so-called “Windsor Framework”. The Windsor Framework is intended to revise the Northern Ireland Protocol to address some of the perceived shortcomings in its operation. The agreement was adopted at the Withdrawal Agreement Joint Committee on March 24, 2023, and the arrangements under the Windsor Framework relating to medicinal products took effect on January 1, 2025. As it relates to marketing authorizations, the United Kingdom has a separate regulatory submission process, approval process and a separate national marketing authorization. Northern Ireland continued, until January 1, 2025, to be covered by the marketing authorizations granted by the European Commission but the Windsor Framework provides that the UK MHRA is the sole regulatory body responsible for granting marketing authorizations for Northern Ireland as of January 1, 2025.

A significant proportion of the regulatory framework in the UK applicable to medicinal products is currently derived from EU Directives and Regulations. The potential for UK legislation to diverge from EU legislation following Brexit could materially impact the regulatory regime with respect to the development, manufacture, import, approval, and commercialization of our product candidates in the UK or the EU.

All of these changes could increase our costs and otherwise adversely affect our business. Any delay in obtaining, or an inability to obtain, any regulatory approvals, as a result of Brexit or otherwise, would prevent us from commercializing our product candidates in the UK and restrict our ability to generate revenue and achieve and sustain profitability in the future. Any further changes in international trade, tariff and import/export regulations as a result of Brexit or otherwise may impose unexpected duty costs or other non-tariff barriers on us. These developments, or the perception that any of them could occur, may significantly reduce global trade and, in particular, trade between the impacted nations and the UK.

These laws and the regulations and policies implementing them, as well as other healthcare reform measures that may be adopted in the future, particularly in light of the upcoming U.S. presidential and Congressional elections, may have a material adverse effect on our industry generally and on our ability to successfully develop and commercialize *neffy* or our current or future intranasal epinephrine technology product candidates.

Disruptions at the FDA, including due to a reduction in the FDA's workforce and/or inadequate funding for the FDA, could prevent the FDA from performing normal functions on which our business relies.*

The ability of the FDA to review and approve new products or review other regulatory submissions can be affected by a variety of factors, including statutory, regulatory and policy changes, inadequate government budget and funding levels, a reduction in the FDA's workforce and its ability to hire and retain key personnel. Disruptions at the FDA and other agencies may also increase the time to meet with and receive agency feedback, review and/or approve our submissions, conduct inspections, issue regulatory guidance, or take other actions that facilitate the development, approval and marketing of regulated products, which would adversely affect our business. In addition, government proposals to reduce or eliminate budgetary deficits may include reduced allocations to the FDA and other related government agencies. For example, the recently established Department of Government Efficiency implemented a federal government hiring freeze and announced certain additional efforts to reduce federal government employee headcount and the size of the federal government. The reductions in the FDA's workforce and budgetary pressures could significantly impact the ability of the FDA to timely review and process our regulatory submissions or take other actions critical to the marketing of our products which could have a material adverse effect on our business.

Governments outside the United States may impose strict price controls, which may adversely affect our revenues, if any.

In some countries, including certain Member States of the EU, the pricing of prescription drugs is, in part, subject to governmental control. Additional countries may adopt similar approaches to the pricing of prescription drugs. In such countries, pricing negotiations with governmental authorities can take considerable time after receipt of regulatory approval for a product. The EU provides options for the EU Member States to restrict the range of drug products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. EU Member States may approve a specific price for a product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the product on the market. Other EU Member States allow companies to fix their own prices for drug products, but monitor and control prescription volumes and issue guidance to physicians to limit prescriptions. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after coverage and reimbursement have been obtained. Reference pricing used by various countries and parallel distribution, or arbitrage between low-priced and high-priced countries, can further reduce prices. In some countries, we may be required to conduct a clinical study or other studies that compare the cost-effectiveness of our current or future intranasal epinephrine technology product candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval, which is time-consuming and costly. This Health Technology Assessment ("HTA") of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some EU Member States, including those representing the larger markets. The HTA process is the procedure to assess therapeutic, economic and societal impact of a given medicinal product in the national healthcare systems of the individual country. The outcome of an HTA will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU Member States. The extent to which pricing and reimbursement decisions are influenced by the HTA of the specific medicinal product currently varies between EU Member States. In December 2021, Regulation No 2021/2282 on HTA amending Directive 2011/24/EU, was adopted in the EU. This Regulation, which entered into force in January 2022 and began to apply on January 12, 2025 through a phased implementation, is intended to boost cooperation among EU Member States in assessing health technologies, including new medicinal products, and providing the basis for cooperation at EU level for joint clinical assessments in these areas. The Regulation foresees a three-year transitional period and permits EU Member States to use common HTA tools, methodologies, and procedures across the EU, working together in four main areas, including joint clinical assessment of the innovative health technologies with the most potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU Member States continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technologies, and making decisions on pricing and reimbursement.

We cannot be sure that such prices and reimbursement will be acceptable to us. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If pricing is set at unsatisfactory levels or if reimbursement of our products is unavailable or limited in scope or amount, our revenues from sales by us or our strategic partners and the potential profitability of our current or future intranasal epinephrine technology product candidates in those countries would be negatively affected.

Our business activities may be subject to the FCPA and similar anti-bribery and anti-corruption laws of other countries in which we may operate, as well as U.S. and certain foreign export controls, trade sanctions, and import laws and regulations. Compliance with these legal requirements could limit our ability to compete in foreign markets and subject us to liability if we violate them.

If we further expand our operations outside of the United States, we must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. Our business activities may be subject to the Foreign Corrupt Practices Act ("FCPA") and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate. The FCPA generally prohibits companies and their employees and third-party intermediaries from offering, promising, giving or authorizing the provision of anything of value, either directly or indirectly, to a non-U.S. government official in order to influence official action or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-U.S. governments. Additionally, in many other countries, hospitals owned and operated by the government, and doctors and other hospital employees would be considered foreign officials under the FCPA. Recently the SEC and Department of Justice have increased their FCPA enforcement activities with respect to biotechnology and pharmaceutical companies. There is no certainty that all of our employees, agents or contractors, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers or employees, disgorgement, and other sanctions and remedial measures, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer *neffy* in one or more countries and could materially damage our reputation, brand, international activities, ability to attract and retain employees, and business, prospects, operating results and financial condition.

In addition, *neffy* or our current or future intranasal epinephrine technology product candidates may be subject to U.S. and foreign export controls, trade sanctions and import laws and regulations. Governmental regulation of the import or export of *neffy* or our current or future intranasal epinephrine technology product candidates, or our failure to obtain any required import or export authorization for *neffy* or our current or future intranasal epinephrine technology product candidates, when applicable, could harm our international sales and adversely affect our revenue. Compliance with applicable regulatory requirements regarding the export of *neffy* or our current or future intranasal epinephrine technology product candidates may create delays in the introduction of any additional indications in international markets or, in some cases, prevent the export of *neffy* or our current or future intranasal epinephrine technology product candidates to some countries altogether. Furthermore, U.S. export control laws and economic sanctions prohibit the shipment of certain products and services to countries, governments, and persons targeted by U.S. sanctions. If we fail to comply with export and import regulations and such economic sanctions, penalties could be imposed, including fines and/or denial of certain export privileges. Moreover, any new export or import restrictions, new legislation or shifting approaches in the enforcement or scope of existing regulations, or in the countries, persons, or products targeted by such regulations, could result in decreased use of *neffy* or our current or future intranasal epinephrine technology product candidates by, or in our decreased ability to export *neffy* or our current or future intranasal epinephrine technology product candidates to existing or potential customers with international operations. Any decreased use of *neffy* or our current or future intranasal epinephrine technology product candidates or limitation on our ability to export or sell *neffy* or our current or future intranasal epinephrine technology product candidates would likely adversely affect our business.

Our relationships with customers, health care professionals and third-party payors may be subject to applicable healthcare laws, which could expose us to penalties, including administrative, civil or criminal penalties, damages, fines, imprisonment, exclusion from participation in federal healthcare programs such as Medicare and Medicaid, reputational harm, the curtailment or restructuring of our operations and diminished future profits and earnings.*

Healthcare professionals and third-party payors will play a primary role in the recommendation and prescription of *neffy* or our current or future intranasal epinephrine technology product candidates for which we obtain marketing approval. Our current and future arrangements with customers, healthcare professionals and third-party payors may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we conduct research, market, sell and distribute *neffy* or our current or future intranasal epinephrine technology product candidates for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations include the following, among others:

- the federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. Although there are several statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution, the exceptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. Further a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- federal civil and criminal false claims laws, including the False Claims Act, prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, or causing to be made, a false statement to get a false claim paid. Over the past few years, several pharmaceutical and other healthcare companies have been prosecuted under these laws for a variety of alleged promotional and marketing activities, including: allegedly providing free items and services, sham consulting fees and grants and other monetary benefits to prescribers; reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in off-label promotion that caused claims to be submitted to government healthcare programs for non-covered, off-label uses; and submitting inflated best price information to the Medicaid Drug Rebate Program to reduce liability for Medicaid rebates. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act;
- federal civil monetary penalties laws impose civil fines for, among other things, the offering or transfer of remuneration to a Medicare or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of services reimbursable by Medicare or a state healthcare program, unless an exception applies;
- HIPAA which prohibits, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, of any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private), willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services; like the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the federal Physician Payment Sunshine Act, which requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the government information related to payments or other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physician assistants and nurse practitioners) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH"), and their respective implementing regulations, which impose obligations on "covered entities," including certain healthcare providers, health plans, and healthcare clearinghouses, as well as their respective "business associates" and their covered subcontractors that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- federal price reporting laws require manufactures to calculate and report complex pricing metrics to government programs, where such reported prices may be used in the calculation of reimbursement and/or discounts on approved products;
- federal and state consumer protection and unfair competition laws broadly regulate marketplace activities and activities that potentially harm consumers; and
- analogous state and foreign laws and regulations of each of the laws described above, such as anti-kickback and false claims laws, that may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; laws that require biotechnology companies to comply with the industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; laws that require biotechnology companies to report information on the pricing of certain drug products; and laws require the registration or pharmaceutical sales representatives. For example, in the EU, interactions between pharmaceutical companies and healthcare professionals and healthcare organizations are also governed by strict laws, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct both at EU level and in the individual EU Member States.

Because of the breadth of these laws and the narrowness of available statutory exceptions and regulatory safe harbors, it is possible that some of our business activities, particularly any sales and marketing activities from *neffy* or our current or future intranasal epinephrine technology product candidates that have been approved for marketing in the United States or elsewhere, could be subject to legal challenge and enforcement actions. If our operations, or those of our partners and collaborators, are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to significant penalties, including administrative, civil and criminal penalties, damages, fines, disgorgement, exclusion from governmental health care programs, a corporate integrity agreement or other agreement to resolve allegations of non-compliance, imprisonment, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results.

We and the third parties with whom we work are subject to stringent and evolving U.S. and foreign laws, regulations, rules, contractual obligations, industry standards, policies and other obligations related to data privacy and security. Our (or the third parties with whom we work) actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation (including class claims) and mass arbitration demands; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse business consequences.*

In the ordinary course of business, we process sensitive data. Our data processing activities subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements, and other obligations relating to data privacy and security.

In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), and other similar laws (e.g., wiretapping laws). For example, the Controlling the Assault of Non-Solicited Pornography and Marketing Act of 2003 ("CAN-SPAM") and the Telephone Consumer Protection Act of 1991 ("TCPA") impose specific requirements on communications with customers. The TCPA, for example, imposes various consumer consent requirements and other restrictions on certain telemarketing activity and other communications with consumers by phone, fax or text message. TCPA violations can result in significant financial penalties, including penalties or criminal fines imposed by the Federal Communications Commission or fines of up to \$1,500 per violation imposed through private litigation or by state authorities.

Numerous U.S. states have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. As applicable, such rights may include the right to access, correct, or delete certain personal data, and to opt-out of certain data processing activities, such as targeted advertising, profiling, and automated decision-making. The exercise of these rights may impact our business and ability to provide any product that receives regulatory approval. Certain states also impose stricter requirements for processing certain personal data, including sensitive information, such as conducting data privacy impact assessments. These state laws allow for statutory fines for noncompliance. For example, the California Consumer Privacy Act of 2018 (the "CCPA"), applies to personal information of consumers, business representatives, and employees, and requires businesses to provide specific disclosures in privacy notices and honor requests of California residents to exercise certain privacy rights. The CCPA provides for civil penalties and allows private litigants affected by certain data breaches to recover significant statutory damages. Although the CCPA exempts some data processed in the context of clinical trials, the CCPA increases compliance costs and potential liability with respect to other personal data we maintain about California residents. Similar laws are being considered in several other states, as well as at the federal and local levels, and we expect more states to pass similar laws in the future.

Additionally, we are subject to new laws governing the privacy of consumer health data, including reproductive, sexual orientation, and gender identity privacy rights. For example, Washington's My Health My Data Act ("MHMD") broadly defines consumer health data, places restrictions on processing consumer health data (including imposing stringent requirements for consents), provides consumers certain rights with respect to their health data, and creates a private right of action to allow individuals to sue for violations of the law. Other states are considering and may adopt similar laws.

Outside the United States, an increasing number of laws, regulations, and industry standards govern data privacy and security. For example, the EU's General Data Protection Regulation ("EU GDPR"), the United Kingdom's GDPR ("UK GDPR") (collectively, "GDPR") and Australia's Privacy Act, impose strict requirements for processing personal data.

For example, under the GDPR, companies may face temporary or definitive bans on data processing and other corrective actions; fines of up to 20 million Euros under the EU GDPR, 17.5 million pounds sterling under the UK GDPR or, in each case, 4% of annual global revenue, whichever is greater; or private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests.

Furthermore, we also conduct clinical trials in Asia and have operations in Japan and are subject to new and emerging data privacy regimes in Asia, including China's Personal Information Protection Law, Japan's Act on the Protection of Personal Information, and Singapore's Personal Data Protection Act. China's PIPL imposes a set of specific obligations on covered businesses in connection with their processing and transfer of personal data and imposes fines of up to RMB 50 million or 5% of the prior year's total annual revenue of the violator.

In addition, we may be unable to transfer personal data from Europe and other jurisdictions to the United States or other countries due to data localization requirements or limitations on cross-border data flows. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the EEA and the UK have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it believes are inadequate. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross-border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA and UK's standard contractual clauses, the UK's International Data Transfer Agreement / Addendum, and the EU-U.S. Data Privacy Framework and the UK extension thereto (which allows for transfers for relevant U.S.-based organizations who self-certify compliance and participate in the Framework), these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States. If there is no lawful manner for us to transfer personal data from the EEA, the UK, or other jurisdictions to the United States, or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activities groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers of personal data out of Europe for allegedly violating the GDPR's cross-border data transfer limitations. Additionally, the U.S. Department of Justice issued a rule entitled the Preventing Access to U.S. Sensitive Personal Data and Government-Related Data by Countries of Concern or Covered Persons, which places additional restriction on certain data transactions involving countries of concern (e.g., China, Russia, Iran) and covered individuals (i.e., individuals and entities located in or controlled by individuals or entities located in those jurisdictions) that may impact certain business activities such as vendor engagements, sale or sharing of data, employment of certain individuals, and investor agreements. Violations of the rule could lead to significant civil and criminal fines and penalties. The rule applies regardless of whether data is anonymized, key-coded, pseudonymized, de-identified or encrypted, which presents particular challenges for companies like ours and may impact our ability to transfer data in connection with certain transactions or agreements.

Additionally, under various privacy laws and other obligations, we may be required to obtain certain consents to process personal data, including clinical trials. Our inability or failure to obtain consent for these practices could result in adverse consequences, including class action litigation and mass arbitration demands.

We publish privacy policies, marketing materials, and other statements, such as statements related to compliance with certain certifications or self-regulatory principles, concerning data privacy, and security. Regulators in the United States are increasingly scrutinizing these statements, and if these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, misleading, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators or other adverse consequences.

In addition, we are contractually subject to industry standards adopted by industry groups and, we are and may become in the future, directly subject to such obligations. We are also bound by contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful.

Obligations related to data privacy and security are quickly changing, becoming increasingly stringent, and creating uncertainty. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with these obligations requires us to devote significant resources, which may necessitate changes to our services, information technologies, systems, and practices and to those of any third parties that process personal or sensitive data on our behalf. In addition, these obligations may require us to change elements of our business model. We may at times fail (or be perceived to have failed) in our efforts to comply with our data privacy and security obligations. Moreover, despite our efforts, our personnel or third parties with whom we work may fail to comply with such obligations, which could negatively impact our business operations. If we or the third parties with whom we work fail, or are perceived to have failed, to address or comply with applicable data privacy and security obligations, we could face significant consequences, including but not limited to: government enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class-action claims) and mass arbitration demands; additional reporting requirements and/or oversight; bans on processing personal data; orders to destroy or not use personal data; and imprisonment of company officials. In particular, plaintiffs have become increasingly more active in bringing privacy-related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for monumental statutory damages, depending on the volume of data and the number of violations.

Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: loss of customers; interruptions or stoppages in our business operations (including clinical trials); inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or substantial changes to our business model or operations.

We will incur costs and demands upon management as a result of complying with the laws and regulations affecting public companies.

We will continue to incur significant legal, accounting and other expenses associated with being a public company, including public company reporting requirements, costs associated with corporate governance requirements, including requirements under the Sarbanes-Oxley Act, as well as new requirements implemented by the SEC and Nasdaq. These rules and regulations are expected to continue to result in meaningful legal and financial compliance costs and to make some activities more time consuming and costly. These rules and regulations also may make it expensive for us to obtain directors' and officers' liability insurance.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. From time to time and in the future, our operations may involve the use of hazardous and flammable materials, including chemicals and biological materials, and may also produce hazardous waste products. Even if we contract with third parties for the disposal of these materials and waste products, we cannot completely eliminate the risk of contamination or injury resulting from these materials. In the event of contamination or injury resulting from the use or disposal of our hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

We maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees, but this insurance may not provide adequate coverage against potential liabilities. However, we do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. Environmental laws and regulations may impair our research, development or production efforts. In addition, failure to comply with these laws and regulations may result in substantial fines, penalties or other sanctions.

Risks Related to Our Dependence on Third Parties

We rely completely on third parties to manufacture and warehouse both our domestic and international supply of neffy and our current and future intranasal epinephrine technology product candidates.

We do not currently have, nor do we plan to acquire, the infrastructure or capability to manufacture or warehouse commercial quantities of *neffy* or our current or future intranasal epinephrine technology product candidates. Our ability to commercially supply *neffy* and our current or future intranasal epinephrine technology product candidates depends, in part, on the ability of third-party manufacturers to supply, manufacture and warehouse the raw materials, API and other important components related to the manufacture of our intranasal epinephrine technology product candidates, including Intravail and our nasal sprayer apparatus. We also rely on third parties to label and package the finished product. These third-party manufacturers currently have limited experience manufacturing our intranasal epinephrine technology product candidates, the raw materials and API for our intranasal epinephrine technology product candidates to be supplied to patients. While we will continue to work with our third-party suppliers and manufacturers to optimize the manufacturing process for *neffy* and our current or future intranasal epinephrine technology product candidates, we cannot guarantee that such efforts will be successful. If we fail to develop and maintain supply relationships with these third parties, we may be unable to successfully commercialize *neffy* and our current or future intranasal epinephrine technology product candidates.

In particular, we rely on third parties for the supply of our intranasal epinephrine technology product candidates unit dose nasal spray devices and glass microvials. We have entered into a manufacturing agreement with Renaissance Lakewood, LLC (“Renaissance”), which has been actively involved in supporting the manufacture of our intranasal epinephrine technology product candidates in our clinical development, and we will continue to rely on Renaissance as the primary source for drug product manufacturing and final packaging. We have also entered into a supply agreement with Nuova Ompi S.r.l. (“Ompi”) pursuant to which Ompi has agreed to supply glass microvials to support the Company’s manufacture and commercialization of *neffy*. We will rely on Ompi as the primary source of glass microvials. Unless and until we can secure alternative sources for microvials, drug product manufacturing and final packaging, our dependence on Renaissance and Ompi will subject us to the possible risks of shortages, interruptions, and price fluctuations.

If we experience supply interruptions or delays, or if a supplier discontinues the sale of certain products, we may have to obtain substitute materials or products, which in turn would require us to obtain amended or additional regulatory approvals, subjecting us to additional expenditures of significant time and resources. In addition, changes in our raw material suppliers could result in significant delays in production, higher raw material costs and loss of sales and customers, because regulatory authorities must generally approve raw material sources for pharmaceutical products, which may be time consuming. Any significant supply interruption effect on our business, condition (financial and otherwise). For example, drug application processes require specification of raw material suppliers, if raw materials from a specified supplier were to become unavailable, FDA or comparable foreign regulatory authority approval of a new supplier would be required. The amount of time required for the FDA or a comparable foreign regulatory authority to qualify a new supplier and confirm that our manufacturing processes meet the necessary standards could cause delays in the manufacturing and marketing of *neffy* and our current or future intranasal epinephrine technology product candidates and could, depending on the particular product, have a material adverse effect on our results of operations and financial condition.

We may be unable to maintain or establish required agreements with third-party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- the failure of the third party to manufacture *neffy* or our current or future intranasal epinephrine technology product candidates according to our schedule, or at all, including if our third-party contractors give greater priority to the supply of other products over our intranasal epinephrine technology product candidates or otherwise do not satisfactorily perform according to the terms of the agreements between us and them;
- the delay or interruption of the production of *neffy* or our current or future intranasal epinephrine technology product candidates due to a third-party contractor or supplier discontinuing the sale of certain products, requiring us to obtain substitute materials or products;
- the reduction or termination of production, raw materials, or deliveries by suppliers, or the raising of prices or renegotiation of terms;
- the termination or nonrenewal of arrangements or agreements by our third-party contractors at a time that is costly or inconvenient for us;
- the breach by the third-party contractors of our agreements with them;
- the failure of third-party contractors to comply with applicable regulatory requirements, whether related to our intranasal epinephrine technology product candidates or another product;
- the failure of the third party to manufacture our intranasal epinephrine technology product candidates, or the raw materials associated therewith, according to our specifications;
- the mislabeling of clinical supplies, potentially resulting in the wrong dose amounts being supplied or study drug or placebo not being properly identified;
- clinical supplies not being delivered to clinical sites on time, leading to clinical trial interruptions, or of drug supplies not being distributed to commercial vendors in a timely manner, resulting in lost sales; and
- the misappropriation of our proprietary information, including our trade secrets and know-how.

We do not have complete control over all aspects of the manufacturing process of, and are dependent on, our contract manufacturing partners for compliance with cGMP regulations for manufacturing both active drug substances and finished drug products. Third-party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside of the United States. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications, including without limitation due to a change in raw materials supply, and the strict regulatory requirements of the FDA and other foreign regulatory authorities, this could affect the sales of *neffy* and our current or future intranasal epinephrine technology product candidates. In addition, other than to conduct audits, we have limited control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our current or future intranasal epinephrine technology product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, and/or raw material suppliers, which would significantly impact our ability to develop, obtain or maintain marketing approvals for and commercialize *neffy* or our current or future intranasal epinephrine technology product candidates. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, application review delays, suspension, variation or withdrawal of approvals, license revocation, import alerts, seizures or recalls of product candidates or drugs, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of *neffy* or our current or future intranasal epinephrine technology product candidates and harm our business and results of operations. Our current and anticipated future dependence upon others for the raw materials associated with, and the manufacture of *neffy* and our current or future intranasal epinephrine technology product candidates may adversely affect our profit margins and our ability to successfully commercialize *neffy* or our current or future intranasal epinephrine technology product candidates on a competitive basis.

We are dependent on international third-party licensees and assignees for the development and commercialization of neffy and our current and future intranasal epinephrine technology product candidates outside the United States. If these third parties are not successful in their development and commercialization efforts or if these third parties fail to meet their contractual, regulatory or other obligations, our business and results of operations could be adversely affected.

We have entered into exclusive licensing and collaboration agreements with third-party partners for the development and commercialization of *neffy* and our current or future intranasal epinephrine technology product candidates worldwide, excluding the United States. As a result, we are dependent on these parties to, at times, achieve regulatory approval of *neffy* and our current or future intranasal epinephrine technology product candidates for marketing and, if approval is obtained, commercialize *neffy* and our current or future intranasal epinephrine technology product candidates outside the United States. The timing and amount of any milestone and royalty payments we may receive under these agreements, as well as the commercial success of *neffy* and our current or future intranasal epinephrine technology product candidates in those regions outside of the United States, will depend on, among other things, the efforts, allocation of resources and successful commercialization of *neffy* and our current or future intranasal epinephrine technology product candidates by our licensing and collaboration partners. We also depend on such licensing and collaboration partners to comply with all applicable laws relative to the development and commercialization of *neffy* and our current or future intranasal epinephrine technology product candidates in those countries. They may take actions or fail to take actions that result in safety issues with *neffy* and our current or future intranasal epinephrine technology product candidates in their licensed territory, and such safety issues could negatively impact *neffy* and our current or future intranasal epinephrine technology product candidates in countries outside of the licensed territory. We do not control the individual efforts of our licensing and collaboration partners and have limited ability to terminate these agreements or have assigned assets returned to us if such licensing and collaboration partners do not perform as anticipated.

The failure of our licensing and collaboration partners to devote sufficient time and effort to the development and commercialization of *neffy* and our current or future intranasal epinephrine technology product candidates; to meet their obligations to us, including for future royalty and milestone payments; to adequately deploy business continuity plans in the event of a crisis; to adequately respond to the adverse impact of military action, sanctions and market disruptions; and/or to satisfactorily resolve significant disagreements with us or address other factors could have an adverse impact on our financial results and operations. In addition, if these third parties violate, or are alleged to have violated, any laws or regulations during the performance of their obligations for us, including with respect to safety, patient and data privacy, antitrust, and bribery and corruption, it is possible that we could suffer financial and reputational harm or other negative outcomes, including possible legal consequences and liabilities. We may not be successful in enforcing the terms and conditions of our licensing and collaboration agreements in court or via agreed upon dispute resolution mechanisms, and even if we were to prevail in any such dispute, the remedies may not be adequate to compensate us for the losses. Any termination, breach or expiration of any of these licensing or collaboration agreements could have a material adverse effect on our financial position by reducing or eliminating the potential for us to receive license fees, milestones and royalties. In such an event, we may be required to devote additional efforts and to incur additional costs associated with pursuing regulatory approval and commercialization of *neffy* and our current or future intranasal epinephrine technology product candidates. Alternatively, we may attempt to identify and transact with a new assignee or licensee, but there can be no assurance that we would be able to identify a suitable partner or transact on terms that are favorable to us. For example, in February 2023, we terminated the Recordati License and Supply Agreement, which eliminated the potential for us to receive milestone and royalty payments from Recordati under the Recordati License and Supply Agreement. Although we found a partner for the regions previously licensed to Recordati, under the Recordati Termination Agreement, we are obligated to pay certain milestone and royalty payments to Recordati.

neffy and our current or future intranasal epinephrine technology product candidates are developed and produced at a few locations, and a business interruption at one or more of these locations or within our supply chain could have a material adverse effect on our business, financial position, and results of operations.

neffy and our current or future intranasal epinephrine technology product candidates are developed and produced at our third-party's manufacturing facilities in Lakewood, New Jersey. Disruptions of these facilities or within our supply chain can occur for many reasons, including events unrelated to us or beyond our control, such as fires and other industrial accidents, floods and other severe weather events, natural disasters, environmental incidents or other catastrophes, utility and transportation infrastructure disruptions, shortages of raw materials, pandemic diseases or viral contagions, and acts of war or terrorism. Natural disasters and adverse weather conditions can be caused or exacerbated by climate change, and the spate of extreme weather events experienced during 2021 presents an alarming trend. During 2021, for example, Tropical Storm Ida brought extreme rainfall and flash flooding to New Jersey that caused damage to local businesses. Such events could compromise our inventory, resulting in significant costs. Furthermore, work stoppages, whether union-organized or not, can also disrupt operations. Business interruption could also be caused by compliance failures. A significant disruption at any of these facilities or otherwise within our supply chain, even on a short-term basis, could impair our ability to produce and ship products to the market on a timely basis or at all, which could have a material adverse effect on our business, financial position, and results of operations.

We rely on third parties to conduct our nonclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties, comply with applicable regulatory requirements or meet expected deadlines, our development programs and our ability to commercialize neffy and our current or future intranasal epinephrine technology product candidates may be delayed.

We are dependent on third parties to conduct our nonclinical studies and any clinical trials. Specifically, we have used and relied on, and intend to continue to use and rely on, medical institutions, clinical investigators, CROs and consultants to conduct our nonclinical studies and past clinical trials in accordance with our clinical protocols and regulatory requirements. These CROs, investigators and other third parties play a significant role in the conduct and timing of these studies and trials. While we have and will have agreements governing the activities of our third-party contractors, we have limited influence over their actual performance. Nevertheless, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on our CROs and other third parties does not relieve us of our regulatory responsibilities. We and our CROs are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for any products or potential products in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs or trial sites fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable, and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. In addition, our clinical trials must be conducted with products produced under cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

There is no guarantee that any of our CROs, investigators or other third parties will devote adequate time and resources to such trials or studies or perform as contractually required. If any of these third parties fail to meet expected deadlines, adhere to our clinical protocols or meet regulatory requirements, or otherwise performs in a substandard manner, our clinical trials may be extended, delayed or terminated. In addition, many of the third parties with whom we contract may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other development activities that could harm our competitive position. In addition, principal investigators for our clinical trials are expected to serve as scientific advisors or consultants to us from time to time and may receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or the FDA or a comparable regulatory authority concludes that the financial relationship may have affected the interpretation of the study, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection by the FDA of any NDA we submit or of comparable applicable submitted to foreign regulatory authorities. Any such delay or rejection could prevent us from commercializing *neffy* and our current or future intranasal epinephrine technology product candidates for potential additional indications, including urticaria.

Our CROs have the right to terminate their agreements with us in the event of an uncured material breach. In addition, some of our CROs have an ability to terminate their respective agreements with us if it can be reasonably demonstrated that the safety of the subjects participating in our clinical trials warrants such termination, if we make a general assignment for the benefit of our creditors or if we are liquidated. If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative third parties on commercially reasonable terms or at all. Switching or adding additional CROs, investigators and other third parties involves additional cost and requires our management's time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, investigators and other third parties, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

Our reliance on third parties requires us to share our trade secrets, know-how and other proprietary information, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Because we currently rely on third parties to manufacture *neffy* and our intranasal epinephrine technology product candidates and to perform quality testing, we must, at times, share our proprietary information, including trade secrets and know-how, with them. We seek to protect our proprietary information, in part, by entering into confidentiality agreements, and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with our current and future licensing and collaboration partners, advisors, employees and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our proprietary information. Despite the contractual provisions employed when working with third parties, the need to share trade secrets, know-how and other proprietary information increases the risk that such proprietary information become known by our competitors, are intentionally or inadvertently incorporated into the technology of others or are disclosed or used in violation of these agreements. We rely, in part, on trade secrets, know-how and other proprietary information to develop and maintain our competitive position and a competitor's discovery of our proprietary information or other unauthorized use or disclosure would impair our competitive position and may have a material adverse effect on our business, financial condition, results of operations and prospects.

Risks Related to Our Intellectual Property

Our commercial success depends on our ability to obtain and maintain sufficient intellectual property protection for neffy, our current and future intranasal epinephrine technology product candidates and other proprietary technologies.*

Our commercial success will depend, in part, on our ability to obtain and maintain patent protection in the United States and other countries with respect to *neffy* and our current or future intranasal epinephrine technology product candidates. If we are unable to obtain or maintain patent protection with respect to *neffy* and our current or future intranasal epinephrine technology product candidates, and its uses, our business, financial condition, results of operations and prospects could be materially harmed.

We generally seek to protect our proprietary position by filing or in-licensing patents or patent applications in the United States and abroad related to *neffy* and our current or future intranasal epinephrine technology product candidates that are important to our business, as appropriate. Our pending and future patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless, and until, patents issue from such applications, and then only to the extent the issued claims cover the technology. There can be no assurance that our patent applications will result in patents being issued or that issued patents will afford sufficient protection against competitors with similar technology, nor can there be any assurance that the patents issued will not be infringed, designed around or invalidated by third parties. Even issued patents may later be found invalid or unenforceable or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts. The degree of future protection for our proprietary rights is uncertain. Only limited protection may be available and may not adequately protect our rights or permit us to gain or keep any competitive advantage. This failure to obtain the intellectual property rights relating to our product could have a material adverse effect on our financial condition and results of operations.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our potential future collaborators will be successful in protecting our intellectual property by obtaining and defending patents. Obtaining and enforcing patents is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications, or maintain and/or enforce patents that may issue based on our patent applications, at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development results before it is too late to obtain patent protection. Recent reforms and changes at government agencies of the United States and those of non-U.S. jurisdictions could increase the uncertainties and costs surrounding the prosecution or maintenance of our patent applications, and the maintenance, enforcement, or defense of our issued patents. For example, the ability of the USPTO and other applicable patent authorities to properly administer their functions is highly dependent on the levels of funding available to the agency and their ability to retain key personnel and fill key leadership appointments, among various factors. Termination of employees or delays in replacing or hiring for key positions could significantly impact the ability of the USPTO and other applicable patent authorities to fulfill their functions and could greatly impact our ability to timely and adequately prosecute or maintain our patent applications, and our ability to timely and adequately maintain, enforce, or defend our issued patents.

Although we enter into non-disclosure and confidentiality agreements with parties who have access to patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, independent contractors, advisors and other third parties, any of these parties may breach these agreements and disclose such results before a patent application is filed, thereby jeopardizing our ability to seek adequate patent protection.

If the scope of any patent protection we obtain is not sufficiently broad, or if we lose any of our patent protection, our ability to prevent our competitors from commercializing similar or identical product candidates would be adversely affected.*

The patent position of pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation, resulting in court decisions, including United States Supreme Court decisions, which have increased uncertainties as to the ability to enforce patent rights in the future. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States, or vice versa.

Further, we may not be aware of all third-party intellectual property rights potentially relating to our research programs and product candidates, or their intended uses, and as a result the potential impact of such third-party intellectual property rights upon the patentability of our own patents and patent applications, as well as the potential impact of such third-party intellectual property upon our freedom to operate, is highly uncertain. Because patent applications are maintained as confidential for a certain period of time, until the relevant application is published, we may be unaware of third-party patents that may be infringed by commercialization of any future product candidates, and we cannot be certain that we were the first to file a patent application related to a product candidate or technology. Moreover, because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that any future product candidates may infringe. In addition, identification of third-party patent rights that may be relevant to our technology is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. There is also no assurance that there is not prior art of which we are aware, but which we do not believe is relevant to our business, which may, nonetheless, ultimately be found to limit our ability to make, use, sell, offer for sale or import our products that may be approved in the future, or impair our competitive position. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. As a result, the issuance, scope, validity, enforceability, and commercial value of our patent rights are highly uncertain.

Our patents or pending patent applications, or the patents or pending patent applications that we license, may be challenged in the courts or patent offices in the United States and other foreign jurisdictions. For example, we are currently a party to an opposition proceeding at the European Patent Office with respect to EP 3678649, and we may be subject to third-party pre-issuance submission of prior art to the U.S. Patent and Trademark Office (“USPTO”) or become involved in post-grant review procedures, derivations, reexaminations, or inter partes review proceedings, in the United States or oppositions or similar proceedings in foreign jurisdictions, challenging our patent rights. The legal threshold for initiating such proceedings may be low, so that even proceedings with a low probability of success might be initiated. An adverse determination in any such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated, or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products.

Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

We may not be able to protect our intellectual property rights throughout the world, which could negatively impact our business.*

Patents are of national or regional effect. Although as of July 11, 2025 we co-own or exclusively license eight issued U.S. patents, granted patents in each of Australia, Canada, China, Hong Kong, Israel, Japan, Mexico, Singapore, South Korea, and member states of the European Patent Organization, including the United Kingdom, directed to *neffy* and its uses, among other things, three pending U.S. non-provisional patent applications, one pending international patent application and over fifteen pending foreign patent applications directed to *neffy* and its uses, among other things, filing, prosecuting and defending patents in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These competitor products may compete with our product, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. Furthermore, while we intend to protect our intellectual property rights in our expected significant markets, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our product. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate, which may have an adverse effect on our ability to successfully commercialize *neffy* and our current or future intranasal epinephrine technology product candidates in all of our expected significant foreign markets.

Various countries outside the United States have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. As a result, a patent owner may have limited remedies in certain circumstances, which could materially diminish the value of such patent. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected. Accordingly, our efforts to protect or enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. Furthermore, while we intend to protect our intellectual property rights in our expected significant markets, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our product. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate, which may have an adverse effect on our ability to successfully commercialize *neffy* and our current or future intranasal epinephrine technology product candidates in all of our expected significant foreign markets.

Further, the standards applied by the USPTO and foreign patent offices in granting patents are not always applied uniformly or predictably. As such, we do not know the degree of future protection that we will have on our technologies, products and product candidates. While we will endeavor to try to protect our technologies, products and product candidates with intellectual property rights such as patents, as appropriate, the process of obtaining patents is time-consuming, expensive and unpredictable.

Further, geo-political actions in the United States and in foreign countries (such as, the Russia and Ukraine conflict and the conflict in the Middle East, including U.S. involvement therein; retaliatory measures by foreign countries in response to actions by the U.S., in particular, tariffs) could increase the uncertainties and costs surrounding the prosecution or maintenance of our patent applications or those of any current or future licensors and the maintenance, enforcement or defense of our issued patents or those of any current or future licensors. Many foreign countries could impose retaliatory measures that may adversely impact our intellectual property rights in those countries. For example, on March 14, 2025, Brazil enacted Law No. 15.122/2025 (known as the “Economic Reciprocity Law”), which provides a framework that allows for the suspension of obligations related to foreign entity’s intellectual property rights. Accordingly, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

On September 16, 2011, the Leahy-Smith America Invents Act (the “Leahy-Smith Act”) was signed into law in the United States. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. In particular, under the Leahy-Smith Act, the United States transitioned in March 2013 to a “first inventor to file” system in which, assuming that other requirements of patentability are met, the first inventor to file a patent application will be entitled to the patent regardless of whether a third party was first to invent the claimed invention. A third party that files a patent application in the USPTO after March 2013 but before we could therefore be awarded a patent covering any of our inventions even if we had made the invention before it was made by such third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application. Furthermore, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our technology, or the technologies we license for our product, and the prior art allow the technology we use for *neffy* and our current or future intranasal epinephrine technology product candidates to be patentable over the prior art. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we were the first to either file any patent application related to *neffy* and our current or future intranasal epinephrine technology product candidates or invent any of the inventions claimed in our patents or patent applications.

The Leahy-Smith Act also included a number of significant changes that affect the way patent applications will be prosecuted and also may affect patent litigation. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including Post Grant Review, Inter Partes Review, and derivation proceedings. An adverse determination in any such submission or proceeding could reduce the scope or enforceability of, or invalidate, our patent rights, which could adversely affect our competitive position. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Thus, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Changes in patent law in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect neffy and our current or future intranasal epinephrine technology product candidates.

As is the case with other pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents relating to *neffy* and our current or future intranasal epinephrine technology product candidates. Obtaining and enforcing patents in the pharmaceutical industry involves both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws, rules and regulations in the United States and other countries could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. We cannot predict the breadth of claims that may be allowed or enforced in the patents we own, co-own or license from third parties. In addition, U.S. Congress or other foreign legislative bodies may pass patent reform legislation that is unfavorable to us.

Depending on decisions by the U.S. Congress, the U.S. federal courts, the USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce the existing patents we own, co-own or license and patents we or our licensors might obtain in the future. For example, the U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained.

Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO, or similar authorities in foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce the existing patents we own, co-own or license and patents that we or our licensors might obtain in the future.

As an example, beginning June 1, 2023, European patent applications and patents may be subjected to the jurisdiction of the Unified Patent Court (the “UPC”). Also, European patent applications will have the option, upon grant of a patent, of becoming a Unitary Patent, which will be subject to the jurisdiction of the UPC. The UPC and Unitary Patent are significant changes in European patent practice. As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation in the UPC.

In 2012, the European Union Patent Package (the “EU Patent Package”) regulations were passed with the goal of providing a single pan-European Unitary Patent and a new European UPC for litigation involving European patents. The EU Patent Package was implemented on June 1, 2023. As a result, all European patents, including those issued prior to ratification of the EU Patent Package, now by default automatically fall under the jurisdiction of the UPC. It is uncertain how the UPC will impact granted European patents in the biotechnology and pharmaceutical industries. During the first seven years of the UPC’s existence, the UPC legislation allows a patent owner to opt its European patents out of the jurisdiction of the UPC. We may decide to opt out our future European patents from the UPC, but doing so may preclude us from realizing the benefits of the UPC. Moreover, if we do not meet all of the formalities and requirements for opt-out under the UPC, our future European patents could remain under the jurisdiction of the UPC. The UPC will provide our competitors with a new forum to centrally revoke our European patents and allow for the possibility of a competitor to obtain pan-European injunction. Such a loss of patent protection could have a material adverse impact on our business and our ability to commercialize our technology and product candidates due to increased competition and, resultantly, on our business, financial condition, prospects and results of operations.

Obtaining and maintaining patent protection depends on compliance with various procedural, document submissions, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or patent applications will be due to be paid to the USPTO and various foreign patent agencies at various stages over the lifetime of our patents and/or patent applications. We have systems in place to remind us to pay these fees, and we rely on our outside patent annuity service to pay these fees when due. In addition, the USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply with these provisions. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If such an event were to occur, it could have a material adverse effect on our business. If we or our licensors fail to maintain the patents and patent applications covering our product, our competitors might be able to enter the market, which would have a material adverse effect on our business, financial conditions, results of operations and growth prospects.

Patent terms may be inadequate to protect our competitive position for neffy and our current or future intranasal epinephrine technology product candidates for an adequate amount of time and may adversely affect our anticipated future revenues and operating earnings.

We rely on patent, trademark, trade secret and other intellectual property protection in the discovery, development, manufacturing and sale of *neffy* and our current or future intranasal epinephrine technology product candidates. In particular, patent protection is important in the development and commercialization of our approved product candidates. Patents covering *neffy* and our current or future intranasal epinephrine technology product candidates normally provide market exclusivity, which is important in order for *neffy* and our current or future intranasal epinephrine technology product candidates to generate profits.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Given the amount of time required for the development, testing and regulatory review, patents protecting any future indications or any product candidates might expire before or shortly after commercialization. Even if patents covering any future indications or any future product candidates are obtained, once the patent life has expired, we may be open to competition from generic products. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

The patents we currently co-own or exclusively license for *neffy* and our intranasal epinephrine technology product candidates are expected to expire as early as 2038, absent any patent term adjustments. The API in *neffy* and our intranasal epinephrine technology product candidates is epinephrine, a generic API that is used in FDA-approved intra-muscular injectables. Since *neffy* was approved by the FDA under the 505(b)(2) regulatory pathway, our U.S. patents for *neffy* are not eligible for patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984. While we are planning to seek additional patent coverage for *neffy*, there can be no assurances that such additional patent protection will be granted, or if granted, that these patents will not be infringed upon or otherwise held enforceable. Even if we are successful in obtaining a patent, patents have a limited lifespan. Without patent protection, we may be open to competition from generic versions of *neffy*.

We cannot ensure that patent rights relating to inventions described and claimed in our pending patent applications will issue or that patents based on our patent applications will not be challenged and rendered invalid and/or unenforceable.

We co-own or exclusively license patent applications in our portfolio relating to *neffy* and our current or future intranasal epinephrine technology product candidates that are pending at the patent offices in the United States, Europe, Japan, and other foreign jurisdictions, however, we cannot predict:

- if and when patents may issue based on the patent applications we own, co-own or exclusively license;
- the scope of protection of any patent issuing based on the patent applications we own, co-own or exclusively license;
- whether the claims of any patent issuing based on the patent applications we own, co-own or exclusively license will provide protection against competitors,
- whether or not third parties will find ways to invalidate or circumvent our patent rights;
- whether or not others will obtain patents claiming aspects similar to those covered by the patent applications we own, co-own or exclusively license;
- whether we will need to initiate litigation or administrative proceedings to enforce and/or defend our patent rights which will be costly whether we win or lose;
- whether the patent applications that we own, co-own or exclusively license will result in issued patents with claims that cover *neffy* and our intranasal epinephrine technology product candidates or uses thereof; and/or
- whether we may experience patent office interruption or delays to our ability to timely secure patent coverage to any potential additional indications or any future product candidates.

We cannot be certain that the claims in our pending patent applications directed to *neffy* and our current or future intranasal epinephrine technology product candidates will be considered patentable by the USPTO or by patent offices in foreign countries. One aspect of the determination of patentability of our inventions depends on the scope and content of the “prior art,” information that was or is deemed available to a person of skill in the relevant art prior to the priority date of the claimed invention. There may be prior art of which we are not aware that may affect the patentability of our patent claims or, if issued, affect the validity or enforceability of a patent claim relevant to our business. There is no assurance that there is not prior art of which we are aware, but which we do not believe is relevant to our business, which may, nonetheless, ultimately be found to limit our ability to make, use, sell, offer for sale or import our products that may be approved in the future, or impair our competitive position. Even if the patents do issue based on the patent applications we own, co-own or exclusively license, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, patents in our portfolio may not adequately exclude third parties from practicing relevant technology or prevent others from designing around our claims. If the breadth or strength of our intellectual property position with respect to any potential additional indications or any future product candidates is threatened, it could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize, any additional potential indications or any future product candidates. In the event of litigation or administrative proceedings, we cannot be certain that the claims in any of our issued patents will be considered valid by courts in the United States or foreign countries.

We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent which might adversely affect our ability to develop and market neffy and our current or future intranasal epinephrine technology product candidates.

As the pharmaceutical industry expands and more patents are issued, the risk increases that *neffy* and our current or future intranasal epinephrine technology product candidates may be subject to claims of infringement of the patent rights of third parties. There can be no assurance that our operations do not, or will not in the future, infringe existing or future third-party patents. Identification of third-party patent rights that may be relevant to our operations is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States and abroad that is relevant to our operations or necessary for the commercialization of *neffy* and our current or future intranasal epinephrine technology product candidates in any jurisdiction.

Numerous U.S. and foreign patents and pending patent applications exist in our market that are owned by third parties. Our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, may have applied for or obtained or may in the future apply for and obtain, patents that will prevent, limit or otherwise interfere with our ability to make, use and sell our products. We do not always conduct independent reviews of pending patent applications and patents issued to third parties. Patent applications in the United States and elsewhere are typically published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Certain U.S. patent applications that will not be filed outside the U.S. can remain confidential until patents issue. In addition, patent applications in the United States and elsewhere can be pending for many years before issuance, or unintentionally abandoned patents or applications can be revived. Furthermore, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our technologies, our products or the use of our products. As such, there may be applications of others now pending or recently revived patents of which we are unaware. These patent applications may later result in issued patents, or the revival of previously abandoned patents that will prevent, limit or otherwise interfere with our ability to make, use or sell *neffy* or our current or future intranasal epinephrine technology product candidates.

The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market *neffy* or our current or future intranasal epinephrine technology product candidates. We may incorrectly determine that our products are not covered by a third-party patent or may incorrectly predict whether a third party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, which may negatively impact our ability to develop and market *neffy* or our current or future intranasal epinephrine technology product candidates. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market *neffy* or our current or future intranasal epinephrine technology product candidates.

We cannot provide any assurances that third-party patents do not exist which might be enforced against our current technology, including our research programs, product candidates, their respective methods of use, and manufacture thereof, and could result in either an injunction prohibiting our manufacture or future sales, or, with respect to our future sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties, which could be significant.

If we are sued for infringing on the intellectual property rights of third parties, such litigation could be costly and time consuming and could prevent or delay us from developing or commercializing neffy or our current or future intranasal epinephrine technology product candidates.*

Our commercial success depends, in part, on our ability to develop, manufacture, market and sell *neffy* and our current or future intranasal epinephrine technology product candidates without infringing the intellectual property and other proprietary rights of third parties. Third parties may allege that we have infringed or misappropriated their intellectual property. For example, on March 25, 2025, Aptargroup, Inc. and Aptar France SAS (collectively, "Aptar") filed a suit against us in the United States District Court for the Southern District of New York, alleging that we violated the Defend Trade Secrets Act (18 USC § 1836), misappropriated trade secrets under New York state law, and committed various breaches of contract (the "Aptar Litigation"). We dispute these allegations and intend to vigorously defend ourselves in the Aptar Litigation. Litigation or other legal proceedings relating to intellectual property claims, with or without merit, is unpredictable and generally expensive and time consuming and, even if resolved in our favor, is likely to divert significant resources from our core business, including distracting our technical and management personnel from their normal responsibilities. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Additionally, delays caused by the federal agencies may increase the time period that we are subject to such claims.

There is a substantial amount of intellectual property litigation in the pharmaceutical industry, and we may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property rights with respect to *neffy* or our current or future intranasal epinephrine technology product candidates. Third parties may assert infringement claims against us based on existing or future intellectual property rights. The pharmaceutical industry has produced a significant number of patents, and it may not always be clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we were sued for patent infringement, we would need to demonstrate that *neffy* or our current or future intranasal epinephrine technology product candidates, or of use either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, and we may not be able to do this. Proving invalidity of third-party patents may be difficult and uncertain. Even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted in defending our rights in these proceedings, which could have a material adverse effect on our business and operations. In addition, we may not have sufficient resources to bring these actions to a successful conclusion.

If we are found to infringe a third party's intellectual property rights, we could be forced, including by court order, to cease developing, manufacturing or commercializing the infringing product candidate or product. Alternatively, we may be required to obtain a license from such third party in order to use the infringing technology and continue developing, manufacturing or marketing the infringing product candidate. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing *neffy* or our current or future intranasal epinephrine technology product candidates or force us to cease some of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time consuming and unsuccessful and could result in a court or administrative body finding our patents to be invalid or unenforceable.*

Even if the patent applications we own, co-own or license are issued, third parties may challenge or infringe upon our patents. To counter infringement, we may be required to file infringement claims, which can be expensive and time-consuming. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including novelty, non-obviousness (or inventive step), written description or enablement. In addition, patent validity challenges may, under certain circumstances, be based upon non-statutory obviousness-type double patenting, which, if successful, could result in a finding that the claims are invalid for obviousness-type double patenting or the loss of patent term if a terminal disclaimer is filed to obviate a finding of obviousness-type double patenting. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld information material to patentability from the USPTO, or made a misleading statement, during prosecution.

Third parties may raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post-grant review, inter partes review, interference proceedings, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in the revocation or cancellation of or amendment to our patents in such a way that they no longer cover our current or future products or provide any competitive advantage. The outcome following legal assertions of invalidity and unenforceability is unpredictable. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we could lose part or all of the patent protection on one or more of our current or future products, which could result in our competitors and other third parties using our technology to compete with us. Such a loss of patent protection could have a material adverse impact on our business, financial condition, results of operations, cash flows and prospects. Additionally, we may be subject to claims of patent infringement during those proceedings, and delays caused by the federal agencies may increase the time period that we are subject to such claims. For example, administrative changes, including reduced staff and budgets experienced by the USPTO Patent and Trial Appeal Board, could further delay our ability to timely challenge any such patents.

We are currently a party to an opposition proceeding at the European Patent Office with respect to EP 3678649. We may, in the future, be a party to other intellectual property litigation or administrative proceedings that are very costly and time-consuming and could interfere with our ability to sell and market our products. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations. In addition, patent holding companies that focus solely on extracting royalties and settlements by enforcing patent rights may target us, especially as we gain greater visibility and market exposure as a public company.

In an infringement proceeding, even one initiated by us, there is a risk that a court will decide that our patents are not valid and that we do not have the right to stop the other party from using the inventions they describe. There is also the risk that, even if the validity of such patents is upheld, the court will refuse to stop the other party on the ground that such other party's activities do not infringe our rights to these patents.

An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our patents against competitors, affect our ability to receive royalties or other licensing consideration from our licensees, and may curtail or preclude our ability to exclude third parties from making, using and selling similar or competitive products. Any of these occurrences could have a material adverse effect on our business, financial condition, results of operations, cash flows and prospects.

Competitors may infringe our patents, trademarks, copyrights or other intellectual property that relate to our research programs and product candidates, their respective methods of use, manufacture and formulations thereof. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming and divert the time and attention of our management and scientific personnel. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents, in addition to counterclaims asserting that our patents are invalid or unenforceable, or both. In any patent infringement proceeding, there is a risk that a court will decide that a patent that we own or have licensed is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of our patents is upheld, the court will construe the claims of our patents narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention at issue. An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our patents against those parties or other competitors, and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Any of these occurrences could adversely affect our competitive business position, business prospects and financial condition. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks and pay for damages.

Even if we establish infringement by competitors, a court may decide not to grant an injunction against further infringing activity by competitors and instead award only monetary damages, which may or may not be an adequate remedy. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. Moreover, we cannot assure you that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such infringement claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings.

neffy or our current or future intranasal epinephrine technology product candidates may face competition from generic inhalable epinephrine products sooner than expected, and our patents may be challenged.*

Our success will depend in part on our ability to obtain and/or maintain patent protection for *neffy* and our current or future intranasal epinephrine technology product candidates and related technologies and to prevent third parties from infringing upon our proprietary rights. We must also operate without infringing upon patents and proprietary rights of others, including by obtaining appropriate licenses to patents or other proprietary rights held by third parties, if necessary. Moreover, the patent applications we have filed or may file in the future may never yield patents that protect our inventions and intellectual property assets. Failure to obtain additional patent coverage and/or maintain existing patent protection for our formulations, methods of treatment, and/or technologies would limit our protection against generic drug manufacturers, pharmaceutical companies and other parties who may seek to copy our products, produce substantially similar products or use technologies substantially similar to those we own, co-own, or exclusively license.

We have not received U.S. non-patent marketing exclusivity for *neffy*, which was approved by the FDA under the 505(b)(2) regulatory pathway. Without non-patent marketing exclusivity for *neffy*, we may face competition by third parties seeking to market generic versions of *neffy* as early as our approval by the FDA. Upon approval of *neffy* by the FDA, we listed 7 patents with claims covering *neffy* in the Orange Book. An eighth patent with claims covering *neffy* was subsequently listed in the Orange Book. Any applicant who files an ANDA seeking approval of a generic equivalent version of *neffy* or an NDA submitted under the 505(b)(2) regulatory pathway referencing *neffy* must make one of the following certifications to the FDA concerning the patents listed in the Orange Book for *neffy*: (a) the patents that are listed have expired; (b) the date on which such patents will expire; or (c) such patents are invalid or will not be infringed upon by the manufacture, use or sale of the generic equivalent version of *neffy* or the drug product submitted under the 505(b)(2) regulatory pathway referencing *neffy*. This last certification is known as a paragraph IV certification. A notice of the paragraph IV certification must be provided to us for each patent to which the ANDA or 505(b)(2) application refers. Following receipt of a paragraph IV notice, we may bring a lawsuit for patent infringement against the paragraph IV filer, and we may be entitled to a statutory 30-month stay of approval of the proposed product of the paragraph IV filer. Although we expect to vigorously defend our patents from infringement by third parties, there can be no assurances that we will be successful with respect to such defense or any other legal proceedings which may arise in the ordinary course of our business. Such a failure may have a material impact on our business, our results of operations, and our financial condition in the future.

In the EU, we received non-patent marketing exclusivity for *EURneffy*, which received marketing authorization grounded on Article 8(3) of Directive 2001/83/EC by the European Commission. *EURneffy* received an eight-year period of data protection whereby another applicant cannot rely the data submitted as part of the *EURneffy* marketing authorization application, and a ten-year period of marketing protection during which a generic, hybrid or biosimilar cannot be placed on the market in the EU.

Because of the expense and uncertainty of litigation, we may not be in a position to enforce our intellectual property rights against third parties.

Because of the expense and uncertainty of litigation, we may conclude that even if a third party is infringing any one of our issued patents or other intellectual property rights, the risk-adjusted cost of bringing and enforcing such an infringement claim or action may be too high or not in the best interest of our company or our stockholders. In such cases, we may decide that the more prudent course of action is to simply monitor the situation or initiate or seek some other non-litigious action or solution.

Intellectual property litigation may lead to unfavorable publicity that harms our reputation.

During the course of any intellectual property litigation, there could be public announcements of the initiation of the litigation as well as results of hearings, rulings on motions, and other interim proceedings in the litigation. Such announcements could harm our reputation, the perceived value of our intellectual property or the market for our existing or future products, which could have a material adverse effect on our business.

We may become subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

We may be subject to claims that former employees, consultants, independent contractors, collaborators or other third parties have an interest in our patents or other intellectual property as an owner, co-owner, inventor or co-inventor. The failure to name the proper inventors on a patent application can result in the patents issued thereon being unenforceable. Inventorship disputes may arise from conflicting views regarding the contributions of different individuals named as inventors, the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent, conflicting obligations of third parties involved in developing *neffy* or our current or future intranasal epinephrine technology product candidates or as a result of questions regarding co-ownership of potential joint inventions. Litigation may be necessary to resolve these and other claims challenging inventorship and/or ownership. Alternatively, or additionally, we may enter into agreements to clarify the scope of our rights in such intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.*

We have registered and pending trademarks in the United States, as well as in several foreign jurisdictions, including but not limited to the United Kingdom, EU, and Japan. We may not be able to obtain applicable corresponding health regulatory approval to use these trademarks for our product. Our trademarks or trade names may be refused, challenged, infringed, circumvented, declared generic or descriptive, or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. We may not be able to register or use our trademarks in all relevant jurisdictions. During trademark registration proceedings, we may receive rejections. Although we would be given an opportunity to respond to or appeal those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. If we are unable to register or use, or obtain corresponding health regulatory approval for, a particular trademark in a given jurisdiction, we may need to adopt a different trademark in that territory, which could entail additional costs and diminish our brand equity. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected. We may license our trademarks and trade names to third parties, such as distributors. Though these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and trade names by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

Once granted, patents may remain open to opposition, interference, re-examination, post-grant review, inter partes review, nullification or derivation action in court or before patent offices or similar proceedings for a given period after allowance or grant, during which time third parties can raise objections against such grant. In the course of such proceedings, which may continue for a protracted period of time, the patent owner may be compelled to limit the scope of the allowed or granted claims thus attacked, or may lose the allowed or granted claims altogether. In addition, the degree of future protection afforded by our intellectual property rights is uncertain because even granted intellectual property rights have limitations, and may not adequately protect our business. The following examples are illustrative:

- others may be able to make formulations that are similar to *neffy* or our current or future intranasal epinephrine technology product candidates but that are not covered by the claims of our patent rights;
- the patents of third parties may have an adverse effect on our business;
- we or our licensors or any future strategic partners might not have been the first to conceive or reduce to practice the inventions covered by the issued patents or pending patent applications that we own, co-own or exclusively license;
- we or our licensors or any future strategic partners might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we may own or co-own or that we exclusively license in the future may not provide us with any competitive advantage, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- third parties performing manufacturing or testing for us using *neffy* or our current or future intranasal epinephrine technology product candidates or technologies could use the intellectual property of others without obtaining a proper license;
- we may not develop additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations and prospects.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patent protection for some of our technology and product candidates, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. Elements of *neffy* or our current or future intranasal epinephrine technology product candidates, including processes for their preparation and manufacture, may involve proprietary know-how, information, or technology that is not covered by patents, and thus for these aspects we may consider trade secrets and know-how to be our primary intellectual property. Any disclosure, either intentional or unintentional, by our employees, the employees of third parties with whom we share our facilities or third-party consultants and vendors that we engage to perform research, clinical trials or manufacturing activities, or misappropriation by third parties (such as through a cybersecurity breach) of our trade secrets or proprietary information could enable competitors to duplicate or surpass our technological achievements, thus eroding our competitive position in our market.

Trade secrets and unpatented know-how can be difficult to protect. We require our employees to enter into written employment agreements containing provisions of confidentiality and obligations to assign to us any inventions generated in the course of their employment. We and any third parties with whom we share facilities enter into written agreements that include confidentiality and intellectual property obligations to protect each party's property, potential trade secrets, proprietary know-how and information. We further seek to protect our potential trade secrets, proprietary know-how and information in part, by entering into non-disclosure and confidentiality agreements with parties who are given access to them, such as our corporate collaborators, outside scientific collaborators, contract research organizations, contract manufacturers, consultants, advisors and other third parties. With our consultants, contractors and outside scientific collaborators, these agreements typically include invention assignment obligations. Although we have taken steps to protect our trade secrets and unpatented know-how, we cannot provide any assurances that all such agreements have been duly executed, and any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. Unauthorized parties may also attempt to copy or reverse engineer certain aspects of our products that we consider proprietary. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets.

Trade secrets may be independently developed by others in a manner that could prevent legal recourse by us. Trade secrets will over time be disseminated within the industry through independent development, the publication of journal articles and the movement of skilled personnel from company to company or academic to industry scientific positions. Though our agreements with third parties typically restrict the ability of our advisors, employees, collaborators, licensors, suppliers, third-party contractors and consultants to publish data potentially relating to our trade secrets, our agreements may contain certain limited publication rights. Because from time-to-time we expect to rely on third parties, we must, at times, share trade secrets with them. Despite employing the contractual and other security precautions described above, the need to share trade secrets increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor or other third party, our competitive position would be harmed.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.*

We employ individuals who previously worked with other companies, including our competitors or potential competitors. We are and could in the future be subject to claims that we or our employees, consultants, or independent contractors have inadvertently or otherwise used or disclosed alleged trade secrets or other confidential information of current or former employers or competitors, including, for example, the Aptar Litigation. Although we try to ensure that our employees, consultants and independent contractors do not use the intellectual property, proprietary information, know-how or trade secrets of others in their work for us, we are, and may in the future, become subject to claims that we caused an individual to breach the terms of his or her non-competition or non-solicitation agreement, or that we or these individuals have, inadvertently or otherwise, used or disclosed the alleged intellectual property, proprietary information, know-how or trade secrets of a current or former employer or competitor.

While we are, and may in the future, litigate to defend against these claims, even if we are successful, litigation could result in substantial costs and could be a distraction to management and other employees. If our defenses to these claims fail, in addition to requiring us to pay monetary damages, a court could prohibit us from using technologies that are essential to *neffy* and our current or future intranasal epinephrine technology product candidates, if such technologies are found to incorporate or be derived from the trade secrets or other proprietary information of the current or former employers. Moreover, any such litigation or the threat thereof may adversely affect our reputation, our ability to form strategic alliances or sublicense our rights to collaborators, engage with scientific advisors or hire employees or consultants, each of which would have an adverse effect on our business, results of operations and financial condition.

In the future, we may need to obtain additional licenses of third-party technology that may not be available to us or are available only on commercially unreasonable terms, and which may cause us to operate our business in a more costly or otherwise adverse manner that was not anticipated.

From time to time, we may be required to license technologies relating to our therapeutic programs from additional third parties to further develop or commercialize *neffy* and our current or future intranasal epinephrine technology product candidates. Should we be required to obtain licenses to any third-party technology, including any such patents required to manufacture, use or sell *neffy*, such licenses may not be available to us on commercially reasonable terms, or at all. The inability to obtain any third-party license required to develop or commercialize any of *neffy* or our current or future intranasal epinephrine technology product candidates could cause us to abandon any related efforts, which could seriously harm our business and operations.

Risks Related to Employee Matters and Managing Growth

Our success is highly dependent on our ability to attract and retain highly skilled executive officers and employees.

Our success depends, and will likely continue to depend, upon our ability to hire and retain the services of our current executive officers and our other highly qualified personnel. We have entered into employment agreements with each of our executive officers but they may terminate their employment or engagement with us at any time. The loss of their services might impede the achievement of our research, development and commercialization objectives.

Our ability to compete in the biotechnology and pharmaceuticals industries depends upon our ability to attract and retain highly qualified managerial, scientific, medical, sales and marketing personnel. Our industry has experienced a high rate of turnover of management personnel in recent years. Replacing executive officers or other key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to develop, gain regulatory approval of and commercialize products successfully.

Our industry has experienced a high rate of turnover in recent years. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these additional key employees on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions.

We rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors, which includes entities owned by our executive officers and directors, may be employed by other entities and may have commitments under consulting or advisory contracts with those entities that may limit their availability to us. If we are unable to continue to attract and retain highly qualified personnel, our ability to develop and commercialize *neffy* and our current or future intranasal epinephrine technology product candidates will be limited.

Our employees, independent contractors, consultants, current and future licensing and collaboration partners and CROs may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements, which could cause significant liability for us and harm our reputation.

We are exposed to the risk that our employees, independent contractors, consultants, current and future licensing and collaboration partners and CROs may engage in fraudulent conduct or other illegal activity. Misconduct by those parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violates:

- FDA regulations or similar regulations of comparable non-U.S. regulatory authorities, including those laws requiring the reporting of true, complete and accurate information to such authorities;
- manufacturing standards;
- federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable non-U.S. regulatory authorities; and
- laws that require the reporting of financial information or data accurately.

Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of clinical trials, creating fraudulent data in our nonclinical studies or clinical trials or illegal misappropriation of product materials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws, standards or regulations. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, disgorgement, integrity oversight and reporting obligations, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs or comparable foreign programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could have a material adverse effect on our ability to operate our business and our results of operations.

We may encounter difficulties in managing our growth, which could disrupt our operations.*

We expanded our organization following FDA approval of *neffy* in August 2024. Specifically, we increased our sales force and made additional hires in the areas of general and administrative, medical, commercial, sales and marketing, and operations. As a result, our headcount has increased from 23 full-time employees and 5 part-time employees as of July 31, 2024 to 162 full-time employees and 5 part-time employees as of June 30, 2025. We may need to further expand our headcount in the future to support our growth strategy. To manage these growth activities, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Our management may need to devote a significant amount of our attention to managing these growth activities. Due to our limited financial resources and the limited experience of our management team in managing a company with such recent and anticipated growth, we may not be able to effectively manage the expansion of our operations, retain key employees, or identify, recruit and train additional qualified personnel. Our inability to manage the expansion of our operations effectively may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. If we are unable to effectively manage our recent and expected growth, our ability to generate revenues or achieve future profitability could be reduced and we may not be able to implement our business strategy, including the successful commercialization of *neffy*.

Risks Related to the Securities Markets and Ownership of Our Common Stock

*The market price of our common stock could be volatile.**

The market price of our common stock could be subject to significant fluctuations. Market prices for securities of pharmaceutical, biotechnology and other life sciences companies have historically been particularly volatile. Some of the factors that may cause the market price of our common stock to fluctuate include:

- failure to meet or exceed financial and development projections we may provide to the public;
- failure to meet or exceed the financial and development projections of the investment community;
- our ability to maintain regulatory approval for *neffy*, or obtain regulatory approvals for additional indications;
- failure of *neffy* or our current or future intranasal epinephrine technology product candidates, to achieve commercial success;
- failure by us to maintain our existing third-party license and supply agreements;
- failure by us or our licensors to prosecute, maintain, or enforce our intellectual property rights;
- changes in laws or regulations applicable to *neffy* or our current or future intranasal epinephrine technology product candidates;
- any inability to obtain adequate supply of *neffy* or our current or future intranasal epinephrine technology product candidates or any of its components, or the inability to do so at acceptable prices;
- adverse regulatory authority decisions;
- introduction of new products, services or technologies by our competitors;
- the perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community;
- announcements of significant acquisitions, strategic collaborations, joint ventures or capital commitments by us or our competitors;
- disputes or other developments relating to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for *neffy* or our current or future intranasal epinephrine technology product candidates;
- additions or departures of key personnel;
- significant lawsuits, including patent or stockholder litigation;
- if securities or industry analysts do not publish research or reports about our business, or if they issue an adverse or misleading opinion regarding our business and stock;
- changes in the market valuations of similar companies;
- general market or macroeconomic conditions, including as a result of actual or threatened tariffs and trade wars;
- sales of our common stock by us or our stockholders in the future;
- trading volume of our common stock;
- announcements by commercial partners or competitors of new commercial products, clinical progress or the lack thereof, significant contracts, commercial relationships or capital commitments;
- adverse publicity generally, including with respect to other products and potential products in such markets;
- the introduction of technological innovations or new therapies that compete with potential products of ours;
- changes in the structure of health care payment systems; and
- period-to-period fluctuations in our financial results.

Moreover, the stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations may also adversely affect the trading price of our common stock.

In the past, following periods of volatility in the market price of a company's securities, stockholders have often instituted class action securities litigation against those companies.

Additionally, a decrease in the stock price of our common stock may cause our common stock to no longer satisfy the continued listing standards of Nasdaq. If we are not able to maintain the requirements for listing on Nasdaq, we could be delisted, which could have a materially adverse effect on our ability to raise additional funds as well as the price and liquidity of our common stock.

Delaware law and provisions in our amended and restated certificate of incorporation and amended and restated bylaws could make a merger, tender offer or proxy contest difficult, thereby depressing the trading price of our common stock.

Our status as a Delaware corporation and the anti-takeover provisions of the Delaware General Corporation Law (“DGCL”) may discourage, delay or prevent a change in control by prohibiting us from engaging in a business combination with an interested stockholder for a period of three years after the person becomes an interested stockholder, even if a change of control would be beneficial to our stockholders. In addition, our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that may make the acquisition of us more difficult, including the following:

- a classified board of directors with three-year staggered terms, which could delay the ability of stockholders to change the membership of a majority of our board of directors;
- the ability of our board of directors to issue shares of preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquirer;
- the exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of our board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;
- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;
- the requirement that a special meeting of stockholders may be called only by a majority vote of our entire board of directors, the chair of our board of directors or our chief executive officer, which could delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors;
- the requirement for the affirmative vote of holders of at least 66-2/3% of the voting power of all of the then-outstanding shares of our voting stock, voting together as a single class, to amend the provisions of our amended and restated certificate of incorporation relating to the management of our business or our amended and restated bylaws, which may inhibit the ability of an acquirer to affect such amendments to facilitate an unsolicited takeover attempt; and
- advance notice procedures with which stockholders must comply to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders’ meeting, which may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer’s own slate of directors or otherwise attempting to obtain control of us.

In addition, as a Delaware corporation, we will be subject to Section 203 of the DGCL. These provisions may prohibit large stockholders, in particular those owning 15% or more of our outstanding voting stock, from merging or combining with us for a certain period of time. A Delaware corporation may opt out of this provision by express provision in its original certificate of incorporation or by amendment to its certificate of incorporation or bylaws approved by its stockholders. However, we have not opted out of this provision.

These and other provisions in our amended and restated certificate of incorporation, amended and restated bylaws and Delaware law could make it more difficult for stockholders or potential acquirors to obtain control of our board of directors or initiate actions that are opposed by our then-current board of directors, including delay or impede a merger, tender offer or proxy contest involving us. The existence of these provisions could negatively affect the price of our common stock and limit opportunities for our stockholders to realize value in a corporate transaction.

Our amended and restated certificate of incorporation designates the state courts of the State of Delaware or, if no state court located within the State of Delaware has jurisdiction, the federal court for the District of Delaware, and the federal district courts of the United States of America to be the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers and employees.

Our amended and restated certificate of incorporation provides that, to the fullest extent permitted by law, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if and only if the Court of Chancery of the State of Delaware lacks subject matter jurisdiction, any state court located within the State of Delaware or, if and only if all such state courts lack subject matter jurisdiction, the federal district court for the District of Delaware) and any appellate court therefrom shall will be the sole and exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: (i) any derivative action or proceeding brought on behalf of us; (ii) any action or proceeding asserting a claim of breach of a fiduciary duty owed by any of our current or former directors, officers or other employees or our stockholders; (iii) any action or proceeding asserting a claim against us or any of our current or former directors, officers or other employees, arising out of or pursuant to any provision of the DGCL, our amended and restated certificate of incorporation or our amended and restated bylaws; (iv) any action or proceeding to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation or our amended and restated bylaws; (v) any action or proceeding as to which the DGCL confers jurisdiction to the Court of Chancery of the State of Delaware; and (vi) any action asserting a claim against us or any of our directors, officers or other employees, governed by the internal affairs doctrine.

This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated certificate of incorporation further provides that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. While the Delaware courts have determined that such choice of forum provisions are facially valid and several state trial courts have enforced such provisions and required that suits asserting Securities Act claims be filed in federal court, there is no guarantee that courts of appeal will affirm the enforceability of such provisions and a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions. If a court were to find either exclusive forum provision in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with litigating Securities Act claims in state court, or both state and federal court, which could seriously harm our business, financial condition, results of operations, and prospects.

These exclusive forum provisions may make it more expensive for stockholders to bring a claim than if the stockholders were permitted to select another jurisdiction and limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees, which may discourage lawsuits against us and our directors, officers and other employees. If a court were to find either exclusive-forum provision in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with resolving the dispute in other jurisdictions, all of which could seriously harm our business.

We do not anticipate paying any cash dividends in the foreseeable future.

We plan to retain our future earnings, if any, to fund the development and growth of our business. As a result, capital appreciation, if any, of our common stock will be our stockholders' sole source of gain, if any, for the foreseeable future.

Future sales of shares by existing stockholders could cause our stock price to decline.

If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after any applicable legal restrictions on resale lapse, the trading price of our common stock could decline. We are not able to predict the effect that sales may have on the prevailing market price of our common stock.

General Risk Factors

Geo-political conditions may have serious adverse consequences on our business, financial condition and stock price.*

International and geo-political events could also have a serious adverse impact on our business. For instance, in February 2022, Russia started a war against Ukraine. In response, the United States and certain other countries imposed significant sanctions and trade actions against Russia and could impose further sanctions, trade restrictions, and other retaliatory actions. Additionally, in October 2023, Hamas initiated an attack against Israel, provoking a state of war and which has resulted in a larger conflict in the Middle East that has included U.S. involvement. While we cannot predict the broader consequences, the conflict and retaliatory and counter-retaliatory actions could materially adversely affect global trade, currency exchange rates, inflation, regional economies, and the global economy, which in turn may increase our costs, disrupt our supply chain, impair our ability to raise or access additional capital when needed on acceptable terms, if at all, or otherwise adversely affect our business, financial condition, and results of operations.

If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about us, our business or our market, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that equity research analysts publish about us and our business. Equity research analysts may elect not to provide research coverage of our common stock, and such lack of research coverage may adversely affect the market price of our common stock. In the event we do have equity research analyst coverage, we will not have any control over the analysts, or the content and opinions included in their reports. The price of our common stock could decline if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of us or fails to publish reports on us regularly, demand for our common stock could decrease, which in turn could cause our stock price or trading volume to decline.

If we fail to maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired.

We are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act and the rules and regulations of Nasdaq. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. We must perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting in our Annual Report on Form 10-K filing for that year, as required by Section 404 of the Sarbanes-Oxley Act.

We may discover weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our financial statements. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act, or if we are unable to maintain proper and effective internal controls, we may not be able to produce timely and accurate financial statements. If that were to happen, the market price of our common stock could decline and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

None.

Item 5. Other Information

Rule 10b5-1 Trading Arrangements

During the three months ended June 30, 2025, our directors and officers (as defined in Rule 16a-1(f) under the Exchange Act) adopted, modified, or terminated trading plans for the orderly disposition of the Company's securities as set forth in the table below.

Name and Position	Action	Adoption / Termination Date	Type of Trading Arrangement		Total Shares of Common Stock to be Sold	Expiration Date
			Rule 10b5-1 ⁽¹⁾	Non-Rule 10b5-1 ⁽²⁾		
Richard Lowenthal, on behalf of Richard E. Lowenthal Charitable Remainder UniTrust Dated January 7, 2020* <i>Chief Executive Officer</i>	Adoption	May 21, 2025	X		1,050,000	May 14, 2027
Richard Lowenthal, on behalf of Lowenthal-Tanimoto Family Trust U/A DTD 4/3/2006* <i>Chief Executive Officer</i>	Adoption	May 21, 2025	X		1,050,000	May 14, 2027
Sarina Tanimoto, on behalf of Sarina Tanimoto Charitable Remainder UniTrust Dated January 7, 2020* <i>Chief Medical Officer</i>	Adoption	May 21, 2025	X		1,050,000	May 14, 2027
Sarina Tanimoto, on behalf of Lowenthal-Tanimoto Family Trust U/A DTD 4/3/2006* <i>Chief Medical Officer</i>	Adoption	May 21, 2025	X		1,050,000	May 14, 2027
Laura Shawver <i>Director</i>	Adoption	May 21, 2025	X		128,562	December 31, 2025
Kathleen Scott <i>Chief Financial Officer</i>	Adoption	May 22, 2025	X		50,000	May 22, 2026
Alexander Fitzpatrick <i>Chief Legal Officer</i>	Termination ⁽³⁾	May 29, 2025	X		100,000	December 31, 2025
Alexander Fitzpatrick <i>Chief Legal Officer</i>	Adoption ⁽³⁾	May 29, 2025	X		100,000	January 30, 2026

- (1) Contract, instruction or written plan intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) under the Exchange Act.
- (2) "Non-Rule 10b5-1 trading arrangement" as defined in Item 408(c) of Regulation S-K under the Exchange Act.
- (3) Represents the modification, as described in Rule 10b5-1(c)(1)(iv) under the Exchange Act, of a written plan adopted on November 27, 2024 and amended on December 13, 2024 that was intended to satisfy the affirmative defense conditions of Rule 10b5-1(e) under the Exchange Act.

* This plan, together with the other three plans marked with an asterisk in this table, are treated as a single "plan" because the individual constituent contracts with each broker-dealer, when taken together as a whole, meet all of the applicable conditions of Rule 10b5-1(e) under the Exchange Act and remain collectively subject to the provisions of such rule, including that a modification of any individual contract acts as modification of the whole contract.

Item 6. Exhibits

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation, as amended (incorporated by reference to Exhibit 3.1 to the registrant's Annual Report on Form 10-K, filed with the SEC on March 23, 2023).
3.2	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2 to the registrant's Current Report on Form 8-K, filed with the SEC on December 8, 2020).
10.1‡*	Co-Promotion Agreement, dated May 2, 2025, by and between ARS Pharmaceuticals, Inc. and ALK-Abelló Inc.
10.2+	Amended and Restated Non-Employee Director Compensation Policy (incorporated by reference to Exhibit 10.1 to the registrant's Quarterly Report on Form 10-Q filed with the SEC on May 14, 2025).
10.3‡	Third Amendment, dated July 10, 2025, to Manufacturing Agreement, dated as September 9, 2020, and as amended July 26, 2023 and September 17, 2024, by and between ARS Pharmaceuticals, Inc. and Renaissance Lakewood, LLC.
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1#	Certification of Principal Executive and Financial Officers Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document—the instance document does not appear in the Interactive Data File as its XBRL tags are embedded within the Inline XBRL document
101.SCH	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents
104	Cover page formatted as Inline XBRL and contained in Exhibit 101

‡ Schedules have been omitted pursuant to Item 601(a)(5) of Regulation S-K.

* Certain information in this exhibit is omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K because it is both not material and is the type that the registrant treats as private or confidential.

+ Indicates management contract or compensatory plan.

The information in Exhibit 32.1 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 in any filing under the Securities Act or the Exchange Act (including this Quarterly Report on Form 10-Q), unless the Registrant specifically incorporates the foregoing information into those documents by reference.

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 thereunto duly authorized.

ARS PHARMACEUTICALS, INC.

Date: August 13, 2025

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

Date: August 13, 2025

By: /s/ Kathleen D. Scott
Kathleen D. Scott
Chief Financial Officer
(Principal Financial and Accounting Officer)

CERTAIN INFORMATION CONTAINED IN THIS EXHIBIT, MARKED BY [*], HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE THE REGISTRANT HAS DETERMINED THE INFORMATION IS BOTH NOT MATERIAL AND IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.**

CO-PROMOTION AGREEMENT

This Co-Promotion Agreement (this “**Agreement**”) is entered into as of May 2, 2025 (the “**Effective Date**”), by and between **ARS Pharmaceuticals Operations, Inc.**, a corporation organized under the laws of Delaware (“**ARS**”), with offices at 11682 El Camino Real, Suite 120, San Diego, CA 92130, and **ALK-Abelló, Inc.**, a Delaware corporation with offices at 135 Route 202/206 Suite #16, Bedminster, New Jersey 07921 (“**ALK**”). Each of ARS and ALK is sometimes referred to individually herein as a “**Party**” and collectively as the “**Parties**”.

WHEREAS, ARS has developed *neffy*®[®], an intranasal epinephrine product for patients with Type I allergic reactions, including anaphylaxis, and has obtained FDA approval to market such product in the United States;

WHEREAS, ALK is engaged in the research, development and commercialization of pharmaceutical products;

WHEREAS, ARS wishes to engage ALK for certain promotional services related to *neffy*®[®] in the United States, in accordance with the terms and conditions set forth herein; and

WHEREAS, ALK desires to perform such promotional services, in accordance with the terms and conditions set forth herein.

NOW, THEREFORE, in consideration of the mutual covenants contained herein, and for other good and valuable consideration, ARS and ALK, intending to be legally bound, hereby agree as follows:

ARTICLE I

DEFINITIONS

Whenever used in this Agreement with an initial capital letter, the terms defined in this Agreement shall have the respective meanings ascribed to them herein.

1.1 “**Affiliate**” means, with respect to a Party, any entity that, directly or indirectly through one or more intermediaries, controls, is controlled by, or is under common control with such Party, but for only so long as such control exists. As used in this section, “control” means (a) to possess, directly or indirectly, the power to direct the management or policies of an entity, whether through ownership of voting securities, by contract relating to voting rights, or corporate governance; or (b) direct or indirect beneficial ownership of more than fifty percent (50%) (or such lesser percentage which is the maximum allowed to be owned by a foreign corporation in a particular jurisdiction) of the voting share capital or other equity interest in such entity.

1.2 “**ALK Commercialization Support Costs**” has the meaning set forth in Section 2.6(b)(x).

1.3 “**ALK House Marks**” means the ALK trade name and logo.

1.4 “**ALK Personnel**” means the Sales Representatives and any other personnel employed by ALK (including supervisory personnel overseeing the activities of the Sales Representatives, and legal, regulatory and other support personnel) who are or may be involved with activities under this Agreement.

1.5 “**Applicable Laws**” means the laws, statutes, rules, or regulations applicable to a Party’s activities to be performed or other obligations under this Agreement, including the FDCA, the federal Anti-Kickback Statute (42 U.S.C. § 1320a-7b(b)), the Federal Civil Monetary Penalties Law (42 U.S.C. § 1320a-7a), the civil False Claims Act (31 U.S.C. §§ 3729 et seq.), the criminal False Claims Law (42 U.S.C. § 1320a- 7b(a)), the criminal Health Care Fraud laws (18 U.S.C. §§ 286, 287, 1347, 1349), the PDMA, the Patient Protection and Affordable Care Act of 2010 (42 U.S.C. § 18001 et seq.), the Federal Sunshine Law, the Generic Drug Enforcement Act of 1992 (21 U.S.C. § 335a et seq.), the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. §§ 1320d et seq.) as amended by the Health Information Technology for Economic and Clinical Health Act (42 U.S.C. §§ 17921 et seq.), the exclusion law (42 U.S.C. § 1320a-7), Medicare (Title XVIII of the Social Security Act), Medicaid (Title XIX of the Social Security Act), state and federal licensure laws, the regulations promulgated pursuant to such laws, the FCPA and other laws relevant to fraud, waste and abuse, anti-corruption and bribery, racketeering, money laundering or terrorism, and any other state or federal law similar to the foregoing.

1.6 “**ARS Compliance Policies**” means the requirements set forth in ARS’s policies and procedures with respect to [***], as such policies and procedures are shared with ALK in writing and updated from time to time. ARS Compliance Policies as of the Effective Date are attached hereto in Exhibit A and incorporated herein by reference.

1.7 “**ARS House Marks**” has the meaning set forth in Section 1.79.

1.8 “**Base Fee**” has the meaning set forth in Section 6.1(a).

1.9 “**Business Day**” means a day other than a Saturday, Sunday or any day on which banks located in California, United States are authorized or obligated to close. Whenever this Agreement refers to number of days, such number shall refer to calendar days unless Business Days are specified.

1.10 “**Change of Control**” shall, with respect to either Party, be deemed to occur when:

(a) any “person” or “group” (as such terms as defined below in this Section 1.10) is or becomes the “beneficial owner” (as defined below in this Section 1.10), directly or indirectly, of shares of capital stock or other interests of such Party then outstanding and normally entitled (without regard to the occurrence of any contingency) to vote in the election of the directors, managers, or similar supervisory positions of such Party representing more than fifty percent (50%) of the total voting power of all outstanding classes of voting stock or equity of such Party,

(b) such Party consummates a merger, consolidation or similar transaction with another Person (whether or not such Party is the surviving entity) and as a result of such merger, consolidation or similar transaction the Persons that beneficially owned, directly or indirectly, the shares of voting stock or equity of such Party immediately prior to such transaction do not beneficially own, directly or indirectly, shares of voting stock or equity of the surviving Person representing at least a majority of the total voting power of all outstanding classes of voting stock or equity of the surviving Person,

(c) such Party sells or transfers to any Third Party, in one or more related transactions, properties or assets representing all or substantially all of such Party’s assets, or

(d) the holders of capital stock or equity of such Party approve a plan or proposal for the liquidation or dissolution of such Party.

For the purpose of this Section 1.10, (i) “person” and “group” have the meanings given such terms under Sections 13(d) and 14(d) of the United States Securities Exchange Act of 1934 and the term “group” includes any group acting for the purpose of acquiring, holding or disposing of securities within the meaning of Rule 13d-5(b)(1) under the United States Securities Exchange Act of 1934, (ii) a “beneficial owner” shall be determined in accordance with Rule 13d-3 under the United States Securities Exchange Act of 1934, and (iii) the term “beneficially owned” and “beneficially own” shall have the meaning correlative to that of “beneficial owner.”

1.11 “**Claims**” has the meaning set forth in Section 10.4.

1.12 “**Codes**” means (a) the applicable general and industry-specific Department of Health and Human Services Office of Inspector General compliance program guidance (“**OIG Compliance Guidance**”); (b) the Code on Interactions with Healthcare Professionals promulgated by the Pharmaceutical Research and Manufacturers of America (“**PhRMA Code**”), (c) the American Medical Association (AMA) Guidelines on Gifts to Physicians from Industry, and (d) the Accreditation Council for Continuing Medical Education (ACCME) Standards for Commercial Support, as any of the foregoing may be amended from time to time.

1.13 “**Collaboration Year**” means each of Collaboration Year 1, Collaboration Year 2, Collaboration Year 3 and Collaboration Year 4.

1.14 “**Collaboration Year 1**” means the period commencing on the Promotion Commencement Date and ending on the last day of the month in which the first anniversary of the Promotion Commencement Date occurs.

1.15 “**Collaboration Year 2**” means the twelve (12) month period commencing on the first day following the end of Collaboration Year 1 and ending on the first anniversary of such starting date.

1.16 “**Collaboration Year 3**” means the twelve (12) month period commencing on the first day following the end of Collaboration Year 2 and ending on the first anniversary of such starting date.

1.17 “**Collaboration Year 4**” means the twelve (12) month period commencing on the first day following the end of Collaboration Year 3 and ending on the first anniversary of such starting date.

1.18 “[***]” means, [***].

1.19 “**Commercialization**” means activities directed to the preparation for sale of, offering for sale of, or sale of the Product in the Territory, including activities related to marketing, advertising or Promoting the Product. When used as a verb, “**Commercialize**” means to engage in Commercialization.

1.20 “**Commercialization Plan**” means the written plan setting forth Commercialization and related activities to be conducted by ALK and the budgeted costs and expenses therefor, where applicable, as such plan is more particularly described in Section 2.6 and as may be amended or updated in accordance with this Agreement.

1.21 “**Competing Product**” has the meaning set forth in Section 3.5.

1.22 “**Confidential Information**” has the meaning set forth in Section 8.1.

1.23 “**Copyrights**” means all statutory and common law copyrights owned or controlled by ARS in and to the Materials, Training Materials or Labels for the Product used in the Territory.

1.24 “**Cost Report**” has the meaning set forth in Section 6.3.

1.25 “**Debarred/Excluded**” has the meaning set forth in Section 10.2(a).

1.26 “**Detail**” means [***] discussion with [***] (excluding medical convention exhibits and displays) during which a Sales Representative makes a presentation of the Product’s clinical attributes, benefits, prescribing information and safety information in a fair and balanced manner strictly in accordance with the Materials, the Labeling, the terms of this Agreement and all Applicable Laws, and in a manner that is customary in the industry in the Territory for the purpose of promoting a prescription pharmaceutical product. For clarity, [***], a “**Detail**” can include [***]. [***]. A “**Detail**” shall not include [***]. When used as a verb, “**Detail**” or “**Detailing**” means to conduct a Detail.

1.27 “**Distributor**” means any Person appointed or engaged by ARS or any of its Affiliates or its or their Licensees to distribute, market and sell (or resell) the Product, as applicable, with or without packaging rights, including wholesalers, in the Territory in circumstances in which such Person purchases its requirements of Product from ARS or its Affiliates or Licensees on an arm’s-length basis but does not otherwise make any royalty or other payments to ARS or its Affiliates or its Licensees with respect to intellectual property with respect to the Product.

1.28 “**Dollar**” means a United States dollar, and “\$” shall be interpreted accordingly.

1.29 “**Epinephrine Product**” means any [***]. The Epinephrine Products existing as of the Effective Date are set forth on Exhibit B.

1.30 “**Executives**” means, (a) with respect to ARS, its [***] or a senior executive of ARS designated by its [***] and, (b) with respect to ALK, its [***] or a senior executive of ALK designated by its [***].

1.31 “**Existing Collaboration Agreement**” means that certain Collaboration, License and Distribution Agreement, dated as of November 9, 2024, by and between ARS and ALK-Abelló A/S, as the same may be amended from time to time in accordance with its terms.

1.32 “**FCPA**” means the U.S. Foreign Corrupt Practices Act (15 U.S.C. Section 78dd-1, et. seq.) as amended.

1.33 “**FDA**” means the United States Food and Drug Administration, or any successor thereto.

1.34 “**FDCA**” means the federal Food, Drug and Cosmetic Act (21 U.S.C. §§ 301 et seq.), as amended, and the regulations promulgated and guidances issued thereunder from time to time.

1.35 “**Federal Sunshine Law**” means 42 U.S.C. 1320a-7h, as amended, and the regulations promulgated thereunder from time to time.

1.36 “**Fixed Percentage**” means, with respect to a Quarter in (a) Collaboration Year 2, thirty percent (30%), and (b) Collaboration Year 3 and Collaboration Year 4, fifty percent (50%).

1.37 “**GAAP**” means generally accepted accounting principles in the United States.

1.38 “**General Compliance Training**” has the meaning set forth in Section 5.5(b).

1.39 “**Gross Sales**” means, with respect to the Product, [***] of the Product in the Territory [***].

1.40 “**Gross-to-Net Percentage**” means the quotient of (a) Net Sales, divided by (b) Gross Sales, expressed as a percentage.

1.41 “**Healthcare Organization**” or “**HCO**” means any entity that may, directly or indirectly, purchase, prescribe, recommend, refer or arrange for the prescribing, purchasing or formulary placement of a health-related product or service in the Territory including, but not limited to, hospitals, pharmacies (including specialty pharmacies), physician groups, nursing homes, group purchasing organizations, insurers, and health plans.

1.42 “**Healthcare Professional**” or “**HCP**” means any individual who is licensed to prescribe or dispense drugs in one or more jurisdictions within in the Territory, or who is in a position to recommend or refer a health-related product or service in the Territory, or who has significant input or influence on prescribing, purchasing or formulary decisions in the Territory, including physicians, physician assistants, nurses, nurse practitioners, pharmacists, medical directors, pharmacy directors, and formulary committee members.

1.43 “**Incentive Compensation**” means the total compensation paid, on an annual basis, by or under the authority of ALK to a Sales Representative involved in Promotion of the Product under this Agreement based on the performance of products (including the Product) being promoted by such Sales Representative in the Territory, including any target bonus, award or other incentive, but excluding salary.

1.44 “**Label**” or “**Labeling**” means: (a) the FDA-approved full prescribing information for the Product; and (b) the FDA-approved labels and other written, printed, or graphic matter accompanying or upon any container, wrapper, or any package insert, utilized with or for the Product.

1.45 “**Licensee**” means a Third Party other than a Distributor to whom ARS or any of its Affiliates grants a (sub)license under its intellectual property to import, promote, distribute, offer for sale or sell the Product in the Territory (either independently from or in cooperation with ARS), beyond the mere right to purchase Products from ARS and its Affiliates. In no event shall ALK or any of its Affiliates be deemed a Licensee under this Agreement.

1.46 “**Losses**” has the meaning set forth in Section 10.4.

1.47 “**Market Share**” means, for any Quarter or month, as applicable, the quotient of (a) the total number of units of the Product sold in the Territory in such Quarter [***], divided by (b) the total number of units of Epinephrine Products sold in the Territory in such Quarter [***]; expressed as a percentage.

1.48 “**Market Share Threshold**” means, (a) with respect to any Quarter in Collaboration Year 2, forty-five percent (45%), and (b) with respect to any Quarter in Collaboration Year 3 or Collaboration Year 4, fifty percent (50%); *provided that* [***].

1.49 “**Materials**” means any and all written, printed, graphic, electronic, audio, video or other materials to be used in connection with any Promotion activities, as developed in accordance with Section 4.1. For clarity, Materials may include materials such as detail aids, reprints and disease state materials, as applicable, as developed in accordance with Section 4.1.

1.50 “**Minimum Detail Requirements**” has the meaning set forth in Section 0.

1.51 “**Net Sales**” means, with respect to the Product, the gross amount invoiced by ARS or its Affiliates or Licensees for sale or other transfer or disposition for value to Third Parties (including Distributors), less [***]:

- (a) [***];
- (b) [***];
- (c) [***]; and
- (d) [***].

[***]

Upon any sale or other transfer or disposition of the Product that should be included within Net Sales for any consideration other than exclusively monetary consideration on bona fide arms'-length terms, then for purposes of calculating Net Sales under this Agreement, the Product shall be deemed to be sold exclusively for money at the average sales price during the applicable reporting period generally achieved for the Product in the Territory in which such sale or other transfer or disposition occurred.

In no event will any particular amount identified above be deducted more than once in calculating Net Sales. Sales of the Product between or among ARS and its Affiliates or Licensees for resale shall be excluded from the computation of Net Sales, but the subsequent resale of the Product to ARS, its Affiliate or (sub)licensee to a Third Party that is not a Licensee shall be included within the computation of Net Sales.

Net Sales will not include Products transferred at no profit for use in connection with clinical trials or other development activity, promotional use, compassionate sales or use, indigent programs, investigator initiated trials, or on a named patient basis.

1.52 “**OC**” has the meaning set forth in Section 2.4(a).

1.53 “[***]” means any HCP who is [***]; provided that [***]. For clarity, [***], unless [***].

1.54 “**Payor**” means any Person that provides a health benefit program for health care products and services, including, any government payor (e.g., Medicaid, Medicare), commercial health plan, and any Person acting on behalf of any government payor or commercial health plan by contract or otherwise.

1.55 “**PDMA**” means the Prescription Drug Marketing Act, as amended, and the regulations promulgated thereunder from time to time.

1.56 “**Pediatrician**” means a physician that is permitted under Applicable Laws to prescribe the Product and who is board certified in the United States to treat pediatric patients.

1.57 “**Performance Bonus**” means, with respect to a given Quarter in which the Market Share for such Quarter equaled or exceeded the Market Share Threshold for such Quarter, a bonus fee equal to the product of (a) the Fixed Percentage of Specified Net Sales for such Quarter, multiplied by (b)(i) the Market Share for such Quarter minus (ii) the applicable Market Share Threshold for such Quarter.

1.58 “**Person**” means an individual, corporation, partnership, limited liability company, trust, business trust, association, firm, joint stock company, joint venture, pool, syndicate, sole proprietorship, unincorporated organization, governmental authority, or any other form of entity not specifically listed herein.

1.59 “**PhRMA Code**” has the meaning set forth in Section 1.12.

1.60 “**Prescriber Data**” means the prescriber data, in sufficient detail to identify (a) [***] and (b) [***], in each case supplied by [***] or an alternative nationally recognized prescription data provider reasonably agreed by the Parties.

1.61 “[***] **Detail**” means a Detail in which the Product (a) is [***], (b) is [***], and (c) is [***].

1.62 “**Product**” means *neffy*®, an intranasal epinephrine product approved by the FDA.

1.63 “**Product Trademarks**” has the meaning set forth in Section 1.79.

1.64 “**Product Training**” means the Product-specific training program conducted in accordance with the Commercialization Plan, Applicable Laws and Codes, which may include, as set forth in the Commercialization Plan, training concerning (a) [***], (b) [***], (c) [***], (d) [***], (f) [***], and (g) [***].

1.65 “**Promotion**” or “**Promote**” means, with respect to the Product, promotional activities to be conducted by Sales Representatives in the Territory that are set forth in the Commercialization Plan or approved in writing by ARS. When used as a verb, “**Promote**” means to engage in one or more of such activities, including the following (as approved by ARS or set forth in a Commercialization Plan): (a) Detailing; and (b) utilizing Materials during Details; in each case, solely within the Territory.

1.66 “**Promotion Commencement Date**” has the meaning set forth in Section 3.2.

1.67 “**Promotion Commencement Timeline**” has the meaning set forth in Section 3.2.

1.68 “**Promotion Report**” has the meaning set forth in Section 7.2.

1.69 “**Quarter**” means each three (3) month period in a given Collaboration Year, with the first Quarter in such Collaboration Year commencing on the first day of such Collaboration Year; *provided* that the first Quarter for Collaboration Year 1 shall commence on the first day of such Collaboration Year and end on the last day of the first full three (3) month period within such Collaboration Year; *provided further* that the last Quarter for the Collaboration Year in which expiration or the effective date of termination of this Agreement occurs shall end on such expiration date or effective date of termination, as the case may be.

1.70 “**Regulatory Authority**” means any United States federal, state, commonwealth, territory, or local government, or political subdivision thereof, or any authority, agency or commission entitled to exercise any administrative, executive, judicial, legislative, police, regulatory or taxing authority or power, any court or tribunal (or any department, bureau or division thereof), or any governmental arbitrator or arbitral body with responsibility for granting approvals necessary for the marketing of the Product in the Territory, including the FDA.

1.71 “**Sales Representative**” means an individual who (a) is employed by ALK (and not by a Third Party contractor, unless and to the extent permitted under Section 3.4) to conduct Promotion and other Commercialization activities with respect to the Product in the Territory pursuant to and in accordance with this Agreement and the Commercialization Plan, and (b) has been sufficiently trained in accordance with this Agreement.

1.72 “[***] **Detail**” means a Detail in which (a) [***] and (b) [***].

1.73 “[***]” means [***].

1.74 “**Specified Net Sales**” means, with respect to a given Quarter, [***] the product of (a) the [***], multiplied by (b) [***], multiplied by (c) the Gross-to-Net Percentage [***]; *provided that*, [***].

1.75 “**Target Prescriber**” means each Pediatrician identified in the Commercialization Plan as being a suitable target for the Promotion and Detailing of the Product in the Territory.

1.76 “**Term**” has the meaning set forth in Section 11.1.

1.77 “**Territory**” means the United States of America excluding its territories and possessions, including Puerto Rico.

1.78 “**Third Party**” means any Person other than a Party or any Affiliate of a Party.

1.79 “**Trademarks**” means: (a) any trademarks that are owned or controlled by ARS and are used, or intended to be used, in connection with the Product in the Territory, including all word marks, logos, trade dress and/or indicia of origin, including applicable branding, color, palette, typeface, tagline and icon (“**Product Trademarks**”); and (b) the ARS trade name and logo (“**ARS House Marks**”); and including, in each case, all registrations and applications for registration of any such Trademarks in the Territory.

1.80 “**Training Materials**” means the materials (which may include written or other recorded, videotaped or Web-based training materials or on-line training programs) to be used in Product Training for the Sales Representatives regarding the Product pursuant to Section 5.5(a).

1.81 “[***]” means, with respect to the Product and a given Quarter, [***].

ARTICLE II

GRANT OF RIGHTS; GOVERNANCE; COMMERCIALIZATION PLAN

2.1 Grant of Rights.

(a) **Promotion.** Subject to the terms and conditions of this Agreement, ARS hereby grants to ALK the right to Promote and Detail the Product to [***] in the Territory during the Term, in compliance with all Applicable Laws, Codes, the terms and conditions of this Agreement and the Commercialization Plan. Such right shall be non-transferable and non-sublicensable, and ALK shall not grant any rights to, or permit or authorize, any other Person to Promote or Detail the Product, except with respect to permitted subcontractors in accordance with Section 3.4.

(b) **Trademarks.** Subject to the terms and conditions of this Agreement, ARS hereby grants to ALK a non-exclusive, royalty-free license to use the Product Trademarks, the ARS House Marks and Copyrights in the Territory solely in connection with Promoting and Detailing the Product to [***] in the Territory in accordance with the terms of this Agreement. Such license shall be non-transferable and non-sublicensable and shall automatically and immediately terminate upon the expiration or earlier termination of this Agreement for any reason.

2.2 **Retained Rights.** Except as specifically set forth in this Agreement, ALK shall have no other rights with respect to the Product. ALK and its Affiliates shall not Promote, market or otherwise Commercialize the Product except as ALK and its Affiliates is expressly authorized to do under this Agreement or the Existing Agreement. ARS and its Affiliates reserve and retain, for itself, its Affiliates and for any Third Party, all rights in and relating to the Product not expressly granted to ALK and its Affiliates under this Agreement or the Existing Collaboration Agreement, including all rights to, and ALK and its Affiliates shall not, Promote the Product (a) outside the Territory, except as set forth in the Existing Collaboration Agreement, or (b) in the Territory to any Person other than [***]. For clarity, ARS and its Affiliates shall continue to have the right to, and to grant to one or more Third Parties the right to, Detail and Promote, sell and market the Product throughout the Territory to any Person other than [***].

2.3 **Sales.** ARS shall book all sales of the Product in the Territory. ARS shall have the sole authority for accepting and filling purchase orders, billing and returns with respect to the Product, and for establishing and modifying the terms and conditions of sale of the Product, including the price at which the Product will be sold, whether the Product shall be subject to any discounts and/or rebates, and the distribution of the Product. ALK and its Sales Representatives are not authorized to, and shall not, discuss or provide any price concessions on the Product in the Territory or enter into any contracts with respect to the Product in the Territory.

2.4 Governance.

(a) **Oversight Committee.** Within [***] after the Effective Date, the Parties shall establish an Oversight Committee (the “OC”), which shall operate during the Term. The OC shall be responsible for facilitating communication between the Parties with respect to the Promotion of the Product to [***] in the Territory and for reviewing and discussing performance and strategic direction with respect to such Promotion. The OC will have an advisory role only and will not have any decision-making authority or any power or authority to amend, modify or waive any of the terms or conditions of this Agreement. For clarity, ARS shall have sole responsibility and authority for establishing the overall marketing and Promotion strategy, messaging, and positioning for the Product.

(b) **OC Membership.** The OC shall be comprised of an equal number of representatives of each Party, including [***] permanent members from each Party. Each Party’s OC representatives will be appropriately knowledgeable regarding commercialization of pharmaceutical products. Each Party will designate one of its representatives as the co-chairperson of the OC. Each Party’s co-chairperson will be responsible, on an alternating basis, for scheduling meetings, preparing and circulating an agenda in advance of each meeting, preparing and issuing minutes of each meeting within [***] days thereafter, revising such minutes to reflect timely comments thereon, and overseeing the ratification of such revised minutes.

(c) **OC Meetings.** The OC shall meet on a regular basis, no less than every [***] for the [***] of the Term and thereafter every [***] (unless mutually agreed otherwise), either in-person or by any means of communication as the members deem necessary or appropriate, including by telephone, videoconference or similar means in which each participant can hear what is said, and be heard, by the other participants. Each Party may, upon prior notice to the other Party: (a) have representative(s) from its organization attend OC meetings as regular participants and (b) invite other subject matter experts to any OC meeting on an as needed basis, *provided* that such attendees shall be bound by obligations of confidentiality and non-use equivalent to those set forth in Article 8. Each Party shall bear its own personnel and travel costs and expenses relating to its participation in the OC and attendance at any OC meetings.

2.5 **Alliance Managers.** Each Party shall, as soon as possible after the Effective Date, appoint a single individual to coordinate all daily, ordinary course of business interactions between the Parties that may be necessary to administer this Agreement effectively and carry out the intent and objectives of the Parties (for each Party, an “Alliance Manager”). The Alliance Managers shall meet with ALK commercial leadership (including sales, marketing, and head of ALK commercial) on a regular basis, no less than [***] for the [***] of the Term and thereafter every [***] (unless mutually agreed otherwise), either in-person or by any means of communication as the members deem necessary or appropriate, including by telephone, videoconference or similar means in which each participant can hear what is said, and be heard, by the other participants. Each Alliance Manager shall be experienced in project management, and be knowledgeable about the marketing and sale of branded pharmaceutical dosage products in general. Each Party may change its Alliance Manager effective upon written notice to the other Party.

2.6 Commercialization Plan. The Parties shall cooperate to develop and update, from time to time upon either Party's request, the Commercialization Plan setting forth the Promotion activities and other Commercialization activities, if any, to be conducted by ALK with respect to the Product in the Territory. [***].

(a) **Initial Plan; Updates.** The Parties have agreed in writing to the initial Commercialization Plan as of the Effective Date. Upon either Party's request, the Parties agree to discuss in good faith updates to the Commercialization Plan, taking into consideration, among other things, ARS's then-current brand strategy for the Product in the Territory. Any amendment or update to the Commercialization Plan shall be subject to review and approval by ARS and ALK. Subject to the foregoing, [***]. Further, [***].

(b) **Content.** The Commercialization Plan will be transparent and specific so that ARS and ALK can coordinate and objectively measure performance. At a minimum, the Commercialization Plan shall contain:

- (i) list of [***];
- (ii) number of [***];
- (iii) number of [***], broken out by [***], and timelines for deployment, broken out by [***];
- (iv) number of Details to be performed by the Sales Representatives, by [***], broken out by [***], on a [***] basis;
- (v) promotion-related key performance indicators that may be used to evaluate the effectiveness of Promotion activities under the Commercialization Plan;
- (vi) product Training, including schedules and topics, consistent with Section 5.5, and training-related key performance indicators;
- (vii) anticipated use of Materials and quantities therefor;
- (viii) Promotion activities (other than Details), if any, to be conducted by the Sales Representatives in the Territory and any costs therefor;
- (ix) other Commercialization activities, if any, to be conducted by ALK in the Territory; and
- (x) detailed budgets for all [***] (this Section 2.6(b)(x) collectively, "**ALK Commercialization Support Costs**").

ARTICLE III

COMMERCIALIZATION RESPONSIBILITIES; RESTRICTIONS

3.1 **Promotion Activities.** Throughout the Term, ALK shall, through the Sales Representatives, Promote the Product in the Territory to the [***] in accordance with the then-current Commercialization Plan, Applicable Law, the Codes, and the terms of this Agreement. Without limiting the foregoing, ALK shall: (a) employ a sufficient number of Sales Representatives and ensure that such Sales Representatives devote the necessary time Promoting the Product to [***], in each case as necessary to meet the Minimum Detail Requirements; and (b) perform Details in accordance with the [***] set forth in the Commercialization Plan. Subject to the terms of this Agreement, ALK shall be responsible for and have decision-making authority with respect to the manner in which it conducts its activities under this Agreement, including communicating with [***]. Each Party shall be solely responsible for all costs it incurs to conduct its activities under this Agreement.

3.2 **Promotion Commencement.** ALK shall commence in-person Detailing activities with respect to the Product in the Territory to the Target Prescribers no later than [***] or such later date as may be agreed by the Parties in writing (the “**Promotion Commencement Date**”). ALK shall [***] pursuant to the Commercialization Plan (collectively, the “**Promotion Commencement Timeline**”); *provided* that [***]. Notwithstanding the foregoing, [***]. For clarity, [***].

Minimum Detail Requirements. ALK shall (a) [***], (b) [***], (c) [***], (d) [***], (e) [***], and (f) [***]. The “Minimum Detail Requirements” will be, collectively, the requirements set forth in each of the foregoing clauses (a) through (f), assessed each [***] during the Term; *provided* that, [***]; *provided further* that, [***]. For clarity, [***]. The Parties agree that the Minimum Detail Requirements can be updated from time to time upon written agreement of both Parties. For clarity, any amendment to this Agreement shall be subject to Section 12.7 and any update to the Commercialization Plan shall be subject to Section 2.6(a).

3.3 **Other Commercialization Activities.** If and to the extent set forth in the Commercialization Plan, ALK shall conduct other Commercialization activities in accordance with the then-current Commercialization Plan and the terms of this Agreement.

3.4 **Subcontracting.** ALK may not subcontract with any Third Parties (including any contract sales organization) to perform any of the Promotion or other Commercialization activities to be performed by ALK under this Agreement, unless such subcontracting has been approved by ARS in writing in advance, which approval shall be granted or withheld in ARS’s sole discretion. ALK shall provide all reasonable information requested by ARS related to any potential subcontractor in order for ARS to evaluate ALK’s request to subcontract. In all cases, ALK shall: (a) ensure that all permitted subcontractors are bound by written obligations as protective of the Product and ARS as the terms and conditions of this Agreement, as applicable to such subcontractors; (b) oversee the performance by its permitted subcontractors of the subcontracted activities; and (c) remain responsible and fully liable for the performance (or non-performance) of any activities by any of its permitted subcontractors in connection with this Agreement as if such activities had been performed by ALK itself.

3.5 **Exclusivity.** ALK shall Detail and Promote the Product in the Territory to the [***] during the Term in accordance with the Commercialization Plan and this Agreement and shall not and shall cause its Affiliates not to, during the Term and, in the case of expiration of this Agreement or termination [***], directly or indirectly, (a) market, promote, sell, distribute or accept orders for the sale of any [***] (“**Competing Product**”) in the Territory, or (b) assist or cooperate in any way with any other Person in connection with the marketing, promotion, sale, distribution or acceptance of orders for the sale of any Competing Product in the Territory; *provided*, however that [***] ALK acknowledges and agrees that the restrictions set forth in this Section 3.5 are reasonable and necessary to protect the legitimate interests of ARS and agrees not to contest such restrictions in any proceeding.

3.6 **Grants; Charitable Requests; HCP/HCO Agreements.** As between the Parties, ARS shall have the right (in its sole discretion) to determine participation in free goods program plans, patient assistance programs and indigent access programs, if applicable, as well as to determine funding levels for grants, sponsorships and other charitable requests (including in support of professional symposia and continuing medical education programs), with respect to the Product in the Territory (including on a national, regional and local level, if applicable). If, for any reason, ALK receives any requests with respect to any of the foregoing activities, including any request with respect to the Product to support any of the foregoing activities, that have not been approved by ARS to be performed by ALK and included in a Commercialization Plan, ALK shall promptly forward such requests to ARS as soon as practicable for ARS’s consideration. Unless explicitly authorized by ARS in writing, ALK shall not enter into any agreements with Healthcare Professionals or Healthcare Organizations relating to speaker programs, advisory boards, consulting arrangements or similar arrangements related to the Product. ARS shall have the sole authority to develop, host and enter into, as the case may be, speaker programs, advisory boards, consulting arrangements and similar arrangements related to the Product in the Territory; *provided* that upon ARS’s reasonable request, ALK shall provide commercially reasonable support to ARS with respect to each of the foregoing.

3.7 **Development and Regulatory Activities.** As between the Parties, ARS shall have the sole right to conduct, and ALK shall not conduct or sponsor (directly or indirectly), clinical trials or other development activities with respect to the Product in the Territory, including providing support or assistance for investigator sponsored trials, cooperative studies, clinical studies, including post-approval studies, or other studies, including health economics and outcomes research and phase 4 studies, or any other research or development activities with respect to the Product. As between the Parties, ARS shall be responsible for reporting of, and shall report, regulatory matters regarding the manufacture, distribution, promotion and safety of the Product (including adverse events and product quality complaints) to or with the FDA and/or other relevant Regulatory Authorities in the Territory, as applicable. For clarity, the foregoing shall not limit ALK’s obligations under Applicable Laws to report its relevant Promotion activities under this Agreement, including ALK’s reporting obligations under Applicable Laws with respect to transparency reporting, as described in Section 5.4. If a Sales Representative receives any inquiry regarding any such matter described in this Section 3.7, ALK shall refer the Person making the inquiry to ARS, in a manner directed by ARS from time to time.

3.8 **Government Price Reporting and Processing.** ARS shall be responsible for all government price calculations, reporting and rebate processing in the Territory relating to the Product. However, ALK shall, to the extent it has in its possession relevant information, cooperate with and assist ARS in complying with its Product-related government price reporting obligations in the Territory, including by providing to ARS or its designee, promptly upon ARS's request in order to satisfy reporting deadlines, all data and other information required for government price reporting that is collected or maintained by or otherwise in the possession or reasonable control of ALK and by promptly responding to ARS's questions and requests for information or assistance.

3.9 [***]

3.10 **Change of Control.** In the event that either Party has been subject to a Change of Control, the affected Party shall provide written notice thereof to the other no later than [***] thereof.

ARTICLE IV

PROMOTIONAL MATERIALS

4.1 **Preparation of Materials.** ARS will (a) develop and produce all Materials to be used by the Sales Representatives pursuant to this Agreement, and (b) provide the Materials to ALK in quantities set forth in the Commercialization Plan. For clarity, neither ALK nor any of its Affiliates or any Sales Representative shall produce any Materials without the express written consent of ARS. All Materials to be used by the Sales Representatives pursuant to this Agreement shall at all times be in compliance with all Applicable Laws and the Labeling. All Materials shall include the Product Trademarks and the ARS House Marks, [***]. As between the Parties, ARS shall own all Copyrights and other right, title and interest in and to all Materials, and ALK hereby assigns to ARS any and all interest that ALK may have in the Materials; *provided*, that [***]. ARS shall be responsible and have the sole and exclusive right for submitting all Materials to the FDA in accordance with applicable FDA requirements.

4.2 Submission; Use of Materials. ALK and the Sales Representatives shall: (a) use the Materials solely for the purposes of conducting the Promotion activities for the Product to the [***] in the Territory, in the manner for which they are approved by ARS, as contemplated by this Agreement and for no other purposes; (b) ensure that the Materials are not modified, changed, misbranded or altered in any way by ALK or any Sales Representative; (c) in conducting Promotion activities hereunder, make only those statements and claims regarding the Product, including as to efficacy and safety, that are consistent with the Materials, the Labeling and Applicable Laws; (d) in Promoting the Product, use only the Materials that are produced in accordance with Section 4.1 and approved by ARS; and (e) promptly notify ARS, and provide ARS with a copy, of any correspondence or other report or complaint received by ALK or any Sales Representative from any Regulatory Authority, including the FDA, or any Third Party claiming that any oral or written statements about the Product or any Materials are inconsistent with the applicable Labeling or are otherwise in violation of Applicable Laws or Codes or that any Sales Representative is making statements or claims regarding the Product that are inconsistent with the Materials or the Labeling. If any Materials provided to ALK by ARS are withdrawn from use for any reason, ARS shall promptly notify ALK of such withdrawal in writing and ALK shall promptly effectuate such withdrawal.

ARTICLE V

PERSONNEL MATTERS; COMPLIANCE; TRAINING; PHARMACOVIGILANCE

5.1 Sales Representatives.

(a) **Qualifications.** ALK shall conduct its Promotion activities (including Details) using Sales Representatives who meet the following requirements and any other requirements of this Agreement: each Sales Representative must: (i) except and to the extent permitted under Section 3.4, be an employee of ALK and a member of its sales force; (ii) possess skills, training and experience that are consistent with industry standards applicable to the promotion of a pharmaceutical product; (iii) have completed the product specific training and other required sales training approved or conducted by ARS; and (iv) have become adequately equipped and knowledgeable with respect to the Product, as determined by satisfaction of criteria approved by ARS in its reasonable discretion. ALK will manage its Sales Representatives performing Promotion activities hereunder in accordance with Applicable Laws and Codes, and shall ensure that no Sales Representative is, has been or shall be Debarred/Excluded. In advance of engaging any Sales Representative to perform Promotion activities or other Commercialization services under this Agreement, and at least [***] thereafter, ALK shall check the debarment/exclusion status of each such Sales Representative and confirm that such Sales Representative is not Debarred/Excluded and, upon ARS's request, provide ARS the results of such status checks. In the event that any Sales Representative becomes Debarred/Excluded, ALK shall remove such Person as a Sales Representative immediately upon learning of such Debarment/Exclusion.

(b) **Compensation and Benefits.** ALK shall be solely responsible for recruiting and hiring all Sales Representatives at ALK's sole cost and expense. ALK shall be solely responsible for: (i) all salaries, wages, benefits and other compensation that the Sales Representatives may be entitled to receive in connection with the performance of the services under this Agreement, including Incentive Compensation, and all taxes, excises, assessments and other charges levied by any agency on, or because of, the services to be provided by ALK under this Agreement; (ii) maintaining all necessary personnel and payroll records for all Sales Representatives; (iii) ensuring that its compensation of the Sales Representatives complies with all Applicable Laws; and (iv) providing workers' compensation and unemployment insurance coverage for the Sales Representatives in amounts as required by Applicable Laws. ALK shall indemnify, defend and hold harmless ARS from and against all Losses to the extent incurred by or imposed upon ARS in connection with or arising from any Claims (including by any Sales Representatives) relating to any of ALK's responsibilities enumerated in the preceding sentence (including any Claims relating to ALK's payment of or failure to pay Incentive Compensation). Each Party acknowledges and agrees that the Sales Representatives are not, and are not intended to be or be treated as, employees of ARS or any of its Affiliates, and that such individuals are not, and are not intended to be, eligible to participate in any benefits programs or in any "employee benefit plan," as such term is defined in Section 3(3) of ERISA, that are sponsored by ARS or any of its Affiliates or that are offered from time to time by ARS or its Affiliates to its or their own employees. [***]

(c) [***]

(d) **General Conduct.** ALK shall be solely responsible and fully liable for: (i) the compliance of all Sales Representatives and ALK Personnel with all Applicable Laws, the Codes, and [***]; (ii) the acts and omissions of the Sales Representatives and ALK Personnel while performing any activities under this Agreement; and (iii) all disciplinary, probationary and termination actions taken by it, as well as for the formulation, content, and dissemination (including content) of all employment policies and rules (including written disciplinary, probationary and termination policies) applicable to any Sales Representatives or ALK Personnel. ALK shall ensure that its Sales Representatives and ALK Personnel are familiar with, trained on pursuant to Section 5.5 and understand [***] and all other procedures, obligations, rights, and responsibilities imposed by the terms of this Agreement as applicable to the performance of Promotion activities and other Commercialization hereunder.

(e) **Removal of Personnel from Product Responsibilities.** ALK shall immediately remove and as soon as reasonably practicable replace any Sales Representative or ALK Personnel from having any responsibilities relating to the Promotion or Commercialization of the Product under this Agreement if required by any Applicable Laws, including if ALK determines that such Sales Representative or ALK Personnel is Debarred/Excluded. Further, upon ARS's reasonable request, ALK shall promptly remove any Sales Representative or ALK Personnel from having any responsibilities relating to the Promotion or Commercialization of the Product under this Agreement if such Sales Representative or ALK Personnel fails to comply with any Applicable Laws, the Codes, ALK's compliance policies, procedures, standards and practices ([***]), and shall replace such Sales Representative or ALK Personnel as soon as reasonably practicable.

5.2 Compliance with Laws, Codes and Policies.

(a) **General.** ALK shall: (i) perform all of its obligations under this Agreement (including Promotion and all activities under the Commercialization Plan) in compliance with all Applicable Laws and Codes and the terms of this Agreement; (ii) instruct the Sales Representatives not to, and shall use reasonable efforts consistent with industry practices to ensure that the Sales Representatives do not, make any representation, statement, warranty or guaranty, oral or written, with respect to the Product that is inconsistent with the then-current Labeling of the Product, the applicable approved Materials, the Commercialization Plan or Applicable Laws; or that is deceptive or misleading in any way; or take any action that disparages or may jeopardize the good name, goodwill or reputation of the Product or of ARS or any of its Affiliates; (iii) maintain and enforce a corporate compliance program consistent with the OIG Compliance Guidance ([***]), including maintaining a mechanism for its personnel to report, at any time and anonymously if they choose, any concerns about potential non-compliance with Applicable Laws, Codes, [***] or ALK policies, procedures, standards and practices, and that requires ALK to promptly and diligently investigate and take appropriate corrective and disciplinary action with regard to any such reports, as applicable; (iv) ensure that all ALK Personnel are trained on pursuant to Section 5.5, understand, and comply with all [***]; and (v) [***]. [***].

(b) **Compliance Program.** ALK shall at all times cause its Sales Representatives and ALK Personnel to comply with [***], ALK's compliance program, policies and procedures, to the extent related to ALK's activities hereunder, which shall be substantially similar to ([***]). Promptly after the Effective Date, [***].

(c) **Verification.** Each year during the Term upon the written request of ARS, ALK shall verify to ARS in writing that it has enforced, and continues to enforce, a code of conduct and compliance program for Sales Representatives and ALK Personnel that is consistent with Applicable Laws and Codes. Without limiting such verification obligations, if there is any material change to ALK's compliance program (including applicable policies and procedures) that relate to or may affect ALK's performance of its Promotion or other activities under this Agreement, ALK shall promptly notify ARS of such material changes.

(d) [***]

(i) [***]

(ii) [***]

(e) [***]. [***]

5.3 Payments to Healthcare Professionals/Healthcare Organizations. ALK shall not directly or indirectly provide any payment, remuneration or other transfer of value to any HCP, HCO, or Payor in connection with Promotion or Commercialization activities, except as provided in accordance with all Applicable Laws, Codes, ALK's policies, procedures, standards and practices, and the Commercialization Plan and subject to ALK's tracking and reporting obligations under Section 5.4.

5.4 Transparency Reporting. Each Party shall be responsible for tracking and reporting all of its direct and indirect payments and transfers of value provided or directed by such Party to HCPs and HCOs in connection with this Agreement in accordance with the Federal Sunshine Law and similar transparency laws required by any state and local government in the Territory that requires such reporting. Without limitation of Article 7, upon ARS's reasonable request, ALK shall timely cooperate [***] with ARS and provide ARS with all relevant information, at ALK's expense and in such form as required by ARS or its designated service provider, relating to reporting of such payments or transfers of value [***].

5.5 Training.

(a) **Product Training.** The Commercialization Plan shall include a Product Training schedule, including timing, location and number of training sessions (including refresher programs), as well as the topics for such Product Training sessions. ARS shall be responsible for planning and conducting all Product Training, consistent with the Commercialization Plan. ALK shall ensure that each Sales Representative and ALK Personnel completes all required Product Training prior to commencing any Promotion or other Commercialization activities under this Agreement and continues to participate in Product Training at least [***] thereafter. ARS shall develop and provide all Training Materials for the Product Training hereunder, and, as between the Parties, shall own all Copyrights and other right, title and interest in and to all such Training Materials.

(b) **General Training.** ALK shall be responsible, at its own expense, for providing, and shall provide, to all Sales Representatives and ALK Personnel a broad general training program (including refresher programs), including training on proper promotion and marketing techniques, ethics, compliance with Applicable Laws and substantial compliance with the Codes, and the compliance with ALK's policies, procedures, standards and practices ("**General Compliance Training**"). ARS shall have the right, at its own expense, to provide to all ALK Personnel a specific training program (including refresher programs) related to the ARS Compliance Policies ("**ARS Compliance Training**"). ALK shall provide copies of such General Compliance Training material to ARS upon request. Notwithstanding the foregoing, at ARS's election, ARS shall have the right to conduct or supplement General Compliance Training and ARS Compliance Training for Sales Representatives and ALK Personnel. [***]

(c) **Testing and Certification.** In connection with each Product Training and ARS Compliance Training, and at other times on reasonable prior notice, ARS may provide testing that verifies, whether through ARS's learning management system or otherwise, that each Sales Representative and ALK Personnel has satisfactorily completed and understood the Product Training and ARS Compliance Training, as applicable. Results and documentation of testing through ARS's learning management system will be provided by ARS to ALK as soon as reasonably practicable after such results are available after testing. Each Sales Representative and ALK Personnel also must certify at the end of each Product Training and Product Compliance Training session, as applicable, that he/she has completed, understood and agrees to comply with such Product Training and ARS Compliance Training.

(d) **Recordkeeping.** ALK shall maintain records related to Product Training, General Compliance Training and ARS Compliance Training sufficient to show the Sales Representatives and ALK Personnel in attendance at each Product Training, General Compliance Training and ARS Compliance Training session, as applicable, including sign-in sheets and computer records for Web-based training. ALK shall maintain all such attendance records and Product training records, including testing records, certifications, and copies of Training Materials used at each Product Training session, in accordance with Section 7.4. ALK shall provide copies of such Product training records to ARS upon request.

5.6 **Requests for Medical Information.** ARS shall have the exclusive right and obligation to respond, in accordance with Applicable Laws and the Codes (as applicable), to all questions or requests for information about the Product that are outside of the Label made by any Healthcare Professional, Healthcare Organization or any other Third Party to the Sales Representatives (each, a "**Product Medical Information Request**" or "**PMIR**") in accordance with the ARS Compliance Policies. The Sales Representatives shall promptly refer such PMIRs to ARS's call center for response in accordance with the ARS Compliance Policies. For clarity, PMIRs shall not be proactively solicited by Sales Representatives. For any PMIR received by ALK's call center, ALK shall promptly transfer such PMIR to ARS's call center.

5.7 **Adverse Events, Product Quality Complaints and Pharmacovigilance.** ALK shall follow the requirements set forth in the ARS Compliance Policies with respect to adverse events and product quality complaints, including ARS's Policy for Reporting Postmarketing Adverse Events & Product Quality Complaints.

ARTICLE VI

PAYMENTS

6.1 Base Fee.

(a) **Base Fee.** Subject to this Section 6.1, ARS shall compensate ALK for its costs of employing and maintaining ALK Personnel to conduct Promotion and Commercialization activities and support thereof hereunder, as well as its Detailing costs, (i) for each Quarter during the Term in Collaboration Year 1, in the amount of [***] per Quarter during the Term in such Collaboration Year; (ii) for each Quarter during the Term in Collaboration Year 2, in the amount of [***] per Quarter during the Term in such Collaboration Year; (iii) for each Quarter during the Term in Collaboration Year 3, in the amount of [***] per Quarter during the Term in such Collaboration Year; and (iv) for each Quarter during the Term in Collaboration Year 4, in the amount of [***] per Quarter during the Term in such Collaboration Year (in each case, such Quarterly payment, the “**Base Fee**”); *provided that* [***].

(b) **Base Fee Payment.** Commencing in Collaboration Year 2, on a Quarterly basis during the Term, within [***] after the end of each Quarter, ALK shall promptly issue to ARS an invoice for the amount of the applicable Base Fee for such Quarter; *provided that* for each Quarter in Collaboration Year 2, such invoice shall also include the applicable Base Fee for the corresponding Quarter in Collaboration Year 1. Within [***] after receipt of the invoice from ALK for a given Quarter with respect to the applicable Base Fee, to the extent that ARS does not dispute in good faith the amount set forth on such invoice, ARS shall pay such applicable Base Fee due to ALK for such Quarter. ARS shall make each such payment to an account designated by ALK pursuant to Section 6.4. For clarity, no Base Fee shall be payable during Collaboration Year 1 and the earned but unpaid Base Fee for Collaboration Year 1 shall be paid in accordance with this Section 6.1 or Section 11.5.

6.2 Performance Bonus.

(a) **Performance Bonus Report.** Commencing in Collaboration Year 2, on a Quarterly basis during the Term, ALK is eligible for a Performance Bonus for any Quarter in which the Market Share for such Quarter equaled or exceeded the applicable Market Share Threshold for such Quarter. Commencing in Collaboration Year 2, on a Quarterly basis during the Term, ARS shall, within [***] after the end of each Quarter, provide ALK with a report showing [***].

(b) **Performance Bonus Invoice and Payment.** Commencing in Collaboration Year 2, on a Quarterly basis during the Term, in the event that the Market Share for such Quarter equaled or exceeded the applicable Market Share Threshold for such Quarter, then, after receipt of each report provided by ARS under Section 6.2(a) above, ALK shall promptly issue to ARS an invoice for the amount of the Performance Bonus set forth in such report. Within [***] after receipt of the invoice from ALK with respect to the Performance Bonus for a given Quarter, to the extent that ARS does not dispute in good faith the amount set forth in such invoice, ARS shall pay to ALK the Performance Bonus for such Quarter to an account designated by ALK pursuant to Section 6.4. For clarity, no Performance Bonus shall be earned or payable during or with respect to Collaboration Year 1.

6.3 ALK Commercialization Support Costs. Within [***] after the end of each Quarter during the Term (and after termination of this Agreement with respect to costs incurred prior to termination of this Agreement), ALK shall provide a written report (each, a “**Cost Report**”) to ARS setting forth in reasonable detail any ALK Commercialization Support Costs incurred by ALK during such Quarter in accordance with the Commercialization Plan and the budget set forth therein. Each Cost Report shall enable ARS to compare the reported out-of-pocket costs against the budget for ALK Commercialization Support Costs set forth in the Commercialization Plan, on both a quarterly basis and a cumulative basis for each activity. With each Cost Report, ALK shall also provide to ARS copies of Third Party invoices and other supporting documentation for all out-of-pocket costs detailed in such Cost Report.

6.4 Payments. All cash payments made under this Agreement shall be made by wire transfer from a banking institution in Dollars in accordance with instructions given in writing from time to time by the Party receiving such payment.

6.5 Taxes.

(a) **Taxes on Income.** Each Party shall be solely responsible for the payment of all taxes imposed on any payments it receives under this Agreement.

(b) **Tax Cooperation.** The Parties agree to cooperate with one another and use reasonable efforts to avoid or reduce tax withholding or similar obligations in respect of payments made under this Agreement. To the extent a Party is required by Applicable Laws to deduct or withhold taxes from any payment to the other Party, such Party will remit such amounts to the proper governmental authority, promptly transmit to the other Party the best available evidence of such payment and remit the remaining amount of such payment to the other Party. For clarity, to the extent amounts are so withheld and remitted in accordance with this Section 6.5(b), such amounts will be treated for all purposes of this Agreement as having been paid to the other Party. Each Party shall provide the other Party any tax forms that may be reasonably necessary in order for such Party to not withhold tax or to withhold tax at a reduced rate under an applicable bilateral income tax treaty, or other Applicable Laws, including an Internal Revenue Service (“**IRS**”) Form W-9, or an appropriate IRS Form W-8, as applicable. Each Party shall provide the other with reasonable assistance to enable the recovery, as permitted by Applicable Laws, of withholding taxes or similar obligations resulting from payments made under this Agreement, such recovery to be for the benefit of the Party bearing such tax. On request of the paying Party, the payee Party shall refund to the paying Party any amounts received from the paying Party or its Affiliates under this Agreement which should have been deducted or withheld under Applicable Laws, but which were not deducted or withheld in full or at all, plus any interest and penalties imposed on such amounts (“**Later Imposed Withholdings**”); and following receipt of such Later Imposed Withholdings, the paying Party shall remit such Later Imposed Withholdings to the appropriate government authority.

ARTICLE VII

REPORTS; MAINTENANCE OF RECORDS; AUDIT RIGHTS

7.1 **Account Management and Reporting System.** ALK shall apply its existing electronic account management and reporting system to document and report its Details and other Promotion activities hereunder, including all of the information that is required to be reported in the Promotion Reports, and to document and report its compliance activities and comply with the transparency reporting requirements under Section 5.4. [***].

7.2 Reports. ALK shall keep ARS regularly informed regarding the conduct of its Promotion activities under this Agreement. Without limiting the foregoing, ALK shall provide ARS with a report (each, a “**Promotion Report**”) within [***] after the end of each Quarter which shall set forth the efforts of the Sales Representatives in conducting Details and other Promotion activities under this Agreement during the preceding Quarter (and in the case of the Promotion Report for the fourth (4th) Quarter in a given Collaboration Year, during the preceding Collaboration Year also), in a form mutually agreed by the Parties, including the following information: (a) the number of Sales Representatives; (b) the number of Details made and recorded by Sales Representatives broken out by region, position of Details and [***]; (c) a written verification by ALK that [***]; (d) all documents and information relevant to the transparency reporting requirements described in Section 5.4; and (e) such other information as may be required in the Commercialization Plan; *provided* that, for the first [***] following the Promotion Commencement Date, ALK shall provide ARS, within [***] following the end of each calendar [***], with a report including (i) the number of Sales Representatives, (ii) the number of Details made and recorded by Sales Representatives broken out by region, position of Details and [***], and (iii) [***]. Each Promotion Report shall be provided in an electronic format or as agreed by the Parties and shall include all applicable information from ALK’s account management system.

7.3 ARS’s Audit Rights Relating to ALK’s Activities.

(a) **Right to Audit.** During the Term, and upon no less than [***] prior written notice from ARS, ALK shall afford to ARS reasonable access during normal business hours (and at such other times as the Parties may mutually agree) to inspect and audit the relevant books, records and other information of ALK in order to monitor ALK’s compliance with its obligations under the Commercialization Plan and the terms of this Agreement and to verify that ALK’s Promotion and other Commercialization activities were accurately reported and conducted in compliance with this Agreement, [***]. Such audit shall occur no more than [***], except that ARS may conduct more frequent inspections and audits for “cause” at any time that ARS learns of any material non-compliance (or of any condition that ARS determines is reasonably likely to result in material non-compliance) with the Commercialization Plan or the terms of this Agreement. Subject to the limitations set forth in this Section 7.3(a), ARS may conduct such audit (i) itself, or by an independent certified public accountant or other applicable consultant appointed by ARS at its expense and reasonably acceptable to ALK, by auditing the relevant financial and compliance records of ALK and its Affiliates at ALK’s [***] facilities as related to the Product; (ii) by conducting surveys of the [***]; and/or (iii) by direct observation of any such Promotion activity. ALK shall keep and maintain complete and accurate records of all Promotion and other Commercialization activities conducted by ALK pursuant to this Agreement in accordance with Section 7.4.

(b) **Audit Results.** All records made available for audit pursuant to this Section 7.3 shall be deemed to be Confidential Information of [***]. In the event that an audit establishes that there was an error in Promotion activities reported by ALK hereunder, ALK shall promptly (but in any event no later than [***] after ALK’s receipt of the audit report so concluding) provide a corrected Promotion Report to ARS. ARS shall bear the full cost of such audit unless such audit discloses a downward adjustment of the number of [***] of more than [***] of the number reported in such statement, in which case ALK shall reimburse ARS for the reasonable out-of-pocket costs incurred by ARS in connection with such audit.

7.4 Maintenance of Books and Records. Each Party shall maintain complete and accurate books and records in sufficient detail, in accordance with all Applicable Laws, to enable verification of such Party's performance of its obligations under this Agreement, including with respect to ALK, all Detailing, Promotion and Product Training, and with respect to ARS, all Prescriber Data, Material and ARS Compliance Policies. Such books and records shall be deemed to be the Confidential Information of the respective Party that is maintaining such books and records and shall be maintained for the latest to occur of: (a) a period of [***] after the end of each calendar year in the Term, (b) longer if required by Applicable Laws or the respective Party's document management program, and (c) until the final resolution of any audit or dispute as to which such records relate.

7.5 Payment Audits.

(a) **Right to Audit.** ARS shall have the right, no more than [***] in the Term, to audit the relevant books and records of ALK in order to verify ALK's reports of ALK Commercialization Support Costs. ALK shall have the right, no more than [***] in the Term, to audit the relevant books and records of ARS in order to verify ARS's reports of Specified Net Sales and Market Share. Upon no less than [***] prior written notice, the Party subject to audit (the "**Audited Party**") shall grant reasonable access to members of a nationally-recognized independent certified public accounting firm selected by the Party conducting the audit (the "**Auditing Party**") (but not, in the case of ALK as the Audited Party, the auditor that conducts or has within the past [***] conducted the audit of ALK's financial statements, or, in the case of ARS as the Audited Party, the auditor that conducts or has within the past [***] conducted the audit of ARS's financial statements) to the relevant books and records of the Audited Party in order to conduct a review or audit thereof. Such access shall be permitted only during normal business hours. The auditor will execute a written confidentiality agreement with the Audited Party and will disclose to the Auditing Party only such information necessary or relevant to verify the Audited Party's reports of (a) in the case of ALK as the Audited Party, ALK Commercialization Support Costs, and (b) in the case of ARS as the Audited Party, Specified Net Sales and Market Share. The accountant shall report its conclusions and calculations to the Parties; *provided* that in no event shall the accountant disclose any information of the Audited Party except to the extent necessary to report inaccuracies in reports of (i) in the case of ALK as the Audited Party, ALK Commercialization Support Costs, and (ii) in the case of ARS as the Audited Party, Specified Net Sales and Market Share. Such examination shall be conducted at the facility(ies) where such books and records are maintained and without disruption to operations of the Audited Party. Except as set forth in Section 7.5(b), the Auditing Party shall bear the full cost of the performance of any such audit. All inspections made under this Section 7.5 shall be made no later than [***] after the reports that are the subject of the investigation were made.

(b) **Audit Results.** If as a result of any audit of books and records under Section 7.5(a), it is shown that the Audited Party's payments to the Auditing Party under this Agreement with respect to the period of time audited were less than the amount which should have been paid, then the Audited Party shall pay to the Auditing Party the amount of such shortfall within [***] after both Parties' receipt of the auditor's report. If instead the audit shows that Audited Party's payments to the Auditing Party under this Agreement with respect to the period of time audited were more than the amount which should have been paid to the Auditing Party pursuant to this Agreement, then the Auditing Party shall refund such overpayment to the Audited Party within [***] after both Parties' receipt of the auditor's report. In addition, if any amount of underpayment by the Audited Party is more than [***] of the amount which should have been paid pursuant to this Agreement with respect to the period in question, then the Audited Party shall also reimburse the Auditing Party for its documented, reasonable, out-of-pocket costs and expenses incurred in connection with the audit.

ARTICLE VIII

CONFIDENTIAL INFORMATION

8.1 **General.** At all times during the Term and for [***] thereafter, each Party (the "**Receiving Party**") shall, and shall cause its officers, directors, employees and agents to, keep confidential and not publish or otherwise disclose, and not use, directly or indirectly, for any purpose, any Confidential Information of the other Party (the "**Disclosing Party**"), except to the extent such disclosure or use is permitted by the terms of this Agreement or is otherwise agreed upon in writing by the Parties. "**Confidential Information**" means any non-public technical, scientific, regulatory, commercial, business or other confidential, proprietary, or trade secret information provided by or on behalf of the Disclosing Party to the Receiving Party pursuant to this Agreement, and the terms of this Agreement, which are the Confidential Information of each Party; *provided* that Confidential Information shall not include any information that the Receiving Party can demonstrate by competent written proof:

(i) is in the public domain by use and/or publication at the time of its receipt from the Disclosing Party or thereafter enters into the public domain through no fault of the Receiving Party; or

(ii) was already in the Receiving Party's possession prior to receipt from the Disclosing Party or is developed independently of information received from the Disclosing Party, in each case as demonstrated by contemporaneous written documentation; or

(iii) is obtained by the Receiving Party from a source (other than a Party or its Representatives (as defined below)) which is not bound by a confidentiality agreement or other contractual restriction that may prohibit the disclosure of such information.

8.2 **Permitted Disclosures.** Each Receiving Party may only disclose Confidential Information of the Disclosing Party to the extent that such disclosure is:

(a) made by the Receiving Party or its Affiliates to its or their employees, agents, attorneys, auditors, advisors, consultants or contractors (“**Representatives**”) on a need-to-know basis and solely in connection with the performance of the Receiving Party’s obligations or the exercise of its rights under this Agreement, *provided* that each Representative must be bound by obligations of confidentiality and non-use equivalent in scope to, and no less restrictive than, those set forth in this Article 8 prior to any such disclosure; or

(b) made in response to a valid order of a court of competent jurisdiction, Regulatory Authority or other governmental authority of competent jurisdiction or, if in the reasonable opinion of the Receiving Party’s legal counsel, such disclosure is otherwise required by law, including by reason of filing with securities regulators; *provided* that, to the extent legally permissible, the Receiving Party shall first have given written notice to the Disclosing Party and given the Disclosing Party a reasonable opportunity to quash such order or to obtain a protective order or confidential treatment requiring that such Confidential Information be held in confidence by such court or governmental authority or, if disclosed, be used only for the purposes for which the order was issued; and *provided* further, that the Confidential Information disclosed in response to such court or governmental authority order shall be limited to that information which is legally required to be disclosed in response to such order.

8.3 **Public Announcements; Agreement Terms.** Without limiting the restrictions set forth in Section 8.1, a Party may not use the name of the other Party in any publicity or advertising or make any public announcement or issue any press release concerning the existence or terms of this Agreement or activities hereunder without the prior written consent of the other Party, including approval of any press release or other public announcement. Notwithstanding the foregoing, (i) a Party may disclose information relating to this Agreement (including any termination hereof) as required by Applicable Laws, including to the United States Securities and Exchange Commission or any other securities exchange or governmental authority as required by law or regulation, *provided* that the disclosing Party shall (1) if practicable, provide the other Party with reasonable advance notice of and an opportunity to comment on any such required disclosure, and (2) if reasonably requested by such other Party, seek, or cooperate with such Party’s efforts to obtain, confidential treatment or a protective order with respect to any such disclosure to the extent available at such other Party’s expense, and (ii) each Party may use the name of the other Party in connection with its Promotion of the Product in accordance with the Commercialization Plan. This Agreement shall be deemed Confidential Information of both ARS and ALK and may only be disclosed by a Party: (A) as may be permitted under Section 8.2 or clause (i) of the preceding sentence in this Section 8.3, (B) to potential or actual investors or acquirers of such Party who are bound by obligations of confidentiality and non-use equivalent in scope to, and no less restrictive than, those set forth in this Article 8 prior to any such disclosure or (C) with the prior written consent of the other Party, which shall not be withheld unreasonably.

8.4 **Injunctive Relief.** Each Party acknowledges that damages resulting from disclosure of the Confidential Information in violation of this Article 8 may not be an adequate remedy and that, in the event of any such disclosure or any indication of an intent to disclose such information, a Party (or its Affiliates) owning such information will be entitled to seek injunctive relief or other equitable relief in addition to any and all remedies available at law or in equity, including the recovery of damages and reasonable attorneys' fees.

ARTICLE IX

INTELLECTUAL PROPERTY RIGHTS

9.1 **Ownership of Materials.** As between the Parties, ARS shall own all right, title and interest in and to the Materials, Training Materials and Labeling, in each case including all content contained therein and all applicable Copyrights and trademark rights (but excluding any trademark or other rights in ALK House Marks). To the extent ALK (or any of its Affiliates or other agents) obtains or otherwise has a claim to the Materials, Training Materials and Labeling, ALK shall assign, and hereby does assign, to ARS (or its designated Affiliate) all of ALK's (and its Affiliate's and other agent's) right, title and interest in and to such Materials, Training Materials, Labeling and all content therein (excluding, in each case, any rights in ALK House Marks). [***].

9.2 Use of Trademarks.

(a) **Use of Trademark.** All Materials shall include the Product Trademarks and the ARS House Marks. [***].

(b) **No Dispute.** Neither Party shall, and shall not knowingly cause another person to, contest or dispute or otherwise impair or endanger the validity of, the exclusive rights of, any of the trademarks (including the Trademarks and ALK House Marks) owned, licensed or maintained, as the case may be, by the other Party or its Affiliates, or any part thereof, or the registrations thereof. Neither Party shall undertake any action in respect of the filing, registration or renewal of any of the other Party's trademarks (including the Trademarks and ALK House Marks) without such other Party's consent.

9.3 **Infringement.** Each Party shall promptly inform the other Party of any material infringement of, or challenge to, any Trademark or any other intellectual property relating to the Product owned or controlled by ARS in the Territory, in each case whether actual or threatened, which comes to the attention of such Party. As between the Parties, ARS shall have the exclusive right (in its sole discretion) to take (or not take, as applicable) action in respect of the defense or infringement of the Trademarks and/or any other material intellectual property relating to the Product, and ALK shall, at ARS's expense, provide reasonable assistance and cooperation with such activities as ARS may reasonably request.

ARTICLE X

REPRESENTATIONS AND WARRANTIES; INDEMNIFICATION

10.1 **Mutual Representations and Warranties.** ALK and ARS each represents and warrants to the other, as of the Effective Date, as follows:

(a) it is duly organized, validly existing and in good standing under the laws of the jurisdiction of its organization, and has all requisite power and authority, corporate or otherwise, to execute, deliver and perform this Agreement;

(b) the execution and delivery of this Agreement and the performance by it of the transactions contemplated hereby have been duly authorized by all necessary corporate action and will not violate: (i) such Party's certificate of incorporation, bylaws or other organizational documents; (ii) any agreement, instrument or contractual obligation to which such Party is bound in any material respect; (iii) any requirement of any Applicable Law; or (iv) any order, writ, judgment, injunction, decree, determination or award of any court or governmental agency presently in effect applicable to such Party; and

(c) this Agreement is a legal, valid and binding obligation of such Party enforceable against it in accordance with its terms and conditions (subject to bankruptcy, insolvency, moratorium, judicial principles affecting the availability of specific performance and other similar Applicable Laws affecting the enforcement of creditors' rights generally).

10.2 **Representations, Warranties and Covenants of ALK.** In addition, ALK represents and warrants to ARS, as of the Effective Date, and covenants to ARS as follows:

(a) neither it, nor any of its Affiliates, nor any of their respective officers, employees, agents, representatives or other Persons used in the performance of its obligations under this Agreement has been debarred or suspended under 21 U.S.C. §335(a) or (b), excluded from a federal health care program, debarred from federal contracting, or convicted of or pled nolo contendere to any felony, or to any federal or state legal violation (including misdemeanors) relating to prescription drug products or fraud ("**Debarred/Excluded**"). ALK shall notify ARS within [***] if it, any of its Affiliates, or any officer, employee, agent, representative or other Person who is performing any activities under this Agreement is or becomes Debarred/Excluded;

(b) (i) it and its Affiliates have promoted its products in the Territory in compliance with Applicable Laws and Codes in all material respects, (ii) as of the Effective Date, neither it nor any of its Affiliates is being investigated by any Regulatory Authority or other government authority in the Territory relating to the promotion of any product in the Territory, nor has it or any of its Affiliates received notice that any Regulatory Authority or other government authority in the Territory intends to conduct any such investigation, and (iii) neither it nor any of its Affiliates (x) is a party or the subject of any action, suit or other proceeding (collectively, “**Proceeding**”) that is pending as of the Effective Date or was pending or filed at any time during the [***] period prior to the Effective Date, that alleges that it or any of its Affiliates have violated any Applicable Laws in the Territory in connection with the promotion of any product in the Territory, nor (y) has it or any of its Affiliates received any threats in writing of any such Proceeding as of the Effective Date or at any time during the [***] period prior to the Effective Date;

(c) neither it nor any of its Affiliates has [***], nor will it or any of its Affiliates, pay, offer or promise to pay, or authorize the payment directly or indirectly of any moneys or anything of value to (i) any government official or employee, or any political party or candidate for political office for the purpose of influencing any act or decision of such official or of the government to obtain or retain business or direct business to any person, in each case with respect to the Product; or (ii) any HCP, HCO or Payor if any one purpose is to encourage, influence or reward the prescribing or purchasing of any Product or recommending the prescribing or purchasing of any Product, except in either case, as permitted by Applicable Laws (such as payments under applicable safe-harbor provisions).

(d) it is, and shall remain, and it shall cause its Affiliates to remain, in material compliance with all Applicable Laws and Codes;

(e) there is no action, suit, proceeding or investigation pending or, to its knowledge, threatened before any court or administrative agency against ALK or its Affiliates which could, directly or indirectly, reasonably be expected to materially affect its ability to perform its obligations hereunder;

(f) it has implemented, and shall maintain, a compliance program designed to comport with all Applicable Laws and the Codes; and

(g) it has and will maintain appropriate technical, organizational, and physical security technologies, processes, procedures and controls aligned with the standard in the industry in which ALK operates that are designed to protect its information technology systems, operational technology systems, networks, internet-enabled applications and/or devices and the data contained within such systems, including Confidential Information, from any unauthorized loss, destruction, alteration, disclosure thereof, access thereto, or loss of control thereof and has in place appropriate plans and procedures to allow it to respond efficiently and effectively to any data loss or unauthorized destruction, alteration, disclosure, or access thereto. If ALK becomes aware of any such incident which it reasonably determines has materially affected or is reasonable likely to materially affect the Confidential Information of ARS, it shall notify ARS within [***].

10.3 Representations and Warranties of ARS. In addition, ARS represents and warrants to ALK that, as of the Effective Date:

(a) neither it nor any of its Affiliates is being investigated by any Regulatory Authority or other government authority in the Territory specifically or primarily relating to the Promotion of the Product in the Territory, nor has it or any of its Affiliates received written notice that any Regulatory Authority or other government authority in the Territory intends to conduct any such investigation; and

(b) ARS has all rights necessary to grant the rights set forth in this Agreement to ALK.

10.4 Defense and Indemnification of ARS by ALK. ALK shall indemnify, defend and hold harmless ARS, its Affiliates, their respective directors, officers, employees and agents, and their respective successors, heirs and assigns (collectively, the “**ARS Indemnitees**”), against all liabilities, damages, losses and expenses (including reasonable attorneys’ fees and expenses of litigation or investigation) (collectively, “**Losses**”) to the extent incurred by or imposed upon the ARS Indemnitees, or any of them, related to claims, suits, actions, demands, investigations, proceedings or judgments brought or obtained by Third Parties (including any Regulatory Authority or governmental authority) (collectively, “**Claims**”), arising out of: (a) a breach of any covenant, representation or warranty of ALK under this Agreement; (b) a negligent, reckless, willful or intentionally wrongful act, error or omission on the part of ALK (or any of its Affiliates), or any officer, director, employee, agent or representative of ALK (or any of its Affiliates), including any Sales Representative, in the performance of this Agreement, including in the performance of Promotion activities hereunder; or (c) the Commercialization, Promotion or Detailing or any other activities with respect to the Product in the Territory by ALK (or any of its Affiliates), or any officer, director, employee, agent or representative of ALK (or any of its Affiliates), including any Sales Representative, in violation of any Applicable Laws, Codes or this Agreement or otherwise not in compliance with the Labeling and Materials; except with respect to any Claims or Losses under the foregoing clauses (a), (b) or (c) to the extent resulting from a Claim for which ARS is required to indemnify ALK under Section 10.5.

10.5 Defense and Indemnification of ALK by ARS. ARS shall indemnify, defend and hold harmless ALK, its Affiliates, their respective directors, officers, employees and agents, and their respective successors, heirs and assigns (collectively, the “**ALK Indemnitees**”), against all Losses to the extent incurred by or imposed upon the ALK Indemnitees, or any of them, related to Claims arising out of: (a) a breach of any covenant, representation or warranty of ARS under this Agreement; (b) a negligent, reckless, willful or intentionally wrongful act, error or omission on the part of ARS (or any of its Affiliates), or any officer, director, employee, agent or representative of ARS (or any of its Affiliates), in the performance of this Agreement; (c) the Commercialization, Promotion, Detailing or medical affairs activities with respect to the Product in the Territory by ARS (or any of its Affiliates), or any officer, director, employee, agent or representative of ARS (or any of its Affiliates), in violation of any Applicable Laws, Codes or this Agreement or otherwise not in compliance with the Labeling; or (d) any product liability claims arising from the Product; except with respect to any Claims or Losses under the foregoing clauses (a) through (d) to the extent resulting from a Claim for which ALK is required to indemnify ARS under Section 10.4.

10.6 Conditions to Defense and Indemnification. A Party seeking recovery under this Article 10 (the “**Indemnified Party**”) with respect to a Claim shall give prompt written notice to the Party from which indemnification is sought (the “**Indemnifying Party**”), and shall permit the Indemnifying Party to control any litigation relating to such Claim and the disposition of such Claim; *provided* that the Indemnifying Party shall: (a) act reasonably and in good faith with respect to all matters relating to the settlement or disposition of such Claim as the settlement or disposition relates to such Indemnified Party; and (b) not settle or otherwise resolve such Claim without the prior written consent of such Indemnified Party [***], *provided* that the Indemnifying Party may settle any Claim or otherwise consent to an adverse judgment with prior written notice to the Indemnified Party but without the consent of the Indemnified Party where the only liability to the Indemnified Party is the payment of money and the Indemnifying Party makes such payment. The failure to deliver written notice to the Indemnifying Party within a reasonable time after the commencement of any action with respect to a Claim shall only relieve the Indemnifying Party of its indemnification obligations under this Article 10 if and to the extent the Indemnifying Party is actually prejudiced thereby. Each Indemnified Party shall cooperate with the Indemnifying Party in its defense of any such Claim in all reasonable respects and shall have the right to be present in person or through counsel at all legal proceedings with respect to such Claim. For clarity, if either Party or any of its Affiliates is entitled to indemnification for a Claim pursuant to Section 10.4 or Section 10.5, as the case may be, such Party shall seek recovery for such Claim under this Agreement and not the Existing Collaboration Agreement.

10.7 Insurance. ALK shall, at its own expense, maintain and keep in full force and effect during the Term and for [***] thereafter insurance policies that are reasonable and customary for the industry that are underwritten by a reputable insurance company or self-insurance and providing adequate coverage for its respective obligations and activities hereunder. A certificate of insurance evidencing the coverage described in this Section 10.7 and naming ARS as an additional insured shall be submitted to ARS by ALK within [***] after the Effective Date and shall bear a certification that the coverage specified therein will not be cancelled or materially changed without at least [***] prior written notice to ARS. Such notices of cancellation or material change shall be given in accordance with Section 12.4 hereof.

10.8 Warranty Disclaimer. EXCEPT AS OTHERWISE EXPRESSLY PROVIDED IN THIS AGREEMENT, NEITHER PARTY MAKES ANY WARRANTY WITH RESPECT TO ANY GOODS, SERVICES, RIGHTS OR OTHER SUBJECT MATTER OF THIS AGREEMENT AND EACH PARTY HEREBY DISCLAIMS ALL WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, AND ANY WARRANTY OF NON-INFRINGEMENT OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS.

10.9 **Limitation of Liability.** NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY OR ANY OF ITS AFFILIATES FOR (A) ANY SPECIAL, PUNITIVE, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES, INCLUDING LOST PROFITS, LOST REVENUES OR PENALTIES, WHETHER OR NOT ADVISED OF THE POSSIBILITY OF SUCH DAMAGES AND WHETHER OR NOT SUCH DAMAGES MAY HAVE BEEN REASONABLY FORESEEABLE, OR (B) COST OF PROCUREMENT OF SUBSTITUTE GOODS, TECHNOLOGY OR SERVICES, WHETHER UNDER ANY CONTRACT, WARRANTY, NEGLIGENCE, STRICT LIABILITY OR OTHER LEGAL OR EQUITABLE THEORY. NOTWITHSTANDING THE FOREGOING, THE LIMITATIONS SET FORTH IN THIS PARAGRAPH SHALL NOT APPLY TO: (I) ANY DEFENSE OR INDEMNITY OBLIGATION OWED BY ONE PARTY TO ANOTHER PARTY FOR THIRD PARTY CLAIMS PURSUANT TO SECTION 10.4 OR 10.5, (II) DAMAGES AVAILABLE FOR BREACH OF ARTICLE 8, OR (III) LOSS ARISING DUE TO FRAUD OR WILLFULL MISCONDUCT.

ARTICLE XI

TERM AND TERMINATION

11.1 **Term.** This Agreement shall commence as of the Effective Date and shall expire on the last day of Collaboration Year 4, unless extended by mutual written agreement of the Parties or unless earlier terminated pursuant to the terms of this Agreement (the “**Term**”). For clarity, the Parties may negotiate to extend the Term during any day of the collaboration provided that neither Party shall be obligated to enter into any such extension.

11.2 **Early Termination.** The Parties shall have the right to terminate this Agreement under the following conditions:

(a) Either Party shall have the right to terminate this Agreement at any time upon written notice to the other Party if the other Party materially breaches this Agreement and such other Party fails to cure such breach within [***] after written notice is given to such other Party specifying the breach.

(b) ARS may terminate this Agreement, effective immediately upon written notice to ALK, in the event of any material breach by ALK of Section 5.2(a).

(c) From and after the date that is twelve (12) months after the Promotion Commencement Date, ARS may terminate this Agreement immediately, upon written notice to ALK, upon [***].

(d) ARS may terminate this Agreement, effective upon [***] prior written notice to ALK, in the event that [***].

(e) (i) ARS may terminate this Agreement, effective upon [***] prior written notice to ALK, in the event that either ALK or ARS has been subject to a Change of Control and (ii) ALK may terminate this Agreement, effective upon [***] prior written notice to ARS, in the event that ALK or ARS has been subject to a Change of Control.

(f) ARS may terminate this Agreement, effective upon [***] prior written notice to ALK, if ALK or any of its Affiliates, directly or indirectly through a Third Party (including via a license to a Third Party): (i) markets, promotes, sells, or otherwise commercializes in the Territory any pharmaceutical product that [***] (“**Distracting Product**”), (ii) manufactures in the Territory any Distracting Product, or (iii) obtains rights from a Third Party to conduct any of the activities described in the foregoing clauses (i) and (ii) with respect to any Distracting Product for which [***].

(g) ARS may terminate this Agreement upon written notice to ALK in the event of the bankruptcy or insolvency, or the filing of an action to commence insolvency proceedings against ALK, or the making or seeking to make or arrange an assignment for the benefit of creditors of ALK, or the initiation of proceedings in voluntary or involuntary bankruptcy, or the appointment of a receiver or trustee of ALK’s property that is not discharged within [***].

(h) From and after the date that is [***], ARS may terminate this Agreement, effective upon [***] prior written notice to ALK, in the event that [***].

(i) From and after the date that is twelve (12) months after the Effective Date, ARS may terminate this Agreement, effective upon [***] prior written notice to ALK, for any reason or no reason.

(j) From and after the date that is twelve (12) months after the Effective Date, ALK may terminate this Agreement, effective upon [***] prior written notice to ARS, for any reason or no reason.

(k) Either Party may terminate this agreement pursuant to Section 12.10.

11.3 Consequences of Termination of Agreement. Upon the expiration or early termination of this Agreement for any reason, the following provisions shall apply.

(a) ALK shall conduct an orderly wind down of ALK’s Promotion activities as agreed by ARS, and ALK shall provide to ARS such Product-related information as is maintained by ALK and is reasonably required to transition ALK’s Promotion responsibilities to ARS. For clarity, commencing reasonably in advance of expiration of the Term or, if applicable, upon notice of early termination of this Agreement pursuant to Section 11.2, ARS shall have the right to engage one or more Third Parties to facilitate the smooth transition of ALK’s obligations hereunder to ARS or its designee.

(b) Except as otherwise agreed by ARS with respect to any wind-down activities, all rights of ALK to perform Promotion activities hereunder shall terminate immediately and be of no further force and effect, and ALK shall promptly cease all Promotion (including Detailing) activities, shall promptly discontinue the use of any Trademarks and Copyrights in the Territory and shall promptly return to ARS, or dispose of in accordance with instructions from ARS, all Materials and Training Materials in its possession or the possession of its Affiliates or any Sales Representative. ALK will provide ARS with a certified statement that all remaining Materials and Training Materials have been returned or otherwise properly disposed of, and that neither ALK nor any Sales Representative are in possession or control of any such Materials or Training Materials, and will not be using any such Materials or Training Materials as of the effective date of termination (unless otherwise agreed by ARS with respect to any wind-down activities).

(c) Each Party shall, at the other Party's request, promptly return to such Party or, at such Party's option, destroy all Confidential Information of the providing Party and provide that Party with a certified statement that all Confidential Information of the providing Party has been returned or destroyed; *provided* that the receiving Party may retain one (1) copy of the Confidential Information of the providing Party in its archives solely for the purpose of establishing the contents thereof and ensuring compliance with its obligations hereunder.

(d) The OC shall cease operation and be disbanded.

11.4 Surviving Provisions. The following provisions will remain in full force and effect after the expiration or termination of this Agreement: Sections 3.5, 3.9, 5.2(d)(i), 5.4, 5.7, 6.1 (with respect to any payments that remain due thereunder), 6.2 (with respect to any payments that remain due thereunder), 6.4, 6.5, 11.4 and 11.5, and Articles 1 (to the extent necessary to give force to, or otherwise understand, surviving provisions including Section 11.5), 7, 8, 9, 10, and 12.

11.5 Accrued Rights; Payments on Termination.

(a) Termination or expiration of this Agreement for any reason will be without prejudice to any rights which will have accrued to the benefit of either Party or any liability incurred by either Party prior to the effective date of termination or expiration, and will not preclude either Party from pursuing all rights and remedies it may have hereunder or at law or in equity with respect to any breach of this Agreement or prejudice either Party's right to obtain performance of any obligation. Except upon termination of this Agreement by ARS pursuant to [***], within [***] following termination of this Agreement, ARS shall pay to ALK all unpaid Base Fees and Performance Bonus payments that have accrued prior to the effective date of termination; *provided* that any such Base Fee or Performance Bonus shall be pro-rated for any partial Quarters within the Term. For clarity, upon termination of this Agreement during Collaboration Year 2, all accrued payments relating to Collaboration Year 1 pursuant to Section 6.1(b) that remain unpaid as of such termination shall accelerate and be payable to ALK within [***] after the effective date of termination pursuant to the immediately preceding sentence. Further, upon termination of this Agreement by ARS pursuant to Section 11.2(i), so long as [***], ALK shall be entitled to receive, for the duration of the Extension Period (as defined below), the Accrual Performance Payment (as defined below) for any Quarter during the Extension Period in which [***].

(b) For purposes of this Section 11.5, (i) [***], (ii) "Accrual Performance Payment" means, [***] and (iii) "Extension Period" means [***].

(c) Upon termination of this Agreement by ARS pursuant to Section 11.2(e) in the event of a Change of Control of ARS, ARS shall pay to ALK a one-time payment in the amount of: (i) if notice of such termination occurs [***], (ii) if notice of such termination occurs [***], [***], (iii) if notice of such termination occurs [***], [***], (iv) if notice of such termination occurs [***], (v) if notice of such termination occurs [***], [***], and (vi) if notice of such termination occurs [***], [***].

(d) With respect to any Quarter for which an Accrual Performance Payment is due pursuant to this Section 11.5, on a Quarterly basis during the Extension Period, ARS shall, within [***] after the end of each Quarter, provide ALK with a report showing [***].

(e) With respect to any Quarter for which an Accrual Performance Payment is due pursuant to this Section 11.5, on a Quarterly basis during the Extension Period, [***] then, after receipt of each report provided by ARS under Section 11.5(d) above, ALK shall promptly issue to ARS an invoice for the amount of the Accrual Performance Payment set forth in such report. Within [***] after receipt of the invoice from ALK with respect to the Accrual Performance Payment for a given Quarter, to the extent that ARS does not dispute in good faith the amount set forth on such invoice, ARS shall pay to ALK the Accrual Performance Payment for such Quarter to an account designated by ALK pursuant to Section 6.4.

ARTICLE XII

MISCELLANEOUS

12.1 **Governing Law.** This Agreement shall be governed by and construed in accordance with the laws of the State of New York, without regard to the application of principles of conflicts of law.

12.2 **Dispute Resolution.**

(a) **Objective.** The Parties recognize that disputes as to matters arising under or in connection with or relating to this Agreement or either Party's rights and obligations hereunder may arise from time to time. It is the objective of the Parties to establish procedures to facilitate the resolution of such disputes in an expedient manner by mutual cooperation and without resort to litigation. To accomplish this objective, the Parties agree to follow the procedures set forth in this Section 12.2 to resolve any such dispute if and when it arises.

(b) **Resolution by Executives.** If an unresolved dispute as to matters arising under or in connection with or relating to this Agreement or either Party's rights and obligations hereunder arises, either Party may refer such dispute to the Executives, who shall meet in person or by telephone within [***] after such referral to attempt in good faith to resolve such dispute. If such matter cannot be resolved by discussion of such officers within such [***] period, or such other time period as the Parties may agree to in writing, such dispute shall be resolved in accordance with Section 12.2(c).

(c) **Arbitration.** If the Parties do not resolve a dispute as provided in Section 12.2(b), and a Party wishes to pursue the matter, each such dispute that is not an "Excluded Claim" (as defined below) shall be resolved by binding arbitration in accordance with the Rules of Arbitration of the International Chamber of Commerce ("ICC") as then in effect (the "ICC Rules"), which ICC Rules are deemed to be incorporated by reference into this clause, and judgment on the arbitration award may be entered in any court having jurisdiction thereof. The decision rendered in any such arbitration will be final and not appealable. If either Party intends to commence binding arbitration of such dispute, such Party will provide written notice to the other Party informing the other Party of such intention and the issues to be resolved. Within [***] after the receipt of such notice, the other Party may, by written notice to the Party initiating binding arbitration, add additional issues to be resolved.

(i) The arbitration shall be conducted by a panel of [***] arbitrators appointed in accordance with the ICC Rules, none of whom shall be a current or former employee or director, or a then-current stockholder, of either Party or their respective Affiliates. The seat, or legal place, of arbitration shall be New York, New York, and all proceedings and communications shall be in English.

(ii) It is the intention of the Parties that discovery, although permitted as described herein, will be limited except in exceptional circumstances. The arbitrators will permit such limited discovery necessary for an understanding of any legitimate issue raised in the arbitration, including the production of documents. No later than [***] after selection of the arbitrators, the Parties and their representatives shall hold a preliminary meeting with the arbitrators, to mutually agree upon and thereafter follow procedures seeking to assure that the arbitration will be concluded within [***] from such meeting. Failing any such mutual agreement, the arbitrators will design and the Parties shall follow procedures to such effect.

(iii) Either Party may apply to the arbitrators for interim injunctive relief until the arbitration award is rendered or the controversy is otherwise resolved. Either Party also may, without waiving any remedy under this Agreement, seek from any court having jurisdiction any injunctive or provisional relief necessary to protect the rights or property of that Party pending the arbitration award. The arbitrators shall have no authority to award punitive or any other non-compensatory damages, except as may be permitted by Section 10.9. The arbitrators shall have the power to order that all or part of the legal or other costs incurred by a Party in connection with the arbitration be paid by the other Party. Each Party shall bear an equal share of the arbitrators' and any administrative fees of arbitration.

(iv) Except to the extent necessary to confirm or enforce an award or as may be required by Applicable Law, neither a Party nor an arbitrator may disclose the existence, content, or results of an arbitration without the prior written consent of both Parties. In no event shall an arbitration be initiated after the date when commencement of a legal or equitable proceeding based on the dispute, controversy or claim would be barred by the applicable New York statute of limitations.

(v) As used in this Section 12.2(c), the term "**Excluded Claim**" means [***].

12.3 Relationship of the Parties. The status of the Parties under this Agreement shall be that of an independent contractor. Neither Party shall have the right to enter into any agreements on behalf of the other Party, nor shall it represent to any person that it has any such right or authority. Nothing in this Agreement shall be construed: (a) to create or imply a general partnership between the Parties; (b) to make either Party or any of their Affiliates or its or their respective personnel the agent of the other for any purpose; (c) to alter, amend, supersede or vitiate any other arrangements between the Parties with respect to any subject matters not covered hereunder; (d) to give either Party the right to bind or act on behalf of the other; (e) to create any duties or obligations between the Parties except as expressly set forth herein; (f) to grant any direct or implied licenses or any other right other than as expressly set forth herein; or (g) that the performance of ALK or any of its Affiliates hereunder is by or on behalf of ARS or any of its Affiliates.

12.4 **Notices.** All notices and communications shall be in writing and delivered personally or by nationally-recognized overnight express courier providing evidence of delivery or mailed via certified mail, return receipt requested, addressed as follows, or to such other address as may be designated from time to time:

If to ARS: ARS Pharmaceuticals Operations, Inc.
11682 El Camino Real, Suite 120
San Diego, CA 92130
Attention: Chief Executive Officer
Email: [***]
Cc: [***]

With a copy (which shall not constitute notice) to:

Cooley LLP
10265 Science Center Dr.
San Diego, CA 92121
Attention: Charity Williams; Ken Rollins
Email: crwilliams@cooley.com; krollins@cooley.com

If to ALK: ALK-Abelló, Inc.
135 Route 202/206 Suite #16
Bedminster, New Jersey 07921
Attention: President

With a copy (which shall not constitute notice) to:

ALK-Abelló A/S
Bøge Allé 6-8
2970 Hørsholm, Denmark
Attention: Vice President, Corporate Affairs & Legal

Except as otherwise expressly provided in this Agreement or mutually agreed in writing, any notice, communication or document (excluding payment) required to be given or made shall be deemed given or made and effective upon receipt.

12.5 **Headings.** Section and subsection headings are inserted for convenience of reference only and do not form a part of this Agreement.

12.6 **Counterparts.** This Agreement may be executed simultaneously in counterparts, each of which shall be deemed an original and both of which, together, shall constitute a single agreement. Signatures to this Agreement delivered by electronic transmission will be deemed binding as originals.

12.7 **Amendment; Waiver.** This Agreement may be amended, modified, superseded or canceled, and any of the terms of this Agreement may be waived, only by a written instrument executed by each Party or, in the case of waiver, by the Party waiving compliance. The delay or failure of either Party at any time or times to require performance of any provisions shall in no manner affect the rights at a later time to enforce the same. No waiver by either Party of any condition or of the breach of any term contained in this Agreement, whether by conduct, or otherwise, in any one or more instances, shall be deemed to be, or considered as, a further or continuing waiver of any such condition or of the breach of such term or any other term of this Agreement.

12.8 **No Third Party Beneficiaries.** No Third Party (including employees of either Party) shall have or acquire any rights by reason of this Agreement.

12.9 **Assignment and Successors.** This Agreement shall not be assignable by either Party to any Third Party without the written consent of the other Party; except each Party may assign this Agreement without the other Party's consent to a Third Party that acquires substantially all of the business or assets of such first Party to which this Agreement relates, whether by merger, acquisition or otherwise, *provided* that the Third Party to whom this Agreement is assigned assumes this Agreement in writing or by operation of law. In addition, ARS shall have the right to assign this Agreement to an Affiliate upon written notice to ALK; *provided* that ARS shall remain directly liable under this Agreement for the performance of this Agreement by such Affiliate.

12.10 **Force Majeure.** Neither Party shall be liable for any failure or delay in performing its obligations under this Agreement when such failure or delay is beyond the reasonable control of the Party seeking relief from its obligations, including without limitation any of the following causes (but only if such cause is beyond the reasonable control of the Party seeking relief): any act of God, flood, fire, explosion, pandemic, epidemic, earthquake, breakdown of plant, shortage of critical equipment, loss or unavailability of manufacturing facilities or material, strike, lockout, labor dispute, casualty or accident, or war, revolution, civil commotion, terrorism and acts of public enemies, blockage or embargo, or any injunction, law, order, proclamation, regulation, ordinance, demand or requirement of any government or of any subdivision, authority or representative of any such government, inability to procure or use materials, labor, equipment, transportation or energy sufficient to meet manufacturing needs without allocation, or any other cause whatsoever, whether similar or dissimilar to those above enumerated, beyond the reasonable control of the Party seeking relief ("**Force Majeure Event**"). In the event that either Party is delayed in the performance of any obligations under this Agreement for reason of any Force Majeure Event, the time for the performance of said obligations shall be extended for the period required by reason of such delay, up to a maximum period of [***], after which, if such delay in performance would constitute a material breach of this Agreement in the absence of such Force Majeure Event, the non-affected Party may terminate this Agreement immediately upon written notice to the other Party. The Party affected by the Force Majeure Event shall inform the other Party of the beginning of and, if possible, the anticipated ending date of the above causes and the circumstances thereof in writing within [***] after the occurrence of such Force Majeure Event.

12.11 **Interpretation.** Unless a context otherwise requires, wherever used: (a) the singular shall include the plural, the plural the singular; (b) the word “or” means “and/or” (regardless of whether the words “and/or” are used on some places and not in others) unless the context dictates otherwise because the subjects of the conjunction are mutually exclusive; (c) the word “**notice**” shall require notice in writing (whether or not specifically stated) and shall include notices, consents, approvals and other communications contemplated under this Agreement; (d) the word “**will**” shall be construed to have the same meaning and effect as the word “**shall**;” (e) the word “**including**” (and words of similar import) is used without limitation and shall mean “**including without limitation**;” (f) the word “**day**” or “**year**” or “**quarter**” shall mean a calendar day or calendar year or calendar quarter, respectively, unless otherwise specified, and (g) provisions that require that a Party or the Parties hereunder “**agree**,” “**consent**” or “**approve**” or the like shall require that such agreement, consent or approval be specific and in writing, whether by written agreement, letter or otherwise.

12.12 **Integration; Severability.** This Agreement, together with the Exhibits attached hereto, sets forth the entire agreement with respect to the subject matter hereof and supersedes all other agreements and understandings between the Parties with respect to such subject matter. For clarity, the Existing Collaboration Agreement shall continue in full force and effect in accordance with its terms; *provided* that no activity of ALK or any of its Affiliates with respect to the Product pursuant to and in accordance with the terms and conditions of this Agreement shall give rise to the ability of ARS (or for clarity any acquirer of ARS following a Change of Control of ARS) to terminate the Existing Collaboration Agreement pursuant to Section 13.5(b) (i) of the Existing Collaboration Agreement or, for clarity, be deemed a breach of or prohibited by the Existing Collaboration Agreement. If any one or more of the provisions of this Agreement are held to be invalid or unenforceable by any court of competent jurisdiction from which no appeal can be or is taken, such provisions will be considered severed from this Agreement and will not serve to invalidate any remaining provisions hereof. The Parties will make a good faith effort to replace any invalid or unenforceable provision with a valid and enforceable one such that the objectives contemplated by the Parties when entering this Agreement, as evidenced by the terms of this Agreement, may be realized.

[Remainder of page intentionally left blank; signature page follows]

IN WITNESS WHEREOF, the Parties have caused this Co-Promotion Agreement to be executed by their duly authorized representatives.

ARS PHARMACEUTICALS OPERATIONS, INC.

By: /s/ Richard Lowenthal
Name: Richard Lowenthal
Title: President and Chief Executive Officer

ALK-ABELLÓ, INC.

By: /s/ Hans Lindeberg
Name: Hans Lindeberg
Title: President

By: /s/ Claus Steensen Sølje
Name: Claus Steensen Sølje
Title: Board Director

Exhibits

Exhibit A ARS Compliance Policies
Exhibit B Epinephrine Products
Exhibit C [***]
Exhibit D [***]

[Signature Page to Co-Promotion Agreement]

Exhibit A
ARS Compliance Policies

[***]

Exhibit B
Epinephrine Products

[**]

Exhibit C

[**]

Exhibit D

[***]

THIRD AMENDMENT TO MANUFACTURING AGREEMENT

This Third Amendment to Manufacturing Agreement (this “**Amendment**”), effective as of July 10, 2025 (the “**Third Amendment Effective Date**”), is made by and between ARS Pharmaceuticals Operations, Inc. formerly known as ARS Pharmaceuticals, Inc., a corporation organized under the laws of the State of California with an office at 11682 El Camino Real, Suite 120 San Diego CA 92130 (“**COMPANY**”) and Renaissance Lakewood, LLC, a limited liability company organized under the laws of the State of Delaware with an office at 1200 Paco Way, Lakewood, New Jersey 08701 (“**RENAISSANCE**”).

RECITALS

A. Reference is made to that certain Manufacturing Agreement, dated as of September 9, 2020, by and between COMPANY and RENAISSANCE, as amended July 25, 2023 and September 17, 2024 (the “**Agreement**”). Capitalized terms used but not otherwise defined herein shall have the respective meanings given in the Agreement.

B. COMPANY and RENAISSANCE desire to enter into this Amendment for purposes of modifying the Agreement as set forth herein.

Now, therefore, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties agree as follows:

1. Amendment of the Agreement.

(a) **Schedule B** of the Agreement is hereby deleted in its entirety and replaced with Schedule B attached hereto.

2. Miscellaneous.

(a) Except as expressly amended herein, the Agreement shall remain in full force and effect.

(b) This validity, interpretation and effect of this Amendment shall be governed by and construed under the laws of the State of Delaware without reference to principles of conflicts of laws.

(c) This Amendment may be executed in counterparts, including electronic counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same original.

(The remainder of this page is intentionally left blank. The signature page follows.)

Each of the parties has caused this Amendment to be duly executed on its behalf as of the Third Amendment Effective Date.

ARS PHARMACEUTICALS OPERATIONS, INC.

By: /s/ Richard Lowenthal

Name: Richard Lowenthal

Title: Chief Executive Officer

RENAISSANCE LAKEWOOD, LLC

By: /s/ Serge Maltais

Name: Serge Maltais

Title: President and Chief Executive Officer

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Richard Lowenthal, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the quarter ended June 30, 2025 of ARS Pharmaceuticals, Inc. ("the registrant");
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 13, 2025

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

**CERTIFICATION OF CHIEF FINANCIAL OFFICER PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Kathleen Scott, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the quarter ended June 30, 2025 of ARS Pharmaceuticals, Inc. ("the registrant");
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 13, 2025

By: /s/ Kathleen D. Scott

Kathleen D. Scott
Chief Financial Officer
(Principal Financial and Accounting Officer)

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report on Form 10-Q of ARS Pharmaceuticals, Inc. (the "Company") for the quarter ended June 30, 2025, to which this Certification is attached, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned officers of the Company hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to their knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 13, 2025

By: /s/ Richard Lowenthal, M.S., MSEL

Richard Lowenthal, M.S., MSEL
President and Chief Executive Officer
(Principal Executive Officer)

Date: August 13, 2025

By: /s/ Kathleen D. Scott

Kathleen D. Scott
Chief Financial Officer
(Principal Financial and Accounting Officer)

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. § 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing. A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.
