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 September 30, 2026

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	**81-1489190**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
11682 El Camino Real, Suite 300 San Diego, California	**92130**
(Address of principal executive offices)	**(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	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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 November 3, 2026, there were 100,528,400 shares of registrant's common stock, $0.0001 par value per share, outstanding.

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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:

- the rate and degree of market acceptance of *neffy* and any future product candidates;
- the likelihood of *neffy* attaining and maintaining favorable coverage;
- our expectation that additional states will place *neffy* on their preferred drug lists;
- 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 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 and geographic markets, the projected growth thereof, and our collaboration and marketing partners' ability to capture and grow those markets;
- our expected competitive position;
- our potential to become the standard in treatment and transform the treatment of allergic reactions;
- the expected intellectual property protection for *neffy;*
- our ability to obtain, maintain and successfully enforce adequate patent and other intellectual property protection for *neffy*, or any future product candidate;
- legislative and regulatory developments in the United States and foreign countries;
- estimates regarding anticipated operating losses, capital requirements and needs for additional funds;
- our expectations regarding the timing of, and our ability to achieve, cash flow breakeven;
- our ability to satisfy our obligations, comply with the covenants, and access, if needed, additional credit under our credit agreement; 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” refer to our voting common stock.

neffy and *EURneffy* are trademarks 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 does 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*. To the extent *neffy* and *EURneffy* are 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 our 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 Credit Agreement contains conditions and restrictions that limit our flexibility in drawing on the additional funds thereunder and in operating our business. We may be required to repay our outstanding indebtedness under the Credit Agreement earlier than we expect and possibly at a time when we do not have sufficient capital to meet such obligations if an event of default occurs (including a material adverse change affecting our business), which could have a material adverse effect on our financial condition and results of operations.
- 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)

	September 30, 2026 (unaudited)	December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	$ 25,621	$ 41,317
Short-term investments	112,733	203,669
Accounts receivable, net	52,757	25,347
Inventories	11,711	8,369
Prepaid expenses and other current assets	8,206	6,194
Total current assets	211,028	284,896
Inventories, noncurrent	21,720	23,053
Property, plant and equipment, net	1,927	2,465
Intangible assets, net	13,624	14,452
Other assets	3,185	2,786
Total assets	$ 251,484	$ 327,652
Liabilities and stockholders' (deficit) equity		
Current liabilities:		
Accounts payable and accrued liabilities (including related party amounts of $2,436 and $1,624, respectively)	$ 63,793	$ 37,948
Contract liability, current	511	609
Other current liabilities	599	588
Total current liabilities	64,903	39,145
Term loans, net (including related party amounts of $4,842 and $4,819, respectively)	121,807	96,374
Financing liability	75,208	72,140
Contract liability, net of current portion	1,047	1,130
Other accrued liabilities	474	4,605
Total liabilities	263,439	213,394
Commitments and contingencies (Note 9)		
Stockholders' (deficit) equity		
Preferred stock, $0.0001 par value per share; 10,000,000 shares authorized at September 30, 2026 and December 31, 2025; no shares issued and outstanding at September 30, 2026 and December 31, 2025	—	—
Common stock, $0.0001 par value per share; 200,000,000 shares authorized at September 30, 2026 and December 31, 2025; 100,248,400 and 99,290,926 shares issued and outstanding at September 30, 2026 and December 31, 2025, respectively	10	10
Additional paid-in capital	441,286	408,726
Accumulated other comprehensive (loss) gain, net	(104)	125
Accumulated deficit	(453,147)	(294,603)
Total stockholders' (deficit) equity	(11,955)	114,258
Total liabilities and stockholders' (deficit) equity	$ 251,484	$ 327,652

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 September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Revenue:				
Product revenue, net	$ 33,414	$ 31,300	$ 77,076	$ 51,863
Revenue under collaboration agreements	1,661	55	4,207	2,859
Revenue under supply agreements	2,635	1,146	12,766	1,469
Total revenue	37,710	32,501	94,049	56,191
Operating expenses:				
Cost of goods sold (including related party amounts of $1,711, $2,046, $4,795, and $3,400, respectively)	10,098	8,191	29,230	14,269
Research and development (including related party amounts of $551, $559, $1,830, and $1,804, respectively)	18,263	2,751	27,297	9,738
Selling, general and administrative (including related party amounts of $101, $123, $362, and $354, respectively)	43,520	74,751	193,303	170,167
Total operating expenses	71,881	85,693	249,830	194,174
Loss from operations	(34,171)	(53,192)	(155,781)	(137,983)
Other income (expense), net:				
Interest income	1,136	2,097	4,709	8,065
Interest expense (including related party amounts of $127, $3, $373, and $3, respectively)	(2,552)	(56)	(7,472)	(56)
Total other (expense) income, net	(1,416)	2,041	(2,763)	8,009
Net loss	$ (35,587)	$ (51,151)	(158,544)	(129,974)
Unrealized gains (losses) on available-for-sale securities	36	39	(229)	(227)
Comprehensive loss	$ (35,551)	$ (51,112)	$ (158,773)	$ (130,201)
Net loss per share, basic and diluted	$ (0.36)	$ (0.52)	$ (1.59)	$ (1.32)
Weighted-average shares outstanding used in computing net loss per share, basic and diluted	99,685,424	98,807,600	99,432,878	98,412,739

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

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

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Gain (Loss), Net	Accumulated Deficit	Total Stockholders' (Deficit) Equity
	Shares	Amount				
Balance at December 31, 2025	99,290,926	$ 10	$ 408,726	$ 125	$ (294,603)	$ 114,258
Exercise of common stock options and release of restricted stock units	9,211	—	62	—	—	62
Stock-based compensation	—	—	7,827	—	—	7,827
Net loss and comprehensive loss	—	—	—	(221)	(60,618)	(60,839)
Balance at March 31, 2026	99,300,137	10	416,615	(96)	(355,221)	61,308
Exercise of common stock options and shares issued under the employee stock purchase plan	137,728	—	786	—	—	786
Stock-based compensation	—	—	12,801	—	—	12,801
Net loss and comprehensive loss	—	—	—	(44)	(62,339)	(62,383)
Balance at June 30, 2026	99,437,865	10	430,202	(140)	(417,560)	12,512
Exercise of common stock options	810,535	—	2,557	—	—	2,557
Stock-based compensation	—	—	8,527	—	—	8,527
Net loss and comprehensive loss	—	—	—	36	(35,587)	(35,551)
Balance at September 30, 2026	100,248,400	$ 10	$ 441,286	$ (104)	$ (453,147)	$ (11,955)

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

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

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Gain (Loss), Net	Accumulated Deficit	Total Stockholders' (Deficit) 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 shares issued 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
Exercise of common stock options	146,520	—	479	—	—	479
Stock-based compensation	—	—	5,967	—	—	5,967
Net loss and comprehensive loss	—	—	—	39	(51,151)	(51,112)
Balance at September 30, 2025	98,844,178	$ 10	$ 400,931	$ (7)	$ (253,279)	$ 147,655

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)

	Nine Months Ended September 30,	
	2026	2025
Cash flows from operating activities:		
Net loss	$ (158,544)	$ (129,974)
Non-cash adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	27,940	16,358
Depreciation and amortization expense	1,228	950
Accretion on investments, net of amortization	(2,070)	(4,520)
Other non-cash items	2,503	2,434
Changes in operating assets and liabilities:		
Accounts receivable	(27,363)	(28,382)
Inventories	(2,564)	(12,269)
Prepaid expenses and other assets	(2,599)	372
Accounts payable and accrued liabilities	22,064	27,945
Contract liability	(181)	(295)
Net cash and cash equivalents used in operating activities	(139,586)	(127,381)
Cash flows from investing activities:		
Purchases of short-term investments, available-for-sale	(67,681)	(193,147)
Proceeds from maturities and sales of short-term investments, available-for-sale	160,458	232,000
Payments of milestone obligations under license agreements	—	(5,860)
Purchases of property and equipment	—	(339)
Net cash and cash equivalents provided by investing activities	92,777	32,654
Cash flows from financing activities:		
Proceeds from term loan, net of issuance costs	24,973	96,989
Proceeds from milestone obligations met and royalties earned under license agreements recognized as an increase to the financing liability	2,735	2,577
Proceeds from exercise of common stock options and issuance of common stock under the employee stock purchase plan	3,405	3,901
Net cash and cash equivalents provided by financing activities	31,113	103,467
Net (decrease) increase in cash and cash equivalents	(15,696)	8,740
Cash and cash equivalents at beginning of period	41,317	50,817
Cash and cash equivalents at end of period	$ 25,621	$ 59,557
Supplemental cash flow information:		
Cash paid for interest	$ 7,011	$ —
Non-cash investing and financing activities:		
Intangible assets included in accounts payable and accrued liabilities	$ —	$ 2,000

The accompanying notes are an integral part of these 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 European Union and United Kingdom by the trade name *EURneffy* and in China by the trade name 优敏速) for needle-free intranasal delivery of epinephrine for emergency treatment of Type I allergic reactions, including anaphylaxis in adults and children who weigh 15 kg or greater. *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 $453.1 million as of September 30, 2026. The Company had cash, cash equivalents, and short-term investments of $138.4 million as of September 30, 2026 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 Therapeutics, Inc. ("Silverback") in November 2022 (the "Merger"), the private placement of convertible preferred stock, the issuance of common stock, licensing, supply and distribution agreements, debt, and net product sales. The Company's currently available cash, cash equivalents, and short-term investments as of September 30, 2026 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 September 30, 2026, 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. 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 accompanying 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 September 30, 2026, the condensed consolidated statements of operations and comprehensive loss for the three and nine months ended September 30, 2026 and 2025, the condensed consolidated statements of stockholders' (deficit) equity for the three and nine months ended September 30, 2026 and 2025, and the condensed consolidated statements of cash flows for the nine months ended September 30, 2026 and 2025, are unaudited. The balance sheet as of December 31, 2025 was derived from the audited financial statements as of and for the year ended December 31, 2025. 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, 2025, 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 September 30, 2026, the condensed consolidated results of its operations for the three and nine months ended September 30, 2026 and 2025, and its cash flows for the nine months ended September 30, 2026 and 2025. The financial data and other information disclosed in these notes related to the three and nine months ended September 30, 2026 and 2025 are also unaudited. The condensed consolidated results of operations for the three and nine months ended September 30, 2026 are not necessarily indicative of the results to be expected for the full year ending December 31, 2026 or any other period.

Use of Estimates

The preparation of the Company's condensed consolidated financial statements requires management 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 and accruals for variable consideration of product revenue. 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.

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, and accounts payable and accrued liabilities are considered to be representative of their respective fair values because of the short-term nature of those instruments.

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, if any. The Company considers all highly liquid investments with remaining maturities when purchased of 90 days or less to be cash equivalents.

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 other (expense) income, net.

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 due under the Company's collaboration agreements and for supply of *neffy* under the Company's supply agreements. Trade accounts receivables 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.

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. The allowance for credit losses was not material at both September 30, 2026 and December 31, 2025.

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 that have operations outside the U.S. 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.

Prior to August 2025, the Company operated under a title model agreement under which the title agent retained all credit and collection risk on product sales to the Company's wholesale distributors and pharmacy customers. As of August 2025, the Company ceased operating under a title model agreement and now retains all credit and collection risk on product sales.

The following table presents customers whose accounts receivable balances represented 10% or more of total accounts receivable as of the dates presented:

	% of Accounts Receivable	
	September 30, 2026	December 31, 2025
Customer A	30%	18%
Customer B	30%	15%
Customer C	25%	21%
Customer D	*	12%
Customer E	*	16%

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* Amounts related to respective customer represented less than 10% for the period presented.

The following table presents customers that accounted for 10% or more of total gross product revenue during the periods presented:

	% of Total Gross Product Revenue			
	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Customer A	27%	25%	25%	22%
Customer B	24%	23%	25%	24%
Customer C	22%	21%	20%	21%
Customer D	*	14%	*	13%

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* Amounts related to respective customer represented less than 10% for the period presented.

For each of the three and nine months ended September 30, 2026, two customers accounted for 100% of revenue under collaboration agreements, with each customer representing 25% and 75% and 30% and 70% of revenue under collaboration agreements, respectively. For the three and nine months ended September 30, 2026, three customers accounted for 93% and 96% of revenue under supply agreements, with each individual customer representing between 12% and 66% and 11% and 47% of revenue under supply agreements, respectively. For each of the three and nine months ended September 30, 2025, one customer accounted for 100% of revenue under collaboration agreements. For the three and nine months ended September 30, 2025, two customers accounted for 100% and 98% of revenue under supply agreements, with each customer representing 19% and 81% and 15% and 83% of revenue under supply agreements, respectively. To date, the Company has not experienced any credit losses from its trade and partner accounts receivable.

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 accompanying 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 that 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.

Intangible Assets

Intangible assets are measured at fair value as of the acquisition date or, in the case of capitalized 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.

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, discounted at 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, determined with reference to 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 accompanying condensed consolidated statements of operations and comprehensive loss.

Impairment of Long-Lived Assets

Long-lived assets consist primarily of property and equipment, the ROU asset, 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 September 30, 2026.

Revenue Recognition

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.

Product revenue, net

The Company's product, *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 sells its product to its wholesale distributor and pharmacy customers in the United States. These customers subsequently resell the products to pharmacies and health care providers or dispense products directly to patients. In accordance with ASC 606, the Company recognizes revenue at a point in time when the customers obtain control of the Company's products, typically upon delivery. The Company also enters into consignment agreements with certain pharmacies, under which revenue is recognized when the product is sold to a patient and control transfers from the Company to the patient.

Product revenue is recorded at the net transaction price, which includes estimates for variable consideration such as distribution service fees, prompt pay discounts, product returns, chargebacks, rebates, co-payment assistance, and other incentives for certain indirect customers. The Company establishes reserves for these estimates based on amounts earned or expected to be claimed on related sales.

The Company uses the expected value method to determine the appropriate amount of variable consideration, considering factors such as contractual and statutory requirements, known market events, industry trends and data, forecasted customer buying and payment patterns, and historical actual data. Estimates 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. Variable consideration is included in net product revenue only to the extent it is probable that a significant revenue reversal will not occur in a future period.

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 of rebates based on the expected number of claims and the related costs associated with the revenue recognized for product that remains in the distribution channel and any rebate amounts for product that has been dispensed to a patient but not invoiced to the Company at the end of each reporting period. Rebate estimates are recorded as other current liabilities on the accompanying 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 amount purchased. These discounts are recorded as contra trade accounts receivable on the accompanying condensed consolidated balance sheets.

Co-payment Programs. 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 recognized for products that remain in the distribution channel and any co-payment assistance amounts not invoiced to the Company at the end of each reporting period. Co-payment program estimates are recorded as other current liabilities on the accompanying 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 limited returns data, the Company uses professional judgment and industry data to estimate returns. As time passes and additional historical sales and returns data becomes available, the Company will update the estimated returns as needed. A reserve for potential product returns is recorded as other current liabilities on the accompanying 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 costs associated with the revenue recognized for product that remains in the distribution channel and any chargeback amounts not invoiced to the Company at the end of each reporting period. Estimated chargebacks are recorded as contra trade accounts receivable on the accompanying condensed consolidated balance sheets.

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 accompanying 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 accompanying condensed consolidated balance sheets.

Revenue under collaboration and supply agreements

The Company licenses certain rights to *neffy* to third parties under collaboration agreements and supplies *neffy* to third parties for commercial sale under supply agreements. At contract inception, the Company evaluates its arrangements to determine whether they involve joint operating activities in which the parties are active participants and share significant risks and rewards in accordance with ASC Topic 808, *Collaborative Agreements* ("ASC 808"). Arrangements that meet these criteria are accounted for as collaborative arrangements under ASC 808. This assessment is updated over the life of the arrangement as roles and responsibilities change.

For collaboration agreements within the scope of ASC 808 that include multiple components, the Company determines which components are accounted for under ASC 808 and which components represent vendor-customer relationships accounted for under ASC 606. For components accounted for under ASC 808, the Company applies a consistent recognition approach based on applicable accounting guidance or a reasonable policy election. Amounts due from or payable to collaboration partners are presented in the income statement based on the nature of the underlying activity. When the Company is the principal in sales to third parties, revenues, cost of goods sold, and operating expenses are recorded on a gross basis. When the Company is not the principal, its share of results is recorded on a net basis as collaboration revenue or expense.

If the Company concludes that some or all components of the agreement are distinct and represent a transaction with a customer, the Company accounts for those elements of the arrangement in accordance with ASC 606 by applying the five-step model described above.

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 on the net sales of licensed products.

Commercial Supply. Arrangements that include a promise for the future supply of drug product for commercial sale 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. Revenue related to commercial supply arrangements, including transfer price revenue, is recorded to revenue under supply agreements on the condensed consolidated statements of operations.

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 in the accompanying condensed consolidated balance sheet. The Company would record such financing obligation as revenue when the right to repurchase has lapsed or was exercised. Revenue related to the licensing of intellectual property is recorded to revenue under collaboration agreements on the condensed consolidated statements of operations.

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. In making the assessment of the constraint, the Company considers several factors, such as the stage of product development, the risks associated with the remaining activities required to achieve the milestones, as well as whether the achievement of the milestone is outside the control of the Company. 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. Revenue related to clinical, regulatory, or commercial milestone payments is recorded to revenue under collaboration agreements on the condensed consolidated statements of operations.

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. Revenue related to transaction price allocation is recorded to revenue under collaboration agreements on the condensed consolidated statements of operations.

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. Revenue related to research and development commitments is recorded to revenue under collaboration agreements on the condensed consolidated statements of operations.

Clinical Supply. Arrangements that include a promise for the future supply of drug product for clinical development 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. Revenue related to clinical supply arrangements is recorded to revenue under collaboration agreements on the condensed consolidated statements of operations.

Royalty Revenues. For arrangements that include sales-based royalties, 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). Revenue related to royalties is recorded to revenue under collaboration agreements on the condensed consolidated statements of operations.

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 in-licensing technology, 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 the first time the advertising takes place. Advertising costs for the three and nine months ended September 30, 2026, were $3.9 million and $71.2 million, respectively. For the three and nine months ended September 30, 2025, advertising costs were $40.9 million and $72.8 million, respectively.

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 under existing agreements are expensed prior to FDA approval and capitalized after FDA approval when technological feasibility has been achieved, based on management's assessment of the ultimate recoverability 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:

	September 30,	
	2026	2025
Warrants to purchase common stock	45,456	45,456
Common stock options outstanding	19,817,214	17,106,592
Estimated shares to be purchased under the employee stock purchase plan	70,531	43,255
Restricted stock units outstanding	—	1,382
Total	19,933,201	17,196,685

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 the Company's financial statements upon adoption.

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. Collaboration, Out-Licensing and Related Agreements

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 sublicensable 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 (the "Alfresa Agreement") for the rights pursuant to the LOI. Under the Alfresa 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 Alfresa 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 December 2025, in connection with the Alfresa Agreement, the Company also entered into a commercial supply agreement (the "Alfresa Supply Agreement") with Alfresa, under which ARS will supply Alfresa's requirements (and Alfresa will purchase from ARS its requirements) for a transfer price in the low-double-digit percentage on net sales of *neffy* in Japan. The Alfresa Supply Agreement is coterminous with the Alfresa Agreement. Either the Company or Alfresa may terminate the Alfresa Supply Agreement in the event of an uncured material breach of the other party. Pursuant to the Alfresa Agreement, at any time, Alfresa may elect to manufacture its own supply of drug product. In the event Alfresa elects to do so, Alfresa is obligated to pay the Company a royalty payment on the net sales of drug product in the Alfresa Territory in an amount equal to monetary value the Company would receive by supplying drug product to Alfresa at the transfer price. The promises under the Alfresa Supply Agreement did not meet the definition of a performance obligation nor did these promises convey a material right to Alfresa.

At inception of the Alfresa Agreement, the Company identified the following performance obligations: (i) the license for *neffy*; and (ii) research and development services, both of which have been satisfied. The initial transaction price was $7.0 million, which included the upfront payment of $2.0 million and a regulatory milestone of $5.0 million that was deemed not probable of significant reversal at the inception of the Alfresa Agreement. Variable consideration related to future milestone payments was fully constrained at inception and excluded from the transaction price until a significant revenue reversal is no longer probable. The transaction price was allocated to performance obligations based on their estimated stand-alone selling prices.

As of September 30, 2026, the Company has earned an aggregate of $15.0 million for the upfront payment and achievement of regulatory and commercial milestones, and there are no remaining regulatory or commercial milestone payments under the Alfresa Agreement. The Company is also entitled to receive a transfer price in the low double-digit percentage on future net sales of *neffy* in Japan.

No revenue under collaboration agreements was recognized under the Alfresa Agreement for the three and nine months ended September 30, 2026 and 2025.

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

In February 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 agreed to pay additional payments upon achievement of certain milestones including: (i) a European Medicines Agency ("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"). As of September 30, 2026, potential royalty payments of up to €4.1 million (approximately $4.7 million in U.S. dollars) remain.

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 consolidated statements of operations for the year ended December 31, 2023. 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 consolidated statements of operations and comprehensive loss during the year ended December 31, 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 intangible assets will be amortized through 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.

Royalty expense from the sale of *neffy* in the Recordati Territory for the three and nine months ended September 30, 2026 was $0.3 million and $0.5 million, respectively, and was recorded in cost of goods sold in the accompanying condensed consolidated statements of operations and comprehensive loss. For the three and nine months ended September 30, 2025, royalty expense was $0.1 million and $0.2 million, respectively.

Pediatrix Agreement

In March 2021, the Company entered into a collaboration and distribution agreement (the "Pediatrix 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 Pediatrix 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 Pediatrix 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.

In January 2026, in connection with the Pediatrix Agreement, the Company also entered into a commercial supply agreement (the "Pediatrix Supply Agreement") with Pediatrix, under which ARS will supply Pediatrix's requirements (and Pediatrix will purchase from ARS its requirements) for a specified price. The Pediatrix Supply Agreement is coterminous with the Pediatrix Agreement. Either the Company or Pediatrix may terminate the Pediatrix Supply Agreement in the event of an uncured material breach of the other party. The promises under the Pediatrix Supply Agreement do not meet the definition of a performance obligation, nor did these promises convey a material right to Pediatrix.

At inception of the Pediatrix Agreement, the Company identified the performance obligations as the delivery of the license for *neffy* in the Pediatrix Territory, which has been satisfied. The initial transaction price was $3.0 million, which includes the upfront payment received at the inception of the Pediatrix Agreement. Variable consideration related to future milestone payments was fully constrained at inception and excluded from the transaction price until a significant revenue reversal is no longer probable. The transaction price was wholly allocated to the performance obligation, and variable consideration is reassessed each reporting period.

As of September 30, 2026, the Company has earned an aggregate of $7.0 million for the upfront payment and achievement of regulatory and commercial milestones and is eligible to receive up to $80.0 million in sales-based milestone payments. There are no regulatory or commercial milestones remaining under the Pediatrix Agreement. Since receiving regulatory approval in the Pediatrix Territory, the Company is also entitled to tiered royalties in the low double-digits on future net sales in the Pediatrix Territory and will receive a per unit supply price for commercial supply sold to Pediatrix under the Pediatrix Supply Agreement.

No revenue under collaboration agreements was recognized under the Pediatrix Agreement for the three and nine months ended September 30, 2026 and 2025.

Seqirus Agreement

In March 2024, the Company entered into a license and distribution agreement (the "Seqirus Agreement") with Seqirus Pty Ltd. ("Seqirus"), which was amended in December 2025, 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.

At inception of the Seqirus Agreement, the Company identified a single performance obligation: the delivery of the license for *neffy* in the Seqirus Territory in combination with the transfer of know-how, which has been satisfied. The license and know-how were considered distinct from potential supply obligations, which are effectively options for Seqirus to purchase commercial supply and do not represent a material right. The initial transaction price was $0.5 million, which includes the upfront payment received at the inception of the Seqirus Agreement. Variable consideration related to future milestone payments was fully constrained at inception and excluded from the transaction price until a significant revenue reversal is no longer probable. The transaction price was wholly allocated to the performance obligation, and variable consideration is reassessed each reporting period.

As of September 30, 2026, the Company has earned an aggregate of $3.9 million for the upfront payment and achievement of regulatory and commercial milestones and is eligible to receive up to $1.0 million in remaining regulatory and commercial milestones. Since receiving approval in the Seqirus Territory, the Company is also entitled to receive a per unit supply price for commercial supply sold to Seqirus.

During the three and nine months ended September 30, 2026, the Company earned a commercial milestone payment of $1.3 million, which was recorded to collaboration revenue. No revenue under collaboration agreements was recognized under the Seqirus Agreement for the three and nine months ended September 30, 2025.

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 the 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, and the Company earned $10.0 million for the achievement of regulatory and commercial milestones. The Company is eligible to receive remaining regulatory milestone payment of $10.0 million and sales-based milestone payments of up to $300.0 million. The Company is entitled to receive tiered royalty payments on net sales in the mid- to high-teens, subject to certain standard reductions and offsets. Royalties will be payable, on a Product-by-Product and country-by-country basis, until the latest of the expiration of the licensed patents covering such Product in such country, 15 years from first commercial sale of such Product in such country, or expiration of regulatory exclusivity for such Product in such country.

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, which was amended in March 2026, 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 regulatory and commercial milestone payments (totaling $20.0 million) were fully constrained at contract inception due to 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 regulatory and commercial milestones, 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.

As of September 30, 2026, the Company has earned an aggregate of $155.0 million in milestone payments for the upfront payment and achievement of regulatory and commercial milestones, of which $74.2 million has been allocated to the EEA License and is accounted for as a financing liability. The Company is eligible to receive remaining regulatory milestone payments of up to $10.0 million and sales-based milestone payments of up to $300.0 million as well as tiered royalties on net sales in the mid- to high-teens, subject to customary reductions and offsets. Royalties are payable on a Product-by-Product and country-by-country basis until the latest of: (i) the expiration of the licensed patents covering such Product in such country; (ii) 15 years from the first commercial sale of such Product in such country; or (iii) expiration of regulatory exclusivity for such Product in such country. The Company is also eligible to receive a per unit supply price for commercial supply sold to ALK under the ALK Supply Agreement.

The Company earned the $5.0 million regulatory milestone during the three months ended March 31, 2026, of which $2.5 million was recognized as revenue under collaboration agreements in the accompanying condensed consolidated statements of operations and comprehensive loss. The remaining $2.5 million was allocated to the development and regulatory performance obligations and EEA license and recognized as increases to the contract liability and financing liability, respectively. Revenue recognized for the performance of development and regulatory services under the ALK Collaboration Agreement for the three and nine months ended September 30, 2026 was $0.1 million and $0.3 million, respectively, and was recorded in revenue under collaboration agreements in the accompanying condensed consolidated statements of operations and comprehensive loss. For the three and nine months ended September 30, 2025, revenue recognized for the performance of development and regulatory services was less than $0.1 million and $0.3 million, respectively.

Contract Liability

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 beginning at the inception of the ALK Collaboration Agreement and are expected to continue through 2028. Development and regulatory service performance obligations were initially recorded as contract liabilities, and revenue earned under these performance obligations is 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.

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

Balance at December 31, 2025	$	1,739
Regulatory milestone allocated to development and regulatory performance obligations		69
Revenue recognized related to development and regulatory performance obligations		(250)
Balance at September 30, 2026	$	1,558

Financing Liability

As discussed above, the Company retains a substantive Repurchase Option for the EEA License, which prevents control from transferring to ALK under ASC 606. As a result, the consideration allocated to the EEA License is accounted for as a financing liability because the repurchase price exceeds the original selling price and will remain outstanding until the Repurchase Option lapses or is exercised. Commercial and sales-based milestones allocated to the EEA License are recognized as increases to the financing liability when earned.

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

Balance at December 31, 2025	$	72,140
Regulatory milestone allocated to the EEA License		2,393
Sales-based royalties earned under the EEA License		675
Balance at September 30, 2026	$	75,208

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, which was subsequently amended in October 2025 and March 2026, and the parties entered into a related side letter in August 2026 (the "ALK Co-Promotion Agreement"), to co-promote *neffy* to over 10,000 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. commenced its promotion activities in May 2025 and is obligated to 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 concluded that it represents a vendor arrangement with ALK U.S. Expense under the ALK Co-Promotion Agreement for the three and nine months ended September 30, 2026 was $1.5 million and $6.8 million, respectively, and was recorded in selling, general and administrative expense in the accompanying condensed consolidated statements of operations and comprehensive loss. For the three and nine months ended September 30, 2025, selling, general and administrative expense under the ALK Co-Promotion Agreement was $2.4 million and $3.8 million, respectively. The corresponding liability was recorded in accounts payable and accrued liabilities in the accompanying condensed consolidated balance sheet as of September 30, 2026.

4. Inventories

Inventories consisted of the following (in thousands):

	September 30, 2026	December 31, 2025
Raw materials	$ 26,997	$ 26,815
Work in process	918	288
Finished goods	5,516	4,319
Total inventories	$ 33,431	$ 31,422
Reported as:		
Inventories	$ 11,711	$ 8,369
Inventories, noncurrent	21,720	23,053
Total inventories	$ 33,431	$ 31,422

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 no zero-cost inventory as of September 30, 2026. The Company held $6.7 million in zero-cost inventory as of December 31, 2025, none of which was determined to be obsolete.

5. Intangible Assets

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

	September 30, 2026	December 31, 2025
Capitalized milestone payments[(1)]	$ 15,360	$ 15,360
Less accumulated amortization	(1,736)	(908)
Total	$ 13,624	$ 14,452

[(1)] As described in Note 3 – Collaboration, Out-Licensing and Related Agreements and Note 10 – In-Licensing and Supply, capitalized milestone payments were recognized from the Recordati Termination Agreement and Aegis License Agreement, respectively.

Amortization expense for the three and nine months ended September 30, 2026 was $0.3 million and $0.8 million, respectively, and was recorded in cost of goods sold in the accompanying condensed consolidated statements of operations and comprehensive loss. For the three and nine months ended September 30, 2025, amortization expense was $0.2 million and $0.5 million, respectively.

The weighted-average amortization period of intangible assets is 12.3 years. As of September 30, 2026, estimated future amortization expense for capitalized intangible assets is expected to be as follows (in thousands):

Year Ended December 31,	Amount
2026 (remaining three months)	$ 276
2027	1,105
2028	1,105
2029	1,105
2030	1,105
2031 and thereafter	8,928
Total	$ 13,624

6. 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, 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
September 30, 2026					
Cash and cash equivalents - Money market mutual funds	1	$ 25,321	$ —	$ —	$ 25,321
Short-term investments - U.S. Treasury securities	2	112,837	—	(104)	112,733
Total		$ 138,158	$ —	$ (104)	$ 138,054
December 31, 2025					
Cash and cash equivalents - Money market mutual funds	1	$ 41,030	$ —	$ —	$ 41,030
Short-term investments - U.S. Treasury securities	2	203,544	134	(9)	203,669
Total		$ 244,574	$ 134	$ (9)	$ 244,699

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 nine months ended September 30, 2026, the Company purchased $33.1 million and $67.7 million in short-term investments, respectively, and $56.5 million and $160.5 million in short-term investments matured or were sold, respectively. During the three and nine months ended September 30, 2025, the Company purchased $127.4 million and $193.1 million in short-term investments, respectively, and $88.5 million and $232.0 million in short-term investments matured, respectively.

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.

For the three and nine months ended September 30, 2026, net unrealized gains on available-for-sale securities were less than $0.1 million and net unrealized losses were $0.2 million, respectively. For the three and nine months ended September 30, 2025, net unrealized gains were less than $0.1 million and net unrealized losses on available-for-sale securities were $0.2 million, respectively. Management determined that the gross unrealized losses on the Company's available-for-sale securities as of September 30, 2026 were primarily attributable to current economic and market conditions and not credit risk. As of September 30, 2026 and December 31, 2025, no allowance for credit losses was recorded for available-for-sale securities. 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 receivable on the Company's available-for-sale securities was $0.5 million and $1.0 million at September 30, 2026 and December 31, 2025, respectively, and was included in prepaid expenses and other current assets in the accompanying condensed consolidated balance sheets.

The Company's Term Loans (as defined in Note 8 – Term Loans) are carried at historical cost, adjusted for the debt discount and debt issuance costs, and are not required to be carried at fair value. The carrying value of the Term Loans approximates fair value due to the use of current market rates that are repriced frequently.

As of September 30, 2026 and December 31, 2025, the Company did not have any liabilities that were measured at fair value on a recurring basis.

7. Balance Sheet Details

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

	September 30, 2026	December 31, 2025
Accounts payable	$ 5,418	$ 5,725
Accrued gross-to-net liabilities	25,540	14,162
Accrued marketing related expenses	15,245	6,880
Accrued compensation	7,202	1,276
Accrued cost of goods sold	3,757	3,165
Other	6,631	6,740
Total	$ 63,793	$ 37,948

8. Term Loans

On September 29, 2025 (the "Closing Date"), the Company and certain direct and indirect subsidiaries of the Company who may become a party thereto from time to time, as guarantors (the "Guarantors"), and ARS Pharmaceuticals Operations, Inc., as the borrower (the "Borrower" and, collectively with the Guarantors, the "Credit Parties"), entered into a credit agreement (the "Credit Agreement"), which was amended in July 2026, with RA Capital Agency Services, LLC (as the "Administrative Agent" and as the "Collateral Agent"), and affiliates of OMERS Administration Corporation and RA Capital Management, L.P., as lenders, and such other lenders who may become a party thereto from time to time (the "Lenders"), providing for an aggregate principal amount of up to $250.0 million of term loans from the Lenders to the Borrower (the "Term Loans"). The Term Loans will mature on September 29, 2030.

Pursuant to the terms of the Credit Agreement, the Term Loans may be advanced in four tranches. The first tranche (the "Term A Loan") was funded in the principal amount of $100.0 million on the Closing Date. The second tranche (the "Term B Loan") was subsequently funded in the principal amount of $25.0 million on September 25, 2026. The third tranche (the "Term C Loan"), in a principal amount of $25.0 million, may be advanced at the Borrower's election during the period commencing on and including the Closing Date and ending no later than the two-year anniversary of the Closing Date, subject to the Company achieving trailing 12-month ("TTM") net revenues for *neffy* of at least $100.0 million and customary conditions. The fourth tranche (the "Term D Loan") of up to $100.0 million is uncommitted and may be advanced at the Borrower's election, subject to the consent of all of the Term D Lenders and customary conditions. All outstanding principal is due at maturity on September 29, 2030. The Term Loans require interest-only payments and do not require scheduled principal payments prior to maturity. The Borrower may prepay principal on the Term Loans, in whole or in part, subject to a prepayment premium and an exit fee.

The Company received $100.0 million in gross cash proceeds from the Term A Loan on the Closing Date, less the upfront fees taken in the form of an original issue discount and third-party fees totaling $3.8 million. The Company also received $25.0 million in gross cash proceeds from the Term B Loan on September 25, 2026, less third-party fees totaling less than $0.1 million. The debt discount and the debt issuance costs associated with each of the Term A Loan and Term B Loan are recorded net of the respective loan balance and are amortized to interest expense over the term of each loan using the effective interest rate method.

The Term Loans will initially bear interest at a per annum rate of 5.50% plus the greater of (i) the three-month forward-looking term SOFR or (ii) 3.00%, which interest rate may be reduced by 25 to 50 basis points based on achieving certain TTM net revenue milestones. The Credit Agreement provides for interest-only payments on a quarterly basis until maturity. At Borrower's election and subject to certain conditions, 100% of accrued interest in the first two years, and 50% of accrued interest in the last three years, may be paid-in-kind, in which case the applicable interest rate for the Term Loans shall increase by 1.00% per annum for the portion of such Term Loans that is paid-in-kind.

The obligations of the Borrower under the Credit Agreement are guaranteed on a full and unconditional basis by the Company and the Guarantors and are secured by substantially all of the respective Credit Parties' tangible and intangible assets and property, including intellectual property, subject to certain exceptions.

The Credit Agreement contains customary representations and warranties, covenants and events of default, including a requirement for the Borrower to maintain at all times, a minimum specified amount of unrestricted cash in deposit accounts. The Credit Agreement also includes customary events of default, including, among others, payment defaults, material misrepresentations, breaches of covenants following any applicable cure period, cross defaults with certain other indebtedness or material agreements, bankruptcy and insolvency events, judgment defaults, the occurrence of certain events that could reasonably be expected to have a "material adverse effect," and the occurrence of a change in control (as defined in the Credit Agreement). The occurrence of an event of default could result in the acceleration of the Company's obligations under the Credit Agreement and the exercise by the Administrative Agent of other rights and remedies provided for under the Credit Agreement.

The Administrative Agent and Collateral Agent, as well as a Lender, are affiliates of RA Capital Management, L.P. ("RA Capital"). Affiliates of RA Capital collectively hold in excess of 10% of the Company's outstanding common stock and are currently the Company's largest stockholder. One of the Company's board members is a controlling person of RA Capital's general partner. The Lender affiliated with RA Capital holds a portion of Term Loans in the principal amount of $5.0 million.

The following table summarizes the composition of the Term Loans as reflected on the accompanying condensed consolidated balance sheet (in thousands):

	September 30, 2026	December 31, 2025
Gross proceeds	$ 125,000	$ 100,000
Unamortized debt discount and debt issuance costs	(3,193)	(3,626)
Total	$ 121,807	$ 96,374

9. Commitments and Contingencies

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. Following oral proceedings on October 7, 2025, the EPO Opposition Division upheld the validity of all claims of the EP '649 Patent. The opponent appealed the decision of the Opposition Division, and the Company filed its response to the grounds of appeal on July 3, 2026. Oral proceedings before the Board of Appeal are scheduled for July 1, 2027. The Company intends to continue to vigorously defend the EP '649 Patent, although the Board of Appeal may reverse the decision of the Opposition Division in whole or in part.

On March 25, 2025, AptarGroup, Inc. ("AptarGroup") 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 an opposition to the motion to dismiss on July 28, 2025, and the Company filed a reply brief on August 27, 2025. On March 30, 2026, the Court granted in part and denied in part the motion to dismiss, dismissing the trade secret misappropriation claim under New York state law and allowing the other claims to proceed. On April 29, 2026, Aptar filed a motion for leave to file an amended complaint to replead the previously dismissed claim, which the Company opposed. The Court granted the motion for leave to file an amended complaint on June 17, 2026, and the Company filed its answer to the amended complaint on July 6, 2026. Aptar moved to further amend the complaint on October 14, 2026, seeking to add Silgan Dispensing Systems Corp. as an additional defendant. The Company intends to vigorously defend itself in this matter. On September 29, 2025, the Company filed a lawsuit against AptarGroup in the U.S. District Court for the Southern District of California, alleging that AptarGroup violated federal antitrust law in connection with its sale of certain constituent parts of *neffy*. On December 16, 2025, Aptar moved to dismiss or in the alternative transfer ARS's lawsuit to the Southern District of New York. On January 27, 2026, ARS filed an opposition to Aptar's motion to dismiss, and Aptar filed a reply brief on February 27, 2026. On July 17, 2026, the Court declined to address Aptar's motion to dismiss arguments and instead transferred the Company's lawsuit to the Southern District of New York. On August 7, 2026, Aptar again moved to dismiss the complaint. The Company filed an opposition on August 21, 2026, and Aptar filed a reply brief on August 28, 2026. The Company intends to diligently pursue this claim and seek all available relief.

On August 29, 2025, the Company filed a lawsuit against Lupin, Inc., Lupin Ltd., and Lupin Pharmaceuticals, Inc. (collectively, "Lupin") in the United States District Court for the District of New Jersey, alleging infringement of U.S. Patent Nos.: 10,576,156, 10,682,414, 11,173,209, 11,191,838, 11,717,571, 11,744,895, 11,918,655, and 12,324,838 and seeking a permanent injunction preventing market entry of a generic product from Lupin prior to the expiry of such patents. The lawsuit follows a Paragraph IV certification notice letter received from Lupin on August 13, 2025, advising the Company that Lupin submitted an Abbreviated New Drug Application to the FDA seeking approval to manufacture and sell a generic version of the Company's product *neffy* 2 mg (epinephrine nasal spray) prior to the expiration of the patents referenced above.

On February 26, 2026, the Company filed a lawsuit against Lupin, Inc., Lupin Ltd., and Lupin Pharmaceuticals, Inc. (collectively, "Lupin") in the United States District Court for the District of New Jersey, alleging infringement of U.S. Patent Nos.: 10,576,156, 10,682,414, 11,173,209, 11,191,838, 11,717,571, 11,744,895, 11,918,655, and 12,324,838 and seeking a permanent injunction preventing market entry of a generic product from Lupin prior to the expiry of such patents. The lawsuit follows a Paragraph IV certification notice letter received from Lupin on February 6, 2026, advising the Company that Lupin submitted an Abbreviated New Drug Application to the FDA seeking approval to manufacture and sell a generic version of the Company's product *neffy* 1 mg (epinephrine nasal spray) prior to the expiration of the patents referenced above. On October 1, 2026, the Company and Lupin entered into a stipulation whereby Lupin, while maintaining its challenges to validity, agreed that its proposed generic 1mg and 2mg epinephrine nasal spray products meet all of the limitations of the asserted claims of U.S. Patents Nos. 10,682,414, 11,191,838, 11,717,571, 11,744,895, 11,918,655, and 12,324,838.

On April 10, 2026, the Company filed a lawsuit against Cipla Ltd. and Cipla USA, Inc. (collectively, "Cipla") in the United States District Court for the District of New Jersey, alleging infringement of U.S. Patent Nos.: 10,576,156, 10,682,414, 11,173,209, 11,191,838, 11,717,571, 11,744,895, 11,918,655, and 12,324,838 and seeking a permanent injunction preventing market entry of a generic product from Cipla prior to the expiry of such patents. The lawsuit follows a Paragraph IV certification notice letter received from Cipla on March 25, 2026, advising the Company that Cipla submitted an Abbreviated New Drug Application to the FDA seeking approval to manufacture and sell a generic version of the Company's product *neffy* 1 mg and 2 mg (epinephrine nasal spray) prior to the expiration of the patents referenced above.

On July 10, 2026, Jonico, Inc. d/b/a Berlin Pharmacy filed a putative class action lawsuit against the Company, and its wholly owned subsidiary, ARS Pharmaceuticals Operations, Inc., in the U.S. District Court for the Western District of Pennsylvania, Civil Action No. 3:26-cv-01339. The complaint alleges that the Company sent, or caused to be sent, facsimile advertisements promoting *neffy* to pharmacies, without the prior express invitation or permission of the recipients and without the requisite opt-out notices, in violation of the Telephone Consumer Protection Act, 47 U.S.C. § 227 (the "TCPA"). The TCPA provides for statutory damages of $500 per violation, which may be trebled up to $1,500 per violation for willful or knowing violations; the complaint also seeks injunctive relief. On September 28, 2026, the Company moved to dismiss the complaint for failure to state a claim, arguing that the alleged facsimile does not qualify as an "advertisement" under the TCPA. On October 19, 2026, before the Company's motion to dismiss was fully briefed and decided, the plaintiff filed an amended complaint (the "First Amended Complaint"). The First Amended Complaint asserts the same TCPA claim as the original complaint. The Company disputes these allegations and intends to vigorously defend itself.

On August 5, 2026, a purported stockholder of the Company filed a securities class action complaint in the U.S. District Court for the Southern District of California against the Company and certain of its current and former officers. The complaint alleges that defendants violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, and Rule 10b-5 promulgated thereunder, by making material misstatements or omissions concerning the Company's expected timeline for expanded insurance coverage for *neffy*. The complaint seeks, on behalf of the putative class, unspecified damages, pre- and post-judgment interest, attorneys' fees, expert fees and costs, as well as class certification and such other relief as the court may deem just and proper. The Company intends to vigorously defend against the claims in this action. Any potential loss arising from this claim is not currently probable or estimable.

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 September 30, 2026.

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 remaining unconditional purchase obligations related to the supply of raw materials is $55.6 million as of September 30, 2026. Purchase obligations by year are as follows: 2026 ($9.4 million), 2027 ($11.8 million), 2028 ($13.8 million), and $2.9 million per year thereafter through 2035. During the three and nine months ended September 30, 2026, the Company made zero and $1.6 million in payments under these agreements, respectively. During the three and nine months ended September 30, 2025, the Company made $0.7 million and $8.0 million in payments under these agreements, respectively.

Subsequent to period end, the Company entered into an amendment to certain arrangements related to the supply of raw materials, reducing the remaining unconditional purchase obligations by $23.9 million.

The total amount of commitments related to the ALK Co-Promotion Agreement is $18.2 million as of September 30, 2026. Commitments by year are as follows: 2026 ($4.4 million), 2027 ($10.7 million), 2028 ($1.8 million), and 2029 ($1.3 million). No payments were made under this agreement during the three and nine months ended September 30, 2026 and 2025.

The amounts above do not represent the entire anticipated expenditure 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"). 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 consolidated statements of operations for the year ended December 31, 2018.

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, the Company made regulatory milestone payments totaling $1.5 million to Aegis, which were recorded as research and development expenses in the consolidated statements of operations.

Since the FDA approval of *neffy* in August 2024, regulatory and commercial milestone payments have been capitalized as intangible assets in the consolidated balance sheets upon achievement. Amortization expense for capitalized milestone payments has been recognized as 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. In August and September 2024, milestone payments of $2.5 million and $5.0 million were recognized for achieving FDA approval of *neffy* and the first commercial sale of *neffy,* respectively. In September 2025, a milestone payment of $2.0 million was recognized for achieving certain annual net product sales of *neffy*. As of September 30, 2026, the Company's remaining milestone payment obligation is $9.0 million upon the achievement of certain annual net 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 an affiliate of OrbiMed. As described in Note 13 – Related Party Transactions, a member of the Company's Board of Directors is a General Partner at OrbiMed.

The Company and Aegis jointly bear certain patent costs incurred in connection with the prosecution and maintenance of patent rights specific to epinephrine and epinephrine products. Legal patent expense under the Aegis Agreement was $0.5 million and $1.5 million for the three and nine months ended September 30, 2026, respectively. No legal patent expense was incurred under the Aegis Agreement for the three and nine months ended September 30, 2025.

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 earlier of the expiration or termination of the Aegis Agreement or June 2028. The Aegis Supply Agreement term may be extended by mutual written agreement.

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 on (a) December 31, 2029 for Renaissance Product designated for commercial sale in the U.S. ("U.S. Initial Term"), and (b) December 31, 2030 for Renaissance Product designated for commercial sale in the EU ("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.

License Agreement

On July 1, 2026, the Company entered into a license agreement (the "License Agreement") with a strategic partner, pursuant to which the Company received exclusive worldwide rights to certain intellectual property related to epinephrine products. The Company paid an upfront license fee of $12.5 million, which was recognized as research and development expense in each of the three and nine months ended September 30, 2026. The License Agreement also includes future development, regulatory and commercial milestone payments of up to $60.0 million in the aggregate, as well as sales-based royalty payments on products incorporating the licensed intellectual property.

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:

	September 30, 2026	December 31, 2025
Common stock options granted and outstanding	19,817,214	16,744,639
Common stock reserved for future awards or option grants	9,118,580	8,085,186
Common stock reserved for future employee stock purchase plan issuances	3,325,048	2,722,563
Warrants to purchase common stock	45,456	45,456
Restricted stock units granted and outstanding	—	1,382
Total	32,306,298	27,599,226

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 Offering℠ 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 September 30, 2026, 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 accompanying condensed consolidated statements of operations and comprehensive loss as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Research and development expense[(1)]	$ 2,089	$ 664	$ 3,941	$ 1,991
Selling, general and administrative expense[(2)]	6,033	5,025	23,999	14,367
Total	$ 8,122	$ 5,689	$ 27,940	$ 16,358

[(1)] Stock-based compensation expense for the three and nine months ended September 30, 2026 included $1.7 million related to the accelerated vesting of previously unvested equity awards upon the termination of a former executive officer.
[(2)] Stock-based compensation expense for the three and nine months ended September 30, 2026 included $1.5 million and $6.8 million, respectively, related to the accelerated vesting of previously unvested equity awards upon the termination of former executive officers.

Stock-based compensation expense capitalized into inventory for the three and nine months ended September 30, 2026 was $0.4 million and $1.2 million, respectively. For the three and nine months ended September 30, 2025, stock-based compensation expense capitalized into inventory was $0.3 million and $0.8 million, respectively.

As of September 30, 2026, the total unrecognized stock-based compensation expense related to outstanding employee options was $43.3 million, which is expected to be recognized over a remaining weighted-average period of approximately 2.8 years.

As of September 30, 2026 and December 31, 2025, there were zero and 1,382 restricted stock units outstanding, respectively.

Equity Incentive Plans

The Company maintains the 2016, 2018 and 2020 Equity Incentive Plans and the Employee Stock Purchase Plan ("ESPP"). Shares of common stock purchased under the ESPP for the nine months ended September 30, 2026 and 2025 were 97,515 shares and 111,918 shares, respectively.

As of September 30, 2026, 30,701,662 shares were authorized under the 2016 and 2020 Equity Incentive Plans, of which 8,821,235 shares were available for future grant, and 16,380,208 shares were outstanding. As of September 30, 2026, 6,634,333 shares were authorized under the 2018 Equity Incentive Plan, of which 297,345 shares were available for future grant, and 3,437,006 shares were outstanding.

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 one- to four-year period. 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 nine months ended September 30, 2026 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, 2025	16,744,639	$ 7.66		
Granted	6,291,834	$ 9.79		
Exercised	(858,577)	$ 3.19		
Forfeited	(2,360,682)	$ 10.70		
Outstanding at September 30, 2026	19,817,214	$ 8.17	5.6	$ 10,644
Exercisable at September 30, 2026	13,282,346	$ 7.54	4.1	$ 10,644

The exercisable shares subject to options outstanding at September 30, 2026 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 September 30, 2026. The aggregate intrinsic value of options exercised during the nine months ended September 30, 2026 and 2025 was $2.1 million and $8.0 million, respectively.

The weighted-average grant date fair value per share of option grants for the nine months ended September 30, 2026 and 2025 was $7.15 and $8.69, respectively. The total fair value of shares vested during the nine months ended September 30, 2026 and 2025 was $29.5 million and $19.4 million, respectively.

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

	Nine Months Ended September 30,	
	2026	2025
Expected term (in years)	5.5 – 6.1	5.5 – 6.1
Expected volatility	81.5% – 85.2%	84.1% – 87.3%
Risk-free interest rate	3.7% – 4.6%	3.9% – 4.4%
Expected dividend yield	0%	0%

The fair value of stock options was determined using the Black-Scholes assumptions described below.

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. 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 Company's former President/Chief Executive Officer/director and his spouse, the former Chief Medical Officer of the Company. Consulting expense under this agreement for the three and nine months ended September 30, 2026 was $0.6 million and $2.0 million, respectively. For the three and nine months ended September 30, 2025, consulting expense under this agreement was $0.6 million and $1.9 million, respectively.

As described in Note 8 – Term Loans, in September 2025, the Company entered into the Credit Agreement with the Administrative Agent and a Lender, who are affiliates of RA Capital. The general partner of RA Capital is RA Capital Management GP, LLC, of which a member of the Board of Directors of the Company is a controlling person. RA Capital Healthcare Fund, L.P. and RA Capital Nexus Fund II, L.P. collectively hold in excess of 10% of the Company's outstanding common stock and are currently the Company's largest stockholder. RA Capital serves as the investment adviser for each of RA Capital Healthcare Fund, L.P. and RA Capital Nexus Fund II, L.P.

As described in Note 10 – In-Licensing and Supply, OrbiMed acquired from the Aegis, the rights to certain royalty interests and milestones related to *neffy* under the Aegis agreement. As a result, certain milestone and royalty payments due under the Aegis Agreement are payable to an affiliate of OrbiMed. A member of the Company's Board of Directors is a General Partner at OrbiMed. Royalty expense payable to an affiliate of OrbiMed for the three and nine months ended September 30, 2026 was $1.7 million and $4.8 million, respectively, and was recorded in cost of goods sold in the accompanying condensed consolidated statements of operations and comprehensive loss. For the three and nine months ended September 30, 2025, royalty expense was $2.0 million and $3.4 million, respectively.

14. 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 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.

Certain prior period segment expenses have been recast to conform to the manner in which our Chief Operating Decision Maker reviews the information during the current period. The recast did not impact the Company's previously reported consolidated results of operations.

Segment reporting for the three and nine months ended September 30, 2026 and 2025 (in thousands) is as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Total revenue	$ 37,710	$ 32,501	$ 94,049	$ 56,191
Less segment operating expenses:				
Cost of goods sold	10,098	8,191	29,230	14,269
Clinical	1,991	1,457	5,725	3,911
Development	14,306	690	17,918	3,942
Medical affairs	811	1,086	3,363	3,104
Sales and marketing	27,649	63,211	140,072	135,259
General and administrative	8,861	5,002	25,369	16,473
Stock-based compensation	8,122	5,689	27,940	16,358
Other segment operating expenses	43	367	213	858
Other segment (income) expense:				
Interest income	(1,136)	(2,097)	(4,709)	(8,065)
Interest expense	2,552	56	7,472	56
Segment net loss	$ (35,587)	$ (51,151)	$ (158,544)	$ (129,974)

The following table summarizes revenue by geographic area based on the customers' location (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
United States	$ 33,414	$ 31,300	$ 77,076	$ 51,863
Denmark	*	*	7,786	4,079
Japan	*	*	5,995	*
Rest of world	4,296	1,201	3,192	249
Total revenue	$ 37,710	$ 32,501	$ 94,049	$ 56,191

* Revenue from this country was not individually material for the indicated period and is included within "Rest of world."

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, 2025 included in our Annual Report on Form 10-K, filed with the Securities and Exchange Commission ("SEC"), on March 9, 2026. 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 "Special Note Regarding Forward-Looking Statements." As a result of many factors, including those factors set forth 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.

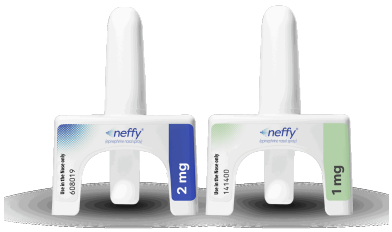
Overview

We are a biopharmaceutical company focused on the commercialization of *neffy*® (also identified in the European Union ("EU") and United Kingdom ("UK") by the trade name *EURneffy* and in China by the trade name 优敏速) for the needle-free intranasal delivery of epinephrine for emergency treatment of Type I allergic reactions, including anaphylaxis. *neffy* is the first and only needle-free epinephrine product approved by the U.S. Food and Drug Administration ("FDA") and the European Commission, and also has approvals in other major markets including the UK, Japan, Australia, China, and Canada. It is 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 there is a multi-billion dollar market opportunity for *neffy* in the United States. Based on published epidemiology data, approximately 40 million people in the U.S. have experienced a Type I allergic reaction. Of these, approximately 20 million are reported to have been diagnosed with severe Type I allergic reactions that may lead to anaphylaxis and to be under the care of a physician. Based on our estimates, more than five million prescriptions for this indication are written annually in the U.S., nearly all of which are for needle-based autoinjectors. However, published studies indicate that approximately one-third of patients with an active prescription consistently carry their device, and fewer than one in five carry the two devices recommended by treatment guidelines. In addition, approximately half of patients delay administration of, or do not administer, their autoinjector during an allergic reaction, and only approximately 10% of patients with a prescription refill at every recommended interval.

As the first and only needle-free epinephrine option, *neffy* has the potential to become the standard of care. In addition to its intranasal delivery, *neffy* is compact and designed to be easy to carry and easy to administer, addressing the barriers to carrying and using epinephrine that exist in the market today.

In August 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, with *neffy* 1 mg subsequently approved in March 2025 for patients who are four years of age and older who weigh 15 kg to less than 30 kg. In March 2026, the FDA approved updating the *neffy* 1 mg label to remove the age criteria so all children and adults who weigh 15 kg or more can utilize *neffy* 1 mg.



Our commercialization strategy for *neffy* in the United States is focused on achieving market share growth through targeted provider engagement, increasing our share in the existing U.S. epinephrine market of approximately five million prescriptions annually, and laying the groundwork to expand into the broader market over time. We believe growth in the existing market can be achieved through account-based sales targeting of high-value prescribers of epinephrine, which account for approximately 44% of the total U.S. market opportunity, as well as the nurses and office staff who often manage the prescription process through fulfillment. Our engagement addresses the well-established limitations of injectable epinephrine in the treatment and prevention of Type I allergic reactions, including anaphylaxis, such as low rates of device carry and the delay or avoidance of administration, with the aim of converting established prescribing habits from injectable epinephrine products to *neffy*.

Our U.S. commercial launch is building momentum, and data shows meaningful physician demand. More than 44,000 healthcare providers have prescribed *neffy* to date. Over 19,000 of these prescribers were unique additions in the third quarter of 2026, representing an increase of approximately 49% over the same period in 2025. This demand has contributed to a total market share by *neffy* of 5%, up from 4% in the third quarter of 2025. Among field-targeted accounts, the leading indicator of demand, *neffy* market share reached approximately 9%, up from 6% a year ago, compared with 2% in non-targeted accounts.

In parallel, our payor coverage remains the same across commercial coverage inclusive of plans with and without prior authorization as well as Medicaid coverage. We continue to engage with stakeholders to further expand access.

Our U.S. commercialization strategy is also supported by a comprehensive program that includes: our *neffy* experience program, allowing healthcare professionals to use *neffy* firsthand as rescue therapy for anaphylaxis during in-clinic allergen challenge; extensive non-personal promotion including 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, including certain pharmacy benefit managers, where the approval processes are actively ongoing for addition of *neffy* to their formularies without prior authorization; our artificial intelligence solution to support healthcare providers by automating the checking and writing of prior authorizations; as well as other programs intended to enable access to *neffy* by patients. We also have an ongoing U.S. post-marketing registry-based study for *neffy* for the treatment of anaphylaxis in oral food challenge or allergen immunotherapy clinics.

In August 2024, the EC granted marketing authorization in the EU for *EURneffy* 2 mg (the trade name for *neffy* 2 mg in the EU and UK), for the emergency treatment of allergic reactions, including anaphylaxis, in adults and children who are four years of age and older who weigh 30 kg or greater. In March 2026, the European Medicines Agency ("EMA") granted marketing authorization in the EU for *EURneffy* 1 mg for children who are four years of age and older who weigh 15 kg to less than 30 kg. Through our collaboration with ALK, *EURneffy* 2 mg was launched in Europe, beginning with Germany in June 2025, followed by the UK in October 2025. We received approval of *neffy* 2 mg and 1 mg in Japan in September 2025, and *neffy* was launched in February 2026 by our collaboration partner, Alfresa. We also received approval of *neffy* 2 mg and 1 mg in Australia in December 2025, and *neffy* was launched in February 2026 by our collaboration partner, Seqirus. In December 2025, we received approval in China of 优敏速 (the trade name for *neffy* 2 mg in China), and 优敏速 was launched by our collaboration partner, Pediatrix, in May 2026. In April 2026, we received approval in Canada of *neffy* 2 mg, and it was launched by our collaboration partner, ALK, in August 2026. *neffy* has already been approved in countries representing approximately 98% of the current global epinephrine autoinjector sales market.

In addition to our *neffy* base business, we aim to expand the reach of our intranasal epinephrine technology beyond Type I allergic reactions, including anaphylaxis. We are currently advancing ARS-2 as a potential needle-free, on-demand rescue treatment for acute flares in patients with chronic spontaneous urticaria ("CSU"). Results from our completed single-dose, randomized, open-label, placebo-controlled Phase 2 trial in 21 patients with CSU experiencing an acute flare were published in a peer-reviewed article in *The Journal of Allergy and Clinical Immunology: In Practice* in 2026. Compared with placebo, both the 1 mg and 2 mg doses of ARS-2 demonstrated statistically significant improvements in pruritus (itchy skin), hives, extent of urticaria (body surface area) and erythema with improvements observed as early as five minutes after dosing and across all endpoints within 30 minutes, sustained through two hours.

In the second quarter of 2025, we initiated a Phase 2b randomized, double-blinded, placebo-controlled, crossover trial evaluating 0.5 mg and 1 mg doses of ARS-2 in patients with CSU who continue to experience flares or exacerbations while on chronic treatment regimens. The Phase 2b trial is designed to assess the efficacy and safety of ARS-2 self-administered by patients in an outpatient setting during acute flares, which we believe more closely reflects how ARS-2 would be used if approved. The interim analysis population was fully enrolled as of May 2026, and we currently expect to report interim Phase 2b data in the first quarter of 2027, with full data later in 2027, which will inform the design of a potential Phase 3 registration program.

Since our inception in 2015 as ARS Pharmaceuticals, Inc., we have devoted substantially all of our efforts to commercialization activities for *neffy* in the U.S., pre-commercial activities, conducting product development and clinical trials, developing and protecting intellectual property, organizing and staffing the Company, business planning, raising capital, building infrastructure, and providing general and administrative support for these operations. We have funded our operations primarily with proceeds from net product sales, debt, licensing, supply and distribution arrangements with our commercialization partners, issuance of common stock, the merger with Silverback Therapeutics, Inc. ("Silverback") in November 2022 (the "Merger"), and the private placement of convertible preferred stock. As of September 30, 2026, we had cash, cash equivalents, and short-term investments of $138.4 million.

We have incurred net losses in most years since our inception. Net loss for the nine months ended September 30, 2026 and 2025 was $158.5 million and $130.0 million, respectively. As of September 30, 2026, we had an accumulated deficit of $453.1 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 royalties and 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. On September 29, 2025, we entered into a Credit Agreement (the "Credit Agreement") with RA Capital Agency Services, LLC (as the "Administrative Agent") and affiliates of OMERS Administration Corporation and RA Capital Management, L.P. as lenders (the "Lenders"), which provides for an aggregate principal amount of up to $250.0 million of term loans from the Lenders to us (the "Credit Facility"). Subject to limited exceptions, we are prohibited from incurring additional indebtedness and entering into certain strategic and licensing transactions without the prior written consent of the Lenders pursuant to the Credit Agreement. 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.

Financial Overview

Revenues

We have recognized 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 to manufacture *neffy* for commercial sale, including 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, royalties on product sales, salaries and related expenses for personnel, and stock-based compensation. Prior to the FDA approval of *neffy* in August 2024, certain inventory components were purchased to manufacture *neffy* and recorded as research and development expenses, resulting in zero-cost inventory components. 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 inventory components are consumed in commercial production and sold to customers.

As of September 30, 2026, we held no zero-cost inventory components.

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:

- 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 contract manufacturing organizations ("CMOs") and other third-party manufacturers;
- costs related to in-licensing of technology;
- costs related to compliance with regulatory requirements and regulatory filings;
- indirect expenses including insurance and facility-related expenses; and
- salaries, payroll taxes, benefits and stock-based compensation charges for personnel engaged in research and development efforts.

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, consultants 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 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 marketing-related expenses and 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 legal fees incurred relating to corporate and patent matters, professional fees incurred for accounting, auditing, tax and administrative consulting services, and insurance costs.

Selling, general and administrative expenses have increased since the commercial launch of *neffy* due to the establishment of our sales force, the development and commencement of our marketing campaigns and initiatives, the co-promotion agreement between us and ALK-Abelló, Inc., which was entered into in May 2025 and subsequently amended in October 2025 and March 2026, with the parties entering into a related side letter in August 2026 (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. While broad consumer advertising has supported our commercialization efforts to date, we are also taking action to align resources with our strategic priorities and support more focused marketing. 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, interest expense on our outstanding debt, and net amortization and accretion associated with our short-term investments.

Results of Operations

Comparison of the Three Months Ended September 30, 2026 and 2025

The following table summarizes our results of operations for the three months ended September 30, 2026 and 2025 (in thousands, except percentages):

	Three Months Ended September 30,		Dollar Change	% Change
	2026	2025		
Revenue:				
Product revenue, net	$ 33,414	$ 31,300	$ 2,114	7%
Revenue under collaboration agreements	1,661	55	1,606	*
Revenue under supply agreements	2,635	1,146	1,489	130%
Total revenue	37,710	32,501	5,209	16%
Operating expenses:				
Cost of goods sold	10,098	8,191	1,907	23%
Research and development[(1)]	18,263	2,751	15,512	*
Selling, general and administrative[(1)]	43,520	74,751	(31,231)	(42%)
Total operating expenses	71,881	85,693	(13,812)	(16%)
Loss from operations	(34,171)	(53,192)	19,021	(36%)
Other income (expense), net:				
Interest income	1,136	2,097	(961)	(46%)
Interest expense	(2,552)	(56)	(2,496)	*
Total other (expense) income, net	(1,416)	2,041	(3,457)	(169%)
Net loss	$ (35,587)	$ (51,151)	$ 15,564	(30%)

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[*] Not meaningful

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

	Three Months Ended September 30,	
	2026	2025
Research and development	$ 2,089	$ 664
Selling, general and administrative	6,033	5,025
Total	$ 8,122	$ 5,689

Revenues. Revenue for the three months ended September 30, 2026 was $37.7 million, as compared to $32.5 million for the three months ended September 30, 2025. Revenue for the three months ended September 30, 2026 includes $33.4 million in net product revenues for sales of *neffy* in the United States, $2.6 million in revenue under supply agreements with partners, and $1.7 million in revenue for the performance of development and regulatory services and achievement of a commercial milestone under our collaboration agreements with ALK-Abelló A/S (the "ALK Collaboration Agreement") and Seqirus Pty Ltd. (the "Seqirus Agreement"). Revenue for the three months ended September 30, 2025 includes $31.3 million in net product revenues for sales of *neffy* in the United States, $1.1 million in revenue under supply agreements with partners, and less than $0.1 million in revenue for the performance of development and regulatory services performance obligations under the ALK Collaboration Agreement. The increase in revenue was primarily driven by higher global unit sales volumes of *neffy*.

Cost of Goods Sold. Cost of goods sold for the three months ended September 30, 2026 was $10.1 million, as compared to $8.2 million for the three months ended September 30, 2025. The increase of $1.9 million was primarily driven by direct and indirect product costs incurred in connection with U.S. product sales and the commercial launches of *neffy* in the U.K., EU, Japan, Australia, and China following regulatory approval in each market. Our global expansion also resulted in a corresponding increase in royalty expense on worldwide net product revenue.

Research and Development Expenses. Research and development expenses for the three months ended September 30, 2026 were $18.3 million, as compared to $2.8 million for the three months ended September 30, 2025. The increase of $15.5 million was primarily due to costs related to in-licensing of technology of $12.5 million, increases in stock-based compensation and personnel-related expenses of $1.9 million, of which, $1.7 million related to accelerated vesting of previously unvested equity awards upon the termination of a former executive officer, product development expenses of $0.8 million, and other research and development expenses of $0.3 million.

The following table summarizes our research and development expenses for the three months ended September 30, 2026 and 2025 (in thousands):

	Three Months Ended September 30,	
	2026	2025
Clinical and regulatory	$ 3,605	$ 1,840
Manufacturing and non-clinical development	14,658	911
Total	$ 18,263	$ 2,751

Selling, General and Administrative Expenses. Selling, general and administrative expenses for the three months ended September 30, 2026 were $43.5 million, as compared to $74.8 million for the three months ended September 30, 2025. The decrease of $31.2 million was primarily due to a decrease in marketing-related expenses of $38.0 million and conference and seminar expenses of $0.6 million, partially offset by increases in stock-based compensation and other personnel-related expenses of $4.2 million, of which $1.5 million related to accelerated vesting of previously unvested equity awards upon the termination of former executive officers, legal fees of $2.6 million and outside services of $0.6 million.

Other (Expense) Income, Net. Other expense, net for the three months ended September 30, 2026 was $1.4 million, as compared to other income, net of $2.0 million for the three months ended September 30, 2025. The change of $3.5 million was primarily due to an increase in interest expense related to our Credit Agreement of $2.5 million and decreases in net accretion of discounts on short-term investments of $0.7 million and interest income of $0.3 million from our cash, cash equivalents, and short-term investments.

Comparison of the Nine Months Ended September 30, 2026 and 2025

The following table summarizes our results of operations for the nine months ended September 30, 2026 and 2025 (in thousands, except percentages):

	Nine Months Ended September 30,		Dollar	%
	2026	2025	Change	Change
Revenue:				
Product revenue, net	$ 77,076	$ 51,863	$ 25,213	49%
Revenue under collaboration agreements	4,207	2,859	1,348	47%
Revenue under supply agreements	12,766	1,469	11,297	*
Total revenue	94,049	56,191	37,858	67%
Operating expenses:				
Cost of goods sold	29,230	14,269	14,961	105%
Research and development[(1)]	27,297	9,738	17,559	180%
Selling, general and administrative[(1)]	193,303	170,167	23,136	14%
Total operating expenses	249,830	194,174	55,656	29%
Loss from operations	(155,781)	(137,983)	(17,798)	13%
Other income (expense), net:				
Interest income	4,709	8,065	(3,356)	(42%)
Interest expense	(7,472)	(56)	(7,416)	*
Total other (expense) income, net	(2,763)	8,009	(10,772)	(134%)
Net loss	$ (158,544)	$ (129,974)	$ (28,570)	22%

[*] Not meaningful

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

	Nine Months Ended September 30,	
	2026	2025
Research and development	$ 3,941	$ 1,991
Selling, general and administrative	23,999	14,367
Total	$ 27,940	$ 16,358

Revenues. Revenue for the nine months ended September 30, 2026 was $94.0 million, as compared to $56.2 million for the nine months ended September 30, 2025. Revenue for the nine months ended September 30, 2026 includes $77.1 million in net product revenues for sales of *neffy* in the United States, $12.8 million in revenue under supply agreements with partners, and $4.2 million in revenue for the achievement of the regulatory and commercial milestones and performance of development and regulatory services under the ALK Collaboration Agreement and the Seqirus Agreement. Revenue for the nine months ended September 30, 2025 includes $51.9 million in net product revenues for sales of *neffy,* $2.9 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 $1.5 million in revenue under supply agreements. The increase in revenue was primarily driven by higher global unit sales volumes of *neffy*.

Cost of Goods Sold. Cost of goods sold for the nine months ended September 30, 2026 was $29.2 million, as compared to $14.3 million for the nine months ended September 30, 2025. The increase of $15.0 million was primarily driven by direct and indirect product costs incurred in connection with U.S. product sales and the commercial launches of *neffy* in the U.K., EU, Japan, Australia, and China following regulatory approval in each market. Our global expansion also resulted in a corresponding increase in royalty expense on worldwide net product revenue.

Research and Development Expenses. Research and development expenses for the nine months ended September 30, 2026 were $27.3 million, as compared to $9.7 million for the nine months ended September 30, 2025. The increase of $17.6 million was primarily due to costs related to in-licensing of technology of $12.5 million, increases in stock-based compensation and other personnel-related expenses of $2.8 million, of which, $1.7 million related to accelerated vesting of previously unvested equity awards upon the termination of a former executive officer, clinical trial costs of $1.2 million, consulting fees of $0.5 million, and other research and development expenses of $0.6 million.

The following table summarizes our research and development expenses for the nine months ended September 30, 2026 and 2025 (in thousands):

	Nine Months Ended September 30,	
	2026	2025
Clinical and regulatory	$ 8,269	$ 5,073
Manufacturing and non-clinical development	19,028	4,665
Total	$ 27,297	$ 9,738

Selling, General and Administrative Expenses. Selling, general and administrative expenses for the nine months ended September 30, 2026 were $193.3 million, as compared to $170.2 million for the nine months ended September 30, 2025. The increase of $23.1 million was primarily due to increases in stock-based compensation expense of $9.6 million, of which $6.8 million relates to accelerated vesting of previously unvested equity awards upon the termination of former executive officers, personnel-related expense of $6.8 million, legal fees of $5.7 million, outside services of $3.1 million, and other general operating costs of $1.2 million, partially offset by decreases in marketing-related expenses of $1.7 million, conference and seminar expenses of $1.2 million, and audit, tax, and valuation fees of $0.7 million.

Other (Expense) Income, Net. Other expense, net for the nine months ended September 30, 2026 was $2.8 million, as compared to other income, net of $8.0 million for the nine months ended September 30, 2025. The change of $10.8 million was primarily due to interest expense related to our Credit Agreement of $7.4 million and decreases in net accretion of discounts on short-term investments of $2.6 million and interest income of $0.8 million from our cash, cash equivalents, and short-term investments.

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 funded our operations to date primarily with proceeds from net product sales, debt, licensing, supply and distribution arrangements, issuance of common stock, the Merger with Silverback, and private placement of convertible preferred stock. As of September 30, 2026, we had cash, cash equivalents, and short-term investments of $138.4 million.

Cash Flows

The following table summarizes our cash flows for the nine months ended September 30, 2026 and 2025 (in thousands):

	Nine Months Ended September 30,	
	2026	2025
Net cash and cash equivalents used in operating activities	$ (139,586)	$ (127,381)
Net cash and cash equivalents provided by investing activities	92,777	32,654
Net cash and cash equivalents provided by financing activities	31,113	103,467
Net (decrease) increase in cash and cash equivalents	$ (15,696)	$ 8,740

Operating Activities

During the nine months ended September 30, 2026, net cash used in operating activities was $139.6 million. This consisted primarily of a net loss of $158.5 million, an increase in our operating assets and operating liabilities of $32.5 million and $21.8 million, respectively, and non-cash charges of $29.6 million. The increase in our operating assets was attributable to increases in accounts receivable of $27.4 million and prepaid expenses and other assets of $2.6 million, and inventories of $2.6 million. The increase in our operating liabilities was primarily attributable to an increase in accounts payable and accrued expenses of $22.1 million. The non-cash charges consisted primarily of non-cash stock-based compensation of $27.9 million, other non-cash items of $2.5 million, and depreciation and amortization expense of $1.2 million, partially offset by $2.1 million in net accretion of discounts on short-term investments. While cash used in operating activities reflects our ongoing investment in the commercialization of *neffy*, we remain focused on allocating resources efficiently and managing operating expenditures in support of our strategic priorities.

During the nine months ended September 30, 2025, net cash used in operating activities was $127.4 million. This consisted primarily of a net loss of $130.0 million, an increase in our operating assets and operating liabilities of $40.3 million and $27.7 million, respectively, and non-cash charges of $15.1 million. The increase in our operating assets was due to increases in accounts receivable of $28.4 million and inventories of $12.3 million, partially offset by a decrease in prepaid expenses and other assets of $0.4 million. The increase in our operating liabilities was primarily attributable to an increase in accounts payable and accrued expenses of $27.9 million, partially offset by a decrease in contract liability of $0.3 million. The non-cash charges consisted primarily of non-cash stock-based compensation of $16.4 million, establishment of an inventory reserve of $2.2 million, and depreciation and amortization expense of $1.0 million, partially offset by $4.5 million in net accretion of discounts on short-term investments.

Investing Activities

During the nine months ended September 30, 2026, cash and cash equivalents provided by investing activities was $92.8 million. This consisted of proceeds from maturities and sales of short-term investments of $160.5 million, partially offset by purchases of short-term investments of $67.7 million. During the nine months ended September 30, 2025, the cash and cash equivalents provided by investing activities was $32.7 million. This consisted of maturities of short-term investments of $232.0 million, partially offset by purchases of short-term investments of $193.1 million, payments of milestone obligations under license agreements of $5.9 million, and purchases of property and equipment of $0.3 million.

Financing Activities

During the nine months ended September 30, 2026, the $31.1 million of cash and cash equivalents provided by financing activities was attributable to net proceeds from the funding of the Term B Loan under the Credit Agreement of $25.0 million, proceeds from exercises and issuance of common stock under the employee stock purchase plan of $3.4 million and proceeds from milestone obligations met and royalties earned under license agreements of $2.7 million. During the nine months ended September 30, 2025, the $103.5 million of cash and cash equivalents provided by financing activities was attributable to net proceeds from the funding of the Term A Loan under the Credit Agreement of $97.8 million, proceeds from stock option exercises and issuance of common stock under the employee stock purchase plan of $3.9 million, and proceeds from milestone obligations met under license agreements of $2.6 million, partially offset by payments of term loan issuance costs of $0.8 million.

Term Loans

On September 29, 2025 (the "Closing Date"), we entered into the Credit Agreement, as amended in July 2026, with the Administrative Agent and the Lenders, which provides for an aggregate principal amount up to $250.0 million of term loans (the "Term Loans") from the Lenders to us, including an initial tranche of $100.0 million under Term A Loan funded on the Closing Date, $25.0 million under Term B Loan funded on September 25, 2026, up to $25.0 million under Term C Loan will be made available at our election during the period commencing on and including the Closing Date and ending no later than the two-year anniversary of the Closing Date, subject to the satisfaction of a certain revenue requirement, and up to $100.0 million under Term D Loan, subject to the consent of the Lenders. The Term Loans will mature on the five-year anniversary of the Closing Date. The Credit Facility enhances our liquidity position and provides additional financial flexibility, subject to the satisfaction of certain customary conditions for future tranches and revenue-based requirements for the Term C Loan.

Future Funding Requirements

Based on our current operating plan, we believe that our existing cash, cash equivalents, short-term investments, revenues from product sales, cash proceeds from collaboration and out-licensing agreements, and additional borrowings on our Term Loans will be sufficient to meet our anticipated cash requirements until we achieve cash flow breakeven. In particular, we expect these resources 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:

- revenue received from commercial sales of *neffy*;
- the timing and amount of any milestone and royalty payments under collaboration, license, distribution, and related agreements;
- 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;
- 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 build and maintain a commercial infrastructure;
- our ability to service our current credit facility under the Credit Agreement and access, if and when needed, additional amounts of principal provided for under the Credit Agreement;
- 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. Subject to limited exceptions, we are prohibited from incurring additional indebtedness and entering into certain strategic and licensing transactions without the prior written consent of the Lenders pursuant to the Credit Agreement. 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.

Future Contractual Cash Obligations

The remaining unconditional purchase obligations related to the supply of raw materials totaled $55.6 million as of September 30, 2026. Our remaining obligations by year are as follows: 2026 ($9.4 million), 2027 ($11.8 million), 2028 ($13.8 million), and $2.9 million per year thereafter through 2035. Subsequent to period end, the Company entered into an amendment to certain arrangements related to the supply of raw materials, reducing our remaining unconditional purchase obligations by $23.9 million.

Under the ALK Co-Promotion Agreement, the remaining obligation totaled $18.2 million as of September 30, 2026. Our remaining obligations by year are as follows: 2026 ($4.4 million), 2027 ($10.7 million), 2028 ($1.8 million), and 2029 ($1.3 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.

Under the Credit Agreement, the outstanding principal of $125.0 million as of September 30, 2026 is due upon maturity on September 29, 2030. Estimated interest payments are calculated based on the outstanding principal, the applicable interest rate and expected timing of scheduled payments as of September 30, 2026. As of September 30, 2026, based on the interest rate in effect at such date, estimated remaining interest payments are $48.5 million, and our estimated remaining interest payments by year are as follows: 2026 ($3.1 million), 2027 ($12.1 million), 2028 ($12.2 million), 2029 ($12.1 million), and 2030 ($9.0 million).

Under the Aegis Agreement, remaining payment obligations are contingent upon our achievement of certain commercial milestones and totaled $9.0 million as of September 30, 2026. 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"). Under the Recordati Termination Agreement, we are required to make royalty payments to Recordati of up to €5.0 million in the aggregate from sales of *neffy* in the Recordati Territory, of which up to €4.1 million (approximately $4.7 million in U.S. dollars) remain as of September 30, 2026. Future royalty payment amounts are indeterminate since they depend on future revenues, which are uncertain.

In May 2026, we entered into a startup agreement (the "Startup Agreement") with a contract development and manufacturing organization for technology transfer and related services. We may be required to make future payments of up to $4.3 million, in the aggregate, upon the achievement of certain technology transfer and regulatory milestones and equipment purchases by the manufacturer, as well as reimbursement of pass-through costs for materials purchased on our behalf. These payments are contingent upon the occurrence of specified contractual events and, accordingly, the timing and amount of such payments are uncertain.

In July 2026, we entered into a license agreement with a strategic partner, pursuant to which we obtained exclusive worldwide rights to certain intellectual property. We may also be required to make future milestone payments. In addition, we may be required to pay tiered royalties on net sales of licensed products, subject to certain reductions, as specified in the license agreement. Future milestone and royalty payments are contingent upon the occurrence of specified contractual events and, accordingly, the timing and amount of such payments 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 September 30, 2026, 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 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 recognized under collaboration agreements and accruals for variable consideration of product revenue. 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 nine months ended September 30, 2026, 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 Estimates" in our Annual Report on Form 10-K filed with the SEC on March 9, 2026 and under the heading "Use of Estimates" in 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 about recent accounting pronouncements, the timing of their adoption, and our assessment, if any, of their potential impact on our financial condition and results of operations.

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 September 30, 2026. 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 September 30, 2026, 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 September 30, 2026 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 9, 2026.

Risks Related to Our Business

We are highly dependent on the successful commercialization of neffy. To the extent neffy and EURneffy are 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. Currently, *neffy* has been approved for the emergency treatment of allergic reactions (anaphylaxis) in the United States, EU, United Kingdom, Japan, and Australia (in the case of *neffy* 2 mg and 1 mg), and China and Canada (in the case of *neffy* 2 mg). 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 abroad through our collaboration partners. 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. 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 receiving 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 over 10,000 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; 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. For example, the U.S. Department of Health and Human Services ("HHS") imposes rebates on many Medicare Part B and Medicare Part D products to penalize price increases that outpace inflation on an annual basis. In addition, HHS has been empowered to negotiate the price of certain single-source drugs that have been on the market for at least seven (7) years covered under Medicare as part of the Medicare Drug Price Negotiation Program. Each year up to twenty (20) products will be selected by HHS for the Medicare Drug Price Negotiation Program. Products subject to the Medicare Drug Price Negotiation Program are expected to experience a significant reduction in reimbursement from the Medicare program on a per unit basis. If coverage and adequate reimbursement are not available, or are available only to limited levels, we may not be able to successfully commercialize *neffy* and any product candidates for which we receive approval, which could have an adverse effect on our operating results and our overall financial condition. 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. Existing products have name recognition, are marketed by companies with established commercial infrastructures, and are marketed with greater financial, technical and personnel resources than we have. We also 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 (Anaphylm) and after receiving a Complete Response Letter from the FDA in January 2026 identifying deficiencies relating primarily to packaging and administration, resubmitted its new drug application, which the FDA has accepted for review with a target action date in March 2027. 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. 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 and patent exclusivity for the reference listed drug in the Orange Book has expired. 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. We have 8 patents with claims covering *neffy* 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. We received paragraph IV certification notice letters from Lupin in August 2025 and February 2026, providing notification to us that Lupin submitted an ANDA to the FDA seeking approval to manufacture, use, or sell a generic version of *neffy* 2 mg and 1 mg, respectively. In August 2025 and in February 2026, we separately filed lawsuits against Lupin in the United States District Court for the District of New Jersey, alleging infringement of certain of our patents and seeking a permanent injunction preventing market entry of a generic product from Lupin prior to the expiry of such patents. We also received a paragraph IV certification notice letter from Cipla in March 2026, providing notification to us that Cipla submitted an ANDA to the FDA seeking approval to manufacture, use, or sell a generic version of *neffy* 1 mg and 2 mg. In April 2026, we filed a lawsuit against Cipla in the United States District Court for the District of New Jersey, alleging infringement of certain of our patents and seeking a permanent injunction preventing market entry of a generic product from Cipla prior to the expiry of such patents. See Note 9 – Commitments and Contingencies to the consolidated financial statements in this Form 10-Q for additional discussion. There is no guarantee that we will be successful in our lawsuits against Lupin and Cipla. Patent litigation is expensive and time consuming, requires significant resources, may absorb significant time of our management and has an unpredictable outcome. If we are unsuccessful in the lawsuit or if a generic competitor is found not to infringe our patents, the resulting generic competition will likely negatively affect our business, financial condition and results of operations.

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.

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. The changes introduced by the Pharma Package (as defined below) will amend exclusivity rules: the eight-year regulatory data protection period would be retained, followed by one year of market protection. Additional periods of market protection may be available where specified conditions are met, subject to a maximum combined protection period of eleven years. Comparable regimes to those in the U.S. 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, the EU, and other foreign jurisdictions, including but not limited to the United Kingdom, China, Japan, Australia, and Canada, 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, pricing and reimbursement approvals may be required before a product can be commercially launched or reimbursed in that jurisdiction, which may delay market access following receipt of marketing authorization. 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 Federal Food, Drug, and Cosmetic Act. 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, institutional review boards ("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 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 for the emergency treatment of allergic reactions (anaphylaxis) in the United States, EU, United Kingdom, Japan and Australia (in the case of *neffy* 2 mg and 1 mg), and China and Canada (in the case of *neffy* 2 mg), 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, impose restrictions on us, *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 one or more 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 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 or 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. For example, threat actors may use an initial compromise of one part of our environment to gain access to other parts of our environment, or leverage a compromise of our networks or systems to gain access to the networks or systems of third parties with whom we work, such as through phishing or supply chain attacks.

Remote work 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 or heightened 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 the third-parties with whom we work 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 the third-parties with whom we work 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 impersonated 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. Relatedly, our contracts with third parties with whom we work may limit the types and/or amounts of damages that we can recover from those third parties, even where the third party is responsible for a privacy or cybersecurity incident or violation. 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. Additionally, our sensitive data could be leaked, disclosed, or revealed as a result of or in connection with the use of generative AI technologies by our employees, personnel, or vendors, which may constitute a cybersecurity incident or data breach, and which may adversely affect our business, operations, reputation, or financial condition.

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 European 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 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 FDA and other regulatory agencies actively enforce the laws and regulations relating to the promotion of our products.*

If we are found to have improperly promoted uses of our products in the U.S., or in other countries, we may become subject to significant liability. Such enforcement has become more common in the industry. The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription drug and device products. In particular, a product may not be promoted in a manner that results in the company making false or misleading claims. If the FDA determines that our or our partners' public disclosures, promotional materials or training constitutes promotion of false or misleading claims, it could request modifications to disclosure policies, training or promotional materials or subject us or our partners to regulatory or enforcement actions, including the issuance of an untitled letter, a Warning Letter, injunction, seizure, civil fine or criminal penalties and a requirement for corrective advertising, including "Dear Doctor" letters. On September 9, 2025 and January 23, 2026, we received untitled letters from the HHS regarding our television advertisements. The letters raised concerns from the FDA that our advertisements made false or misleading claims, including with respect to suggesting the avoidance of injectable treatments for emergency treatment of allergic reactions and reducing needle-fear concerns. We submitted responses to the FDA regarding our plan to address its concerns. The FDA completed an evaluation of our responses and issued two close-out letters in June 2026 stating that it appears that we have addressed all the concerns contained in each of the untitled letters. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our or our partners' promotional or training materials to constitute promotion of false or misleading claims which could result in significant civil, criminal and/or administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from government-funded healthcare programs, such as Medicare and Medicaid, or comparable foreign programs, contractual damages, reputational harm, increased losses and diminished profits and the curtailment or restructuring of operations, any of which could adversely affect our or our partners' ability to operate and, thus, adversely impact our business and our financial results. The FDA or other enforcement authorities could also request that we enter into a consent decree or a corporate integrity agreement or seek a permanent injunction against us under which specified promotional conduct is monitored, changed, or curtailed. If we cannot successfully manage the promotion of our product in the U.S. or in other countries, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

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 have 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 remain in the early stages of our commercialization efforts, 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 loss for the nine months ended September 30, 2026 was $158.5 million. As of September 30, 2026, we had an accumulated deficit of $453.1 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;
- incur and pay the interest expense under the Credit Agreement;
- 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, cash equivalents, short-term investments, revenues from product sales, cash proceeds from collaboration and out-licensing agreements, and additional borrowings on our Term Loans will be sufficient to meet our anticipated cash requirements until we achieve cash flow breakeven. However, we may not achieve cash flow breakeven within the timeline we anticipate, in which case the foregoing resources by themselves may not be sufficient to support our cash requirements prior to achieving cash flow breakeven. In addition, due to the uncertainties discussed below, our cash requirements may increase beyond what we currently project, in which case our resources may not be sufficient by themselves to support our cash requirements prior to achieving cash flow breakeven. We expect to incur significant expenses related to commercialization, such as sales force compensation, cost of goods sold, marketing, medical affairs, 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. Due to these uncertainties, we may not be able to accurately 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, and to support our business operations.

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;
- our ability to service our current credit facility under the Credit Agreement and access, if and when needed, additional amounts of principal provided for under the Credit Agreement;
- 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, potential draw-downs under the Credit Agreement, each subject to its own conditions, 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.*

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. 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 Offering℠ 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. On September 29, 2025, we entered into the Credit Agreement, which subjects us to a number of restrictive covenants, including among others (subject to certain qualifications and exceptions), limitations on our ability to incur additional debt; create liens and encumbrances; merge, dissolve, liquidate or consolidate; make acquisitions, investments, or advances, dispose of or transfer assets, pay dividends, and enter into transactions with affiliates. 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.

Our Credit Agreement contains conditions and restrictions that limit our flexibility in drawing on the additional funds thereunder and in operating our business. We may be required to repay our outstanding indebtedness under the Credit Agreement earlier than we expect and possibly at a time when we do not have sufficient capital to meet such obligations if an event of default occurs (including a material adverse change affecting our business), which could have a material adverse effect on our financial condition and results of operations.*

As of September 30, 2026, we had an outstanding principal balance under our Credit Agreement of $125.0 million. We may also draw, at our election, up to an additional (i) $25.0 million under the Term C Loan which will be made available at our election during the period commencing on and including the Closing Date and ending no later than the two-year anniversary of the Closing Date, subject to the satisfaction of a certain revenue requirement under the Credit Agreement, and (ii) $100.0 million under the Term D Loan, subject to the consent of the Lenders. If we are unable to achieve the revenue requirement by the applicable date, we would be unable to borrow additional funds under the Term C Loan under the Credit Agreement, which could negatively impact our ability to fund our operations.

Furthermore, the Credit Agreement contains various covenants that limit or restrict our ability to engage in specified types of transactions. Subject to certain exceptions, these covenants limit our ability to, among other things, incur additional indebtedness; create liens and encumbrances; merge, dissolve, liquidate or consolidate; make acquisitions, investments, or advances, dispose of or transfer assets, pay dividends, and enter into transactions with affiliates. The Credit Agreement also contains a minimum liquidity covenant that requires us to maintain at all times at least $25.0 million of unrestricted cash and cash equivalents. These covenants may limit our flexibility in operating our business and our ability to take actions that might be advantageous to us and our shareholders. In the case of a continuing event of default under the Credit Agreement, including an event of default that arises due to our failure to comply with the covenants (subject to applicable notice and grace periods), the Lenders under the Credit Agreement could elect to declare all amounts outstanding to be immediately due and payable, proceed against the collateral in which we granted to the Lenders a security interest, or otherwise exercise the rights of a secured creditor. We are currently in compliance with the Credit Agreement covenants.

We cannot assure you that we will maintain a level of cash reserves or cash flows from operating activities sufficient to permit us to pay the principal, premium, if any, and interest on our existing or future indebtedness. If our cash flows and capital resources are insufficient to fund our debt service obligations, we may be forced to reduce or delay capital expenditures, sell assets or operations, seek additional capital or restructure or refinance our indebtedness. We cannot assure you that we would be able to take any of these actions, or that these actions would permit us to meet our scheduled debt service obligations. We may not have sufficient funds or may be unable to arrange for additional financing to repay our indebtedness or to make any accelerated payments, and the Lenders could seek to enforce security interests in the collateral securing such indebtedness, which would harm our business and financial condition. We cannot be certain that future working capital, borrowings or equity financings will be available to repay or refinance our debt to the Lenders or any other debt we may incur in the future. To the extent we are required to use cash from operations or the proceeds of any future financing to service our indebtedness instead of funding working capital, capital expenditures or other general corporate purposes, we will be less able to plan for, or react to, changes in our business, industry and in the economy generally. This may place us at a competitive disadvantage compared to our competitors that have less indebtedness.

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 ("OBBBA") 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 in a taxable year is limited to 80% of taxable income in such year. 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 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.

The FDA and other regulatory agencies also closely regulate and monitor the post-approval marketing and promotional claims that may be made about drug products to ensure that the product is not promoted in a manner that results in the company making false or misleading claims. If the FDA or other agency determines that any of our advertising or promotional claims are misleading, not substantiated or not permissible, we may be subject to enforcement actions, including warning letters, and we may be required to revise our promotional claims and make other corrections or restitutions.

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. Since its enactment, there have been amendments and judicial, executive and Congressional challenges to certain aspects of the ACA. For example, on July 4, 2025, the OBBBA was signed into law, which narrowed access to ACA marketplace exchange enrollment and declined to extend the ACA enhanced advanced premium tax credits that expired at the end of 2025, which, among other provisions in the law, are anticipated to reduce the number of Americans with health insurance. The OBBBA also is expected to reduce Medicaid spending and enrollment by implementing work requirements for some beneficiaries, capping state-directed payments, reducing federal funding, and limiting provider taxes used to fund the program. Congress is considering proposed legislation intended to further reduce healthcare costs with alternatives to replace the expired ACA subsidies. It is unclear how any such challenges, and the healthcare reform measures of the current 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. For example, additional changes include aggregate reductions to Medicare payments to providers 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.

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. For example, the current administration has announced agreements with certain pharmaceutical companies that require the drug manufacturers to offer, through a direct-to-consumer platform (TrumpRx), U.S. patients and Medicaid programs prescription drug Most-Favored-Nation pricing equal to or lower than those paid in other developed nations, with additional mandates for direct-to-patient discounts and repatriation of foreign revenues. Other recent actions include, for example: (1) directing agencies to reduce agency workforce and cut programs; (2) 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; (3) imposing tariffs on certain imported pharmaceutical products; and (4) as part of the Make America Healthy Again Commission's recent Strategy Report, working across government agencies to increase enforcement on direct-to-consumer pharmaceutical advertising. Additionally, the current administration recently called on Congress to enact "The Great Healthcare Plan," to codify and expand Most-Favored Nation pricing, lower government subsidies to private insurance companies, increase healthcare price transparency, expand pharmaceutical drugs available for over-the-counter purchase, and enact restrictions on pharmacy benefit manager payment methodologies, among other things. These actions and policies may significantly reduce U.S. drug prices, potentially impacting manufacturers' global pricing strategies and profitability, while increasing their operational costs and compliance risks. 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. In June 2024, in Loper Bright Enterprises v. Raimondo, the U.S. Supreme Court greatly reduced judicial deference to regulatory agencies, which could increase successful legal challenges to federal regulations affecting our operations. Congress may introduce and ultimately pass healthcare related legislation that could, among others, impact the drug approval process, modify the Medicare Drug Price Negotiation Program, expand orphan drug exclusions, 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 is 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 development plans.

In addition, on December 11, 2025, the European Parliament and the Council reached a provisional political agreement on the Pharma Package ("Pharma Package"), which comprises a new directive and regulation intended to replace significant portions of the existing EU pharmaceutical framework. The reform encompasses a broad range of measures, including, among other things, changes to regulatory data and market protection periods, intellectual property exemptions intended to facilitate earlier generic and biosimilar market entry, marketing authorization procedures, and measures relating to the availability and supply of medicinal products. Under the agreed framework, medicinal products would generally benefit from eight years of regulatory data protection and one year of market protection, with opportunities to obtain additional market protection if specified conditions are satisfied. The Council formally adopted its first-reading position on September 28, 2026. The legislation remains subject to formal adoption by the European Parliament, following which it will be published in the Official Journal of the European Union. The new framework is expected to enter into force in late 2026 and to be subject to transitional arrangements, with general application not anticipated before 2028. Any decrease in data and market exclusivity opportunities for our current or future intranasal epinephrine technology product candidates in the EU could make them open to generic or biosimilar competition earlier than is currently the case with a related reduction in reimbursement status, and adversely affect the commercial prospects of any product candidates we are able to commercialize in the EU. Other legislative initiatives include the proposed Supplementary Protection Certificate Regulation revision, the proposed Critical Medicines Act (for which a provisional political agreement was reached in May 2026), the proposed Biotech Act, and the proposal to amend the Medical Devices Regulation.

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, 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, government shutdowns and 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 addition, medicinal products may be subject to Health Technology Assessments ("HTA") at the EU and national levels, which is time-consuming and costly. This HTA is a multidisciplinary process that summarizes information regarding the medical, patient and social aspects, as well as economic and ethical issues, related to the use of a health technology. 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. At the EU level, on January 12, 2025, Regulation No 2021/2282 on Health Technology Assessment ("HTA Regulation"), entered into application through a phased implementation. The Regulation initially applies to new active substances for oncology and Advanced Therapy Medicinal Products. It will be expanded to orphan medicinal products in January 2028, and to all centrally authorized medicinal products as of 2030. Select high-risk medical devices also came into scope in 2026. The HTA Regulation is intended to boost cooperation among Member States in assessing health technologies, including new medicinal products. The Regulation establishes a framework for EU-level joint clinical assessments, joint scientific consultations, and the early identification of emerging health technologies. It enables EU Member States to use common tools, methodologies, and procedures and requires them to take into account EU-level joint clinical assessment reports for the clinical components of their national HTA evaluations. Individual EU Member States will 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 play a primary role in the recommendation and prescription of products for which we receive marketing approval, including *neffy*, and will play a similar role for any product candidates for which we obtain marketing approval in the future. 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;
- the Health Insurance Portability and Accountability Act ("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 manufacturers 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; state laws that require certain regulatory licenses to manufacture or distribute products commercially and/or the registration of pharmaceutical sales representatives in the jurisdiction; 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; and laws that require biotechnology companies to report information on the pricing of certain drug products. 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, and in certain cases has led, 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. On July 10, 2026, Jonico, Inc. d/b/a Berlin Pharmacy filed a putative class action lawsuit against us and our wholly owned subsidiary, ARS Pharmaceuticals Operations, Inc., in the U.S. District Court for the Western District of Pennsylvania, Civil Action No. 3:26-cv-01339. The complaint alleges that we sent, or caused to be sent, facsimile advertisements promoting *neffy* to pharmacies, without the prior express invitation or permission of the recipients and without the requisite opt-out notices, in violation of the Telephone Consumer Protection Act, 47 U.S.C. § 227 (the "TCPA"). We moved to dismiss the complaint on September 28, 2026, and the plaintiff filed an amended complaint on October 19, 2026, asserting the same TCPA claim as the original complaint. Although we dispute these allegations and intend to vigorously defend ourselves, the outcome is uncertain and the litigation could ultimately result in a material adverse effect on our operations and financial condition.

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 ("CCPA") applies to personal information of consumers, business representatives, and employees who are California residents, and requires businesses to provide specific disclosures in privacy notices and honor requests of such individuals to exercise certain privacy rights. The CCPA provides for fines and allows private litigants affected by certain data breaches to recover significant statutory damages. Although the CCPA and other comprehensive U.S. state privacy laws exempt some data processed in the context of clinical trials, these developments may further complicate compliance efforts and increase compliance costs and potential liability for us and the third parties with whom we work. 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 Personal Information Protection Law 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 the ordinary course of business, we transfer personal data from Europe and other jurisdictions to the United States or other countries. However, evolving privacy and security laws and regulations may impact our ability to transfer personal data from Europe and other jurisdictions to the United States or other countries, or may require us to take additional actions in order to continue or resume such cross-border data flows (such as implementing new processes or additional safeguards). 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 or have already adopted similarly stringent 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 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 restrictions on certain data transactions involving countries of concern (e.g., China, Russia, Iran) and covered persons (i.e., individuals and entities who are designated as such by the U.S. Attorney General or considered "foreign persons" and are majority owned by, organized under the laws of, a primary resident in, or a contractor of, a covered person or country of concern, as applicable) 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 engage in transactions or agreements. with certain third parties.

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.

Further, our employees and personnel, and those of any third parties involved in our operations, including vendors, service providers, collaborators, contractors, and consultants, develop and/or use artificial intelligence or machine learning technologies, including generative artificial intelligence or automated decision-making tools (collectively, "AI technologies") in the course of performing work for us. The disclosure and use of personal data in AI technologies is subject to various privacy laws and other privacy obligations and the disclosure and use of sensitive data in AI technologies may subject us to various legal, contractual, and reputational risks and liabilities. Governments have passed and are likely to pass additional laws and regulations regulating AI technologies. Our use of this technology could result in additional compliance costs, regulatory investigations and actions, and lawsuits. If we are unable to use or limited in our use of AI technologies, it could make our business less efficient and result in competitive disadvantages.

However, use of AI technologies in connection with our confidential, proprietary, or otherwise sensitive information, including personal data, may result in leaks, disclosure, or otherwise unauthorized or unintended access to or use or other processing of such information, including incorporation of such information into the applicable AI technology system or use of such information to further refine and train the AI technology models. Any such access or use, or any improper or inappropriate use, of AI technologies could, for example, reveal trade secrets or other confidential information that may enable third parties to replicate or improve upon our technologies and programs, advance their technologies or programs more rapidly than we do, or otherwise negatively impact the value of, or our ability to obtain or maintain, intellectual property rights. Access to and use and other processing of personal data may subject us to risks and potential liability and obligations under applicable data privacy laws. Further, we may use the output of AI technologies in our technologies, programs, and other aspects of our business, and such output could incorporate third-party intellectual property, or we may otherwise be unable to own, protect, further develop, or ultimately use such output, which could significantly harm our business to the extent such technologies, programs, or other aspects of our business rely upon such output. Such output may also be false, non-sensical, biased, or otherwise harmful to our operations and business if incorporated therein. Further, our ability to use AI technologies or further develop or use its output may depend on access to specific third-party software and infrastructure, such as processing hardware or third-party artificial intelligence models, and we cannot control the availability or pricing of such software and infrastructure, especially in a highly competitive environment. We may also face novel and urgent cybersecurity risks and emerging ethical risks relating to the use of AI technologies, which could adversely affect our operations, assets, including intellectual property and data, and reputation, as well as those of any third parties involved in our operations. Use of AI technologies in general, and generative AI in particular, in our business could subject us to additional costs and expenses, litigation, regulatory actions and investigations, and other negative consequences. There is significant uncertainty with respect to the nature of the laws and regulations that have been and may in the future be adopted, including how such laws and regulations will be interpreted and applied, both within and outside of the U.S., with respect to the use of AI technologies in general, and generative AI in particular, including the ownership of or right to use the output of generative AI. We may need to expend significant resources to modify and maintain our business practices to comply with such laws and regulations and to otherwise ensure appropriate and lawful use of artificial intelligence technologies, including generative AI and its output, in our technologies, programs, and other aspects of our business.

Obligations related to data privacy and security (and consumers' data privacy expectations) 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 or restrictions 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. Unless and until we can secure alternative sources, drug product manufacturing and final packaging, our dependence on Renaissance 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 some 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.

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 perform 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. Failure to obtain sufficient 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. We may, in the future, 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 September 30, 2026 we own, co-own or exclusively license eight issued U.S. patents, granted patents in each of Australia, Canada, China, the Eurasian Patent Organization, Hong Kong, Israel, Japan, Mexico, Singapore, South Korea, Ukraine, and over thirty member states of the European Patent Organization, including the United Kingdom, directed to *neffy* and its uses, among other things, five pending U.S. patent applications, one pending international patent application and twenty-three pending foreign patent applications directed to *neffy* and its uses, among other things, and two pending U.S. provisional patent applications directed to formulations of epinephrine and its derivatives and methods of their use, 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. Increased patent-related fees from the USPTO and patent offices in foreign countries may significantly increase our operating costs and limit our ability to protect our intellectual property. These increased costs may require us to be more selective in the inventions we choose to patent or the jurisdictions in which we seek protection. If we are unable to adequately fund our patent prosecution and maintenance, or if the costs of defending our patents against third-party challenges become prohibitive, our competitive position could be weakened. Furthermore, these fee structures may incentivize our competitors to adopt more aggressive litigation strategies, potentially increasing our legal expenses and the risk of being unable to exclude others from using our proprietary technology. 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, geopolitical actions in the United States and in foreign countries 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, 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 injunctions. 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 own, 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 own, 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. 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. For example, recent shifts in USPTO policy and increased discretionary denials may restrict our ability to challenge third-party patents, potentially increasing our litigation costs and risk of infringement liability. Our ability to use *inter partes* review (IPR) and other post-grant proceedings to challenge the validity of third-party patents is subject to evolving procedural rules and increased administrative discretion. If we are unable to use the Patent Trial and Appeal Board to invalidate questionable patents, we may face increased litigation expenses in slower and more costly district court venues. These policy shifts could result in our inability to invalidate patents asserted against us by third parties, our infringement liability, our increased legal expenses, the need to pay significant licensing fees by us, being enjoined from selling certain our products and could adversely affect our product development timelines, market share, and overall financial condition. 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.

Also, there may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our current and future products and product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our current or future products or product candidates may infringe.

In addition, third parties may obtain patent rights in the future and claim that use of our technologies infringes upon their rights. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our product or product candidates, any molecules formed during the manufacturing process, methods of treating certain diseases or conditions that we are pursuing with our product or product candidates, our formulations including combination therapies, or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product or product candidate unless we obtained a license under the applicable patents, or until such patents expire. Such a license may not be available on commercially reasonable terms or at all. In addition, we may be subject to claims that we are infringing other intellectual property rights, such as trademarks or copyrights, or misappropriating the trade secrets of others, and to the extent that our employees, consultants or contractors use intellectual property or proprietary information owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

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 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, co-own or have exclusively 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 intranasal 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*. Upon approval of *neffy* by the FDA, we listed 8 patents with claims covering *neffy* 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. We received paragraph IV certification notice letters from Lupin in August 2025 and February 2026, providing notification to us that Lupin submitted an ANDA to the FDA seeking approval to manufacture, use, or sell a generic version of *neffy* 2 mg and 1 mg, respectively. In August 2025 and in February 2026, we separately filed lawsuits against Lupin in the United States District Court for the District of New Jersey, alleging infringement of certain of our patents and seeking a permanent injunction preventing market entry of a generic product from Lupin prior to the expiry of such patents. We also received a paragraph IV certification notice letter from Cipla in March 2026, providing notification to us that Cipla submitted an ANDA to the FDA seeking approval to manufacture, use, or sell a generic version of *neffy* 1 mg and 2 mg. In April 2026, we filed a lawsuit against Cipla in the United States District Court for the District of New Jersey, alleging infringement of certain of our patents and seeking a permanent injunction preventing market entry of a generic product from Cipla prior to the expiry of such patents. See Note 9 – Commitments and Contingencies to the consolidated financial statements in this Form 10-Q for additional discussion. There is no guarantee that we will be successful in our lawsuits against Lupin and Cipla. Patent litigation is expensive and time consuming, requires significant resources, may absorb significant time of our management and has an unpredictable outcome. If we are unsuccessful in the lawsuit or if a generic competitor is found not to infringe our patents, the resulting generic competition will likely negatively affect our business, financial condition and results of operations. In general, 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 issuing 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 many foreign jurisdictions. 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 203 full-time employees and 3 part-time employees as of September 30, 2026. 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;
- perceived and actual risks associated with our Credit Agreement;
- 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.

Securities-related class action litigation could divert our resources and management's attention and harm our business.*

Securities-related class action lawsuits and/or derivative lawsuits have often been brought against companies, including biotechnology and biopharmaceutical companies, that experience volatility in the market price of their securities. Such lawsuits and any other related lawsuits are subject to inherent uncertainties, and the actual defense and disposition costs will depend upon many unknown factors. The outcome of such lawsuits is necessarily uncertain. We could be forced to expend significant resources in the defense of the pending lawsuit and any additional lawsuits, and we may not prevail. On August 5, 2026, a purported stockholder filed a securities class action complaint in the U.S. District Court for the Southern District of California against us and certain of our current and former officers. The complaint alleges that defendants violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, and Rule 10b-5 promulgated thereunder, by making material misstatements or omissions concerning our expected timeline for expanded insurance coverage for *neffy*. The outcome of this litigation is uncertain and could ultimately result in a material adverse effect on our operations and financial condition. If we are not successful in defense of these claims, we may have to make significant payments to, or other settlements with, our stockholders and their attorneys. Even if such claims are not successful, the litigation will result in additional costs, which could be substantial, and could divert our resources and management's attention from the operation of our business, which could have a material adverse effect on our business, operating results or financial condition. We may also become subject to additional securities class action or related derivative litigation in the future. Any such litigation could also harm our reputation.

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 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 or otherwise, the trading price of our common stock could decline. Furthermore, our former executive officers continue to hold a significant number of shares of our common stock. Sales of a substantial portion of these shares, or the perception that such sales may occur, could cause the market price of our common stock to decline and could also increase the volatility of our stock price and impair our ability to raise capital through future equity offerings. We are not able to predict the effect that sales, or the perception that such sales may occur, may have on the prevailing market price of our common stock.

General Risk Factors

Geopolitical conditions may have serious adverse consequences on our business, financial condition and stock price.

International and geopolitical events could also have a serious adverse impact on our business. While we cannot predict the broader consequences, the conflict and retaliatory and counter-retaliatory actions associated with geopolitical conflicts 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 September 30, 2026, our officers (as defined in Rule 16a-1(f) under the Exchange Act) adopted 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*						
Former Chief Executive Officer	Termination[3]	August 28, 2026	X		1,050,000	May 14, 2027
Richard Lowenthal, on behalf of Lowenthal-Tanimoto Family Trust U/A DTD 4/3/2006*						
Former Chief Executive Officer	Termination[3]	August 28, 2026	X		1,050,000	May 14, 2027
Sarina Tanimoto, on behalf of Sarina Tanimoto Charitable Remainder UniTrust Dated January 7, 2020*						
Former Chief Medical Officer	Termination[3]	August 28, 2026	X		1,050,000	May 14, 2027
Sarina Tanimoto, on behalf of Lowenthal-Tanimoto Family Trust U/A DTD 4/3/2006*						
Former Chief Medical Officer	Termination[3]	August 28, 2026	X		1,050,000	May 14, 2027
Eric Karas		August 18,				January 29,
Former Chief Commercial Officer	Termination[4]	2026	X		100,000	2027
Alexander Fitzpatrick		August 30,				December 31,
Chief Legal Officer	Termination[5]	2026	X		103,355	2026
Alexander Fitzpatrick		September 4,				September 1,
Chief Legal Officer	Adoption	2026	X		454,652	2028

(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 termination, as described in Rule 10b5-1(c) under the Exchange Act, of a trading plan adopted on May 21, 2025, that was intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) under the Exchange Act.

(4) Represents the termination, as described in Rule 10b5-1(c) under the Exchange Act, of a trading plan adopted on December 11, 2025, that was intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) under the Exchange Act.

(5) Represents the termination, as described in Rule 10b5-1(c) under the Exchange Act, of a trading plan adopted on December 5, 2025, that was intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) 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(c) 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*	First Amendment to Credit Agreement, dated July 1, 2026, by and between ARS Pharmaceuticals Operations, Inc., ARS Pharmaceuticals, Inc. and certain of its subsidiaries from time to time party thereto, the lenders from time to time party thereto, and RA Capital Agency Services, LLC.
10.2+	Release Agreement, effective as of July 15, 2026, by and between the Company and Richard Lowenthal.
10.3+	Release Agreement, effective as of July 15, 2026, by and between the Company and Sarina Tanimoto.
10.4+‡	Executive Employment Agreement, dated August 12, 2026, by and between the Company and Margaret Smith.
10.5*	Side Letter to Co-Promotion Agreement, dated August 31, 2026, by and between the Company and ALK-Abelló, Inc.
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

* 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.

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

\# 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: November 5, 2026

By: /s/ Donn Casale
Donn Casale
President and Chief Executive Officer
(Principal Executive Officer)

Date: November 5, 2026

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

Exhibit 10.1

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.

FIRST AMENDMENT TO CREDIT AGREEMENT

This **FIRST AMENDMENT TO CREDIT AGREEMENT** (this "Amendment") is made and entered into as of July 1, 2026 by and among **ARS PHARMACEUTICALS OPERATIONS, INC.**, a Delaware corporation (the "Borrower"), **ARS PHARMACEUTICALS, INC.**, a Delaware corporation ("Parent"), as a Guarantor, the Lenders party hereto and **RA CAPITAL AGENCY SERVICES, LLC**, as administrative agent for the Lenders (together with its Affiliates, successors, transferees and assignees, the "Administrative Agent").

WHEREAS, the Borrower, Parent, the Lenders and the Administrative Agent entered into a Credit Agreement, dated as of September 29, 2025 (the "Credit Agreement"), pursuant to which the Lenders have extended credit to the Borrower on the terms set forth therein;

WHEREAS, pursuant to Section 12.01 of the Credit Agreement, the Credit Agreement may be amended by an instrument in writing signed by the Borrower or the applicable Loan Party and the Required Lenders and acknowledged by the Administrative Agent;

WHEREAS, the undersigned Lenders comprise all Lenders (including the Required Lenders) under the Credit Agreement; and

WHEREAS, the Borrower, Parent and the Lenders desire to amend certain provisions of the Credit Agreement as provided in this Amendment.

NOW, THEREFORE, in consideration of the mutual agreements herein contained, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto agree as follows:

1. **Definitions; Loan Document**. Capitalized terms used herein without definition shall have the meanings assigned to such terms in the Credit Agreement. This Amendment shall constitute a Loan Document for all purposes of the Credit Agreement and the other Loan Documents.

2. **Amendments to Section 1.1**.

(a) Section 1.01 of the Credit Agreement is hereby amended by inserting the following new defined terms therein in the proper alphabetical order:

"First Amendment" means the First Amendment to the Agreement, dated as of the First Amendment Effective Date, among Parent, the Borrower, the Lenders party thereto and the Administrative Agent.

"First Amendment Effective Date" means July 1, 2026.

"[***] License" means the exclusive license granted to the Borrower under the Licensed Technology to Exploit the Licensed Products (as each such term is defined under the [***] License Agreement) pursuant to the [***] License Agreement.

"[***] License Agreement" means that certain License Agreement, dated as of the First Amendment Effective Date, by and between the Borrower and [***], as amended, supplemented, or otherwise modified in accordance with the terms hereof from time to time.

"[***] Milestone Payment" has the meaning given to the term "Milestone Payment" in the [***] License Agreement.

"[***] Royalty" has the meaning given to the term "Royalty" in the [***] License Agreement.

"[***] Upfront Payment" has the meaning given to the term "Upfront Payment" in the [***] License Agreement.

(b) The definition of "Key Contracts" in Section 1.01 of the Credit Agreement is hereby amended by (i) replacing the phrase " and (b)" with the phrase ", (b)" and (ii) inserting the phrase "and (c) the [***] License Agreement." at the end of the first sentence thereof.

(c) The definition of "Loan Documents" in Section 1.01 of the Credit Agreement is hereby amended by inserting "the First Amendment," immediately after the phrase "each Note," in such definition.

(d) The definition of "Permitted Acquisition" in Section 1.01 of the Credit Agreement is hereby amended by replacing the phrase "or (y)" in such definition with the phrase ", (y) such Acquisition is the [***] License or (z)".

3. **Amendment to Section 7.02**. Section 7.02 of the Credit Agreement is hereby amended by inserting a new clause (o) immediately after clause (n) of such section as follows:

"(o) concurrently with the delivery of the financial statements referred to in Sections 7.01(a) and (b), (x) an update on budgeted expenses to actual expenses of Parent and its Subsidiaries, and (y) written commentary providing a good faith estimate on any then-expected material changes to the budget, including a description of the key risks that could reasonably be expected to cause or result in material deviations from the business plan over the next two (2) quarters."

4. **Amendment to Section 8.03**. Section 8.03(k) of the Credit Agreement is hereby amended by replacing the phrase "or (ii)" in such clause with the phrase ", (ii) obligations in respect of the [***] Upfront Payment, [***] Milestone Payments and [***] Royalty in each case as required by and in accordance with the terms of the [***] License Agreement (as such [***] License Agreement exists as of the First Amendment Effective Date or as amended, supplemented or otherwise modified to the extent permitted under Section 8.12), or (iii)".

5. **Amendment to Section 8.12**. Section 8.12(e) of the Credit Agreement is hereby amended by inserting the phrase "(provided that any amendment to the [***] License Agreement that increases the amount of any [***] Milestone Payment or [***] Royalty shall be deemed to be adverse to the Lenders in a material respect)" at the end of clause (ii) thereof.

6. **Conditions to Effectiveness of Amendment**. This Amendment shall become effective upon receipt by the Administrative Agent, the Lenders, the Borrower and Parent of a counterpart signature of the other to this Amendment duly executed and delivered by the Required Lenders, the Administrative Agent, Parent and the Borrower.

7. **Post Closing**. The Borrower agrees to deliver to the Administrative Agent and the Lenders, immediately after entering into this Amendment, duly executed copies of (i) the [***] License Agreement and (ii) that certain Common Interest Agreement to be entered into by and between the Borrower and [***], including all exhibits and schedules thereto and in each case in substantially the form delivered to the Administrative Agent and the Lenders prior to the date hereof.

8. **Expenses**. The Borrower agrees to pay on demand all expenses of the Administrative Agent and the Lenders (including, without limitation, the fees and out-of-pocket expenses of Covington & Burling LLP, counsel to the Administrative Agent and the Lenders) incurred in connection with the negotiation, preparation, execution and delivery of this Amendment.

9. **Representations and Warranties**. Each of Parent and the Borrower represents and warrants to the Lenders, as of the effective date of this Amendment, as follows:

(a) True, complete and correct copies of the [***] Collaboration Agreement and the [***] License Agreement, in each case, including all exhibits and schedules thereto, have been provided.

(b) The representations and warranties of Parent, the Borrower and the other Subsidiaries contained in the Credit Agreement or any other Loan Document are true and correct in all material respects (and in all respects if any such representation or warranty is already qualified by materiality or reference to Material Adverse Effect) as of the date hereof, except to the extent that such representations and warranties specifically refer to an earlier date, in which case they shall be true and correct in all material respects (and in all respects if any such representation or warranty is already qualified by materiality or reference to Material Adverse Effect) as of such earlier date.

(c) No Default or Event of Default under the Credit Agreement has occurred and is continuing or would result from the effectiveness of this Amendment.

10. **No Implied Amendment or Waiver**. Except as expressly set forth in this Amendment, this Amendment shall not, by implication or otherwise, limit, impair, constitute a waiver of or otherwise affect any rights or remedies of the Administrative Agent and the Lenders under the Credit Agreement or the other Loan Documents, or alter, modify, amend or in any way affect any of the terms, obligations or covenants contained in the Credit Agreement or the other Loan Documents, all of which shall continue in full force and effect. Nothing in this Amendment shall be construed to imply any willingness on the part of the Administrative Agent or any Lender to agree to or grant any similar or future amendment, consent or waiver of any of the terms and conditions of the Credit Agreement or the other Loan Documents.

11. **Waiver and Release**. TO INDUCE THE ADMINISTRATIVE AGENT AND THE LENDERS TO AGREE TO THE TERMS OF THIS AMENDMENT, PARENT, THE BORROWER AND THEIR RESPECTIVE AFFILIATES (COLLECTIVELY, THE "**RELEASING PARTIES**") REPRESENT AND WARRANT THAT, AS OF THE DATE HEREOF, THERE ARE NO CLAIMS OR OFFSETS AGAINST, OR RIGHTS OF RECOUPMENT WITH RESPECT TO, OR DISPUTES OF, OR DEFENSES OR COUNTERCLAIMS TO, THEIR OBLIGATIONS UNDER THE LOAN DOCUMENTS, AND IN ACCORDANCE THEREWITH THE RELEASING PARTIES:

(a) WAIVE ANY AND ALL SUCH CLAIMS, OFFSETS, RIGHTS OF RECOUPMENT, DISPUTES, DEFENSES AND COUNTERCLAIMS, WHETHER KNOWN OR UNKNOWN, ARISING PRIOR TO THE DATE HEREOF.

(b) FOREVER RELEASE, RELIEVE, AND DISCHARGE THE ADMINISTRATIVE AGENT, THE LENDERS, THEIR AFFILIATES AND THEIR RESPECTIVE OFFICERS, DIRECTORS, SHAREHOLDERS, MEMBERS, PARTNERS, PREDECESSORS, SUCCESSORS, ASSIGNS, ATTORNEYS, ACCOUNTANTS, AGENTS, EMPLOYEES, AND REPRESENTATIVES (COLLECTIVELY, THE "**RELEASED PARTIES**"), AND EACH OF THEM, FROM ANY AND ALL CLAIMS, LIABILITIES, DEMANDS, CAUSES OF ACTION, DEBTS, OBLIGATIONS, PROMISES, ACTS, AGREEMENTS, AND DAMAGES, OF WHATEVER KIND OR NATURE, WHETHER KNOWN OR UNKNOWN, SUSPECTED OR UNSUSPECTED, CONTINGENT OR FIXED, LIQUIDATED OR UNLIQUIDATED, MATURED OR UNMATURED, WHETHER AT LAW OR IN EQUITY, WHICH THE RELEASING PARTIES EVER HAD, NOW HAVE, OR MAY, SHALL, OR CAN HEREAFTER HAVE, DIRECTLY OR INDIRECTLY ARISING OUT OF OR IN ANY WAY BASED UPON, CONNECTED WITH, OR RELATED TO MATTERS, THINGS, ACTS, CONDUCT, AND/OR OMISSIONS AT ANY TIME FROM THE BEGINNING OF THE WORLD THROUGH AND INCLUDING THE DATE HEREOF, INCLUDING WITHOUT LIMITATION ANY AND ALL CLAIMS AGAINST THE RELEASED PARTIES ARISING UNDER OR RELATED TO ANY OF THE LOAN DOCUMENTS OR ANY OF THE TRANSACTIONS CONTEMPLATED THEREBY.

(c) IN CONNECTION WITH THE RELEASE CONTAINED HEREIN, ACKNOWLEDGE THAT THEY ARE AWARE THAT THEY MAY HEREAFTER DISCOVER CLAIMS PRESENTLY UNKNOWN OR UNSUSPECTED, OR FACTS IN ADDITION TO OR DIFFERENT FROM THOSE WHICH THEY KNOW OR BELIEVE TO BE TRUE, WITH RESPECT TO THE MATTERS RELEASED HEREIN. NEVERTHELESS, IT IS THE INTENTION OF THE RELEASING PARTIES, THROUGH THIS AMENDMENT AND WITH ADVICE OF COUNSEL, FULLY, FINALLY, AND FOREVER TO RELEASE ALL SUCH MATTERS, AND ALL CLAIMS RELATED THERETO, WHICH DO NOW EXIST, OR HERETOFORE HAVE EXISTED. IN FURTHERANCE OF SUCH INTENTION, THE RELEASES HEREIN GIVEN SHALL BE AND REMAIN IN EFFECT AS A FULL AND COMPLETE RELEASE OR WITHDRAWAL OF

SUCH MATTERS NOTWITHSTANDING THE DISCOVERY OR EXISTENCE OF ANY SUCH ADDITIONAL OR DIFFERENT CLAIMS OR FACTS RELATED THERETO.

(d) COVENANT AND AGREE NOT TO BRING ANY CLAIM, ACTION, SUIT, OR PROCEEDING AGAINST THE RELEASED PARTIES, DIRECTLY OR INDIRECTLY, REGARDING OR RELATED IN ANY MANNER TO THE MATTERS RELEASED HEREBY, AND FURTHER COVENANT AND AGREE THAT THIS AMENDMENT IS A BAR TO ANY SUCH CLAIM, ACTION, SUIT, OR PROCEEDING.

(e) REPRESENT AND WARRANT TO THE RELEASED PARTIES THAT THEY HAVE NOT HERETOFORE ASSIGNED OR TRANSFERRED, OR PURPORTED TO ASSIGN OR TRANSFER, TO ANY PERSON OR ENTITY ANY CLAIMS OR OTHER MATTERS HEREIN RELEASED.

(f) ACKNOWLEDGE THAT THEY HAVE HAD THE BENEFIT OF INDEPENDENT LEGAL ADVICE WITH RESPECT TO THE ADVISABILITY OF ENTERING INTO THIS RELEASE AND HEREBY KNOWINGLY, AND UPON SUCH ADVICE OF COUNSEL, WAIVE ANY AND ALL APPLICABLE RIGHTS AND BENEFITS UNDER, AND PROTECTIONS OF, CALIFORNIA CIVIL CODE SECTION 1542, AND ANY AND ALL STATUTES AND DOCTRINES OF SIMILAR EFFECT. CALIFORNIA CIVIL CODE SECTION 1542 PROVIDES AS FOLLOWS:

> *A general release does not extend to claims that the creditor or releasing party does not know or suspect to exist in his or her favor at the time of executing the release, and that if known by him or her, would have materially affected his or her settlement with the debtor or released party.*

12. **Counterparts; Governing Law**. This Amendment may be executed in counterparts (and by different parties hereto in different counterparts), each of which shall constitute an original, but all of which when taken together shall constitute a single contract. Delivery of an executed counterpart of a signature page of this Amendment by fax transmission or e-mail transmission (e.g., "pdf" or "tif") shall be effective as delivery of a manually executed counterpart of this Amendment. THIS AMENDMENT AND ANY CLAIMS, CONTROVERSY, DISPUTE OR CAUSE OF ACTION (WHETHER IN CONTRACT OR TORT OR OTHERWISE) BASED UPON, ARISING OUT OF OR RELATING TO THIS AMENDMENT AND THE TRANSACTIONS CONTEMPLATED HEREBY SHALL BE GOVERNED BY, AND CONSTRUED IN ACCORDANCE WITH, THE INTERNAL LAWS OF THE STATE OF NEW YORK (INCLUDING FOR SUCH PURPOSE SECTIONS 5-1401 AND 5-1402 OF THE GENERAL OBLIGATIONS LAW OF THE STATE OF NEW YORK).

[Remainder of Page Intentionally Left Blank]

IN WITNESS WHEREOF, the parties hereto have caused this Amendment to be executed by their respective officers thereunto duly authorized as of the day and year first above written.

ARS PHARMACEUTICALS OPERATIONS, INC.
as the Borrower

By: /s/ Richard Lowenthal

Name: Richard Lowenthal

Title: Chief Executive Officer

ARS PHARMACEUTICALS, INC.
as Parent

By: /s/ Richard Lowenthal

Name: Richard Lowenthal

Title: Chief Executive Officer

RAC SCF HOLDINGS I, LLC
as a Lender

By: /s/ Jeremy Lack

Name: Jeremy Lack

Title: Manager

OCM IP HEALTHCARE PORTFOLIO LP, by its general partner, **OCM IP HEALTHCARE PORTFOLIO G.P. INC.**
as a Lender

By: /s/ Brendan Rowaan

Name: Brendan Rowaan

Title: Vice President

By: /s/ Danial K. Lam

Name: Danial K. Lam

Title: Vice President

ACKNOWLEDGED BY:

RA CAPITAL AGENCY SERVICES, LLC
as the Administrative Agent

By: /s/ Adam Kaye

Name: Adam Kaye

Title: Manager

Exhibit 10.2

RELEASE AGREEMENT

I understand and agree completely to the terms set forth in the ARS Pharmaceuticals, Inc. Change in Control and Severance Benefit Plan (the "*Plan*") and the Executive Employment Agreement between me and ARS Pharmaceuticals, Inc. (the "*Company*"), dated September 14, 2018 (the "*Employment Agreement*").

I understand that this Release Agreement (the "***Release***"), together with the Plan and Employment Agreement, constitutes the complete, final and exclusive embodiment of the entire agreement between the Company, affiliates of the Company and me with regard to the subject matter hereof. I am not relying on any promise or representation by the Company or an affiliate of the Company that is not expressly stated therein, and I acknowledge and agree that any prior severance or other post-employment termination benefits offered to me are hereby withdrawn. Certain capitalized terms used in this Release are defined in the Plan.

I hereby represent that I have been paid all compensation owed and for all hours worked; I have received all the leave and leave benefits and protections for which I am eligible pursuant to the Family and Medical Leave Act (if applicable), or otherwise; and I have not suffered any on-the-job injury for which I have not already filed a workers' compensation claim.

I hereby acknowledge and agree to abide by my continuing obligations under my confidential information and invention assignment agreement with the Company and/or an affiliate of the Company.

I hereby confirm that, except for materials the Company has expressly authorized me to retain in writing, I have returned to the Company all Company property, including, but not limited to, all equipment, vehicles, product samples, computers, pass codes, keys, swipe cards, credit cards, documents, or other materials, in whatever form or format that I received, prepared, or helped prepare them; and that I have not retained, whether in hard copy or electronic form, any copies, duplicates, reproductions, computer disks, or excerpts thereof.

If I am an officer or director of the Company or any of its affiliated entities, effective immediately, I agree to (and hereby do) resign from any and all offices and directorships with any such entities, and agree to execute all documents reasonably requested by the Company to effectuate such resignation(s).

I understand that I may apply for unemployment insurance benefits after my employment with the Company ends and that the Company will not contest my eligibility for such benefits; *provided*, *however*, that I understand that the state agency responsible for administering unemployment insurance benefits, and not the Company, is ultimately responsible for determining my eligibility for such benefits. I further understand that, in response to any request for references from a prospective employer, the Company will only confirm my dates of employment and last job title.

I understand that if I timely sign this Release, and permit it to become effective and irrevocable in accordance with its terms, then the Company will provide me with the severance benefits to which I am entitled in the event of a termination without Cause under my Employment Agreement or a

"Regular Termination" under the Plan, each as applicable and set forth under the Employment Agreement and Plan. In addition, as part of this Release I understand and agree to the additional terms set forth on the addendum attached hereto.

In consideration of the severance benefits and other consideration provided to me under the Plan and Employment Agreement that I am not otherwise entitled to receive, I hereby generally and completely release the Company and its affiliates and assigns, and their parents, subsidiaries, successors, predecessors and affiliates, and their current and former partners, members, directors, officers, employees, stockholders, shareholders, agents, attorneys, predecessors, successors, insurers, affiliates and assigns (collectively, the "***Releasees***"), from any and all claims, liabilities and obligations, both known and unknown, that arise out of or are in any way related to events, acts, conduct, or omissions occurring at any time prior to and including the date I sign this Release (collectively, the "***Released Claims***"). The Released Claims include, but are not limited to: (a) all claims arising out of or in any way related to my employment with the Company and any other Releasees, or their affiliates, or the termination of that employment; (b) all claims related to my compensation or benefits, including salary, bonuses, commissions, vacation pay, expense reimbursements, severance pay, fringe benefits, stock, stock options, or any other ownership, equity, or profits interests in the Company and any other Releasees; (c) all claims for breach of contract, wrongful termination, and breach of the implied covenant of good faith and fair dealing; (d) all tort claims, including claims for fraud, defamation, emotional distress, and discharge in violation of public policy; and (e) all federal, state, and local statutory claims, including claims for discrimination, harassment, retaliation, attorneys' fees, penalties, or other claims arising under the federal Civil Rights Act of 1964, the federal Americans with Disabilities Act of 1990, the federal Age Discrimination in Employment Act (as amended) ("***ADEA***"), the federal Employee Retirement Income Security Act of 1974, the California Fair Employment and Housing Act and the California Labor Code, all including any amendments and their respective implementing regulations, and any other federal, state, local, or foreign law (statutory, regulatory, or otherwise) that may be legally waived and released.

In releasing claims unknown to me at present, I am waiving all rights and benefits under the following provision of Section 1542 of the California Civil Code, and any law or legal principle of similar effect in any domestic or international jurisdiction: "**A general release does not extend to claims which the creditor or releasing party does not know or suspect to exist in his or her favor at the time of executing the release and that, if known by him or her, would have materially affected his or her settlement with the debtor or released party**."

Notwithstanding the foregoing, I understand that the following rights or claims are not included in the Released Claims: (a) any rights or claims for indemnification I may have pursuant to any written indemnification agreement with the Company or any other Releasees to which I am a party, the charter, bylaws, or operating agreements of the Company or any other Releasees, or under applicable law; or (b) any rights that cannot be waived as a matter of law. In addition, I understand that nothing in this Release prevents me from filing, cooperating with, or participating in any proceeding before the Equal Employment Opportunity Commission, the Department of Labor, the National Labor Relations Board, the Occupational Safety and Health Administration, the California Civil Rights Department, the Securities and Exchange Commission or any other federal, state or local governmental agency or commission (each a "***Government Agency***"). While this Release does not limit my right to receive an award for information provided to the Securities and Exchange Commission, I understand and agree that, to the maximum extent permitted by law, I am otherwise waiving any and all rights I may have to individual relief based on any claims that I have released and any rights I have waived by signing this Release. In addition, I understand that nothing in this Release Agreement prevents me from discussing or disclosing information about unlawful acts in the workplace, such as harassment, discrimination, retaliation, or any other conduct that I have reason to believe is unlawful. Furthermore, I understand that nothing in this Release Agreement waives any rights I may have under Section 7 of the National Labor Relations Act (subject to the release of claims set forth herein). In addition, nothing herein shall be interpreted or applied in a manner that limits my ability to challenge, under the Older Workers Benefit Protection Act ("***OWBPA***") (29 U.S.C. § 626), the knowing and voluntary nature of my release of any claims under the ADEA. I hereby represent and warrant that, other than the foregoing excluded claims I am not aware of any claims I have or might have that are not included in the Released Claims. (This paragraph may be referred to herein as the "***Protected Rights***" paragraph.)

I acknowledge that I am knowingly and voluntarily waiving and releasing any rights I may have under the ADEA and the OWBPA, and that the consideration given under the Plan for the waiver and release in this paragraph is in addition to anything of value to which I was already entitled. I further acknowledge that I have been advised by this writing, as required by the ADEA, that: (a) my waiver and release do not apply to any rights or claims that may arise after the date I sign this Release; (b) I should consult with an attorney prior to signing this Release (although I may choose voluntarily not do so); (c) I have twenty-one (21) days to consider this Release (although I may choose voluntarily to sign this Release earlier); (d) I have seven (7) days following the date I sign this Release to revoke the Release by providing written notice of such revocation to the Company's Human Resources department or the Company's General Counsel; and (e) this Release shall not be effective until the date upon which the revocation period has expired, which shall be the eighth day after I sign this Release, provided I have not earlier revoked it.

I understand and agree that nothing in this Release or in the Plan or in the Employment Agreement is to be construed as an admission of liability or wrongdoing by the Company or any other Releasees, and that the Company and other Releasees disclaim any such liability or wrongdoing.

I understand and agree that while the I may apply for future employment with the Company or its successor, I have no right to such future employment, and the Company or its successor may, in its sole discretion, deny my employment application. I further understand

and agree that in the event I obtain employment with the Company or its successor, the Company or its successor may, in its sole discretion, terminate my employment. I also acknowledge and agree that my rehire may affect the amount of severance pay and benefits to which I am entitled under the Plan (as provided in Section 2 of the Plan).

I agree that except for disclosures made (i) in confidence to my attorneys, financial advisors, accountants, spouse, or registered domestic partner, (ii) to a Government Agency, or (iii) as allowed under the Protected Rights paragraph above, I will keep this Release and its terms confidential and will not reveal its contents to anyone, unless necessary to enforce my rights hereunder or as other otherwise required by law.

I further agree not to, at any time, take any action through any medium or in any forum, to directly or indirectly disparage the employees, products, business reputation, abilities, or capabilities of the Company or any other Releasees. This provision includes, without limitation, email, any electronic media, and any postings to the Internet. Notwithstanding the foregoing, it shall not be a breach of this paragraph for me to comply with the lawful orders or processes of any court, including the obligation to testify truthfully in any legal proceeding. Additionally, this paragraph does not apply to communications between me and any Government Agency, or between me and the Company or any other Releasee, or as allowed under the Protected Rights paragraph above.

This Release, together with the Plan and Employment Agreement, constitutes the entire understanding and agreement with respect to the subject matter hereof. The provisions of this Release and the Plan and Employment Agreement are severable and if any part is found to be unenforceable, the other portions shall remain fully valid and enforceable. Additionally, if any of the waivers and releases set forth in this Release are held to be invalid, illegal, void and/or unenforceable: (i) the remaining waivers and releases shall remain fully valid and enforceable; and (ii) upon request by the Company, I shall immediately execute and deliver to the Company a release and waiver that is legal and enforceable to the fullest extent of the law. The construction and interpretation of this Release shall be subject to the terms and conditions of the Plan and Employment Agreement, and no ambiguity in this Release, Employment Agreement or the Plan shall be construed against any party as the drafter. I acknowledge that I must sign and return this Release to the Company so that it is received not later than twenty-one (21) days following the date it is provided to me. By signing below, I represent that: I have read this Release, the Employment Agreement and the Plan; I have had adequate time to consider them; I have been advised to consult with an attorney before signing this Release; I understand the meaning and application of this Release and the Plan and Employment Agreement; and that I sign this Release knowingly and voluntarily and with the intent of being bound by it.

[Remainder of this Page Intentionally Left Blank]

Eligible Employee:

By: /s/ Richard Lowenthal

Name: Richard Lowenthal

Date: July 15, 2026

ARS PHARMACEUTICALS, INC.

By: /s/ Donn Casale

Name: Donn Casale

Title: Chief Executive Officer

Date: July 15, 2026

ADDENDUM

I hereby agree to this Addendum to the Release Agreement between me and **ARS Pharmaceuticals, Inc.** (the "***Company***") to which this Addendum is attached**.** Capitalized terms used but not defined herein shall have the meanings ascribed to them in the Release Agreement.

- I and the Company agree my separation from the Company is a Termination Without Cause or Resignation for Good Reason, as defined in Section 7.2. of my Employment Agreement and the Company will pay me the following severance benefits described in sections 7.2.1 through Section 7.2.3 of that Agreement, which include: 12 month's pay as severance, 12 months acceleration of outstanding stock option, and 12 months of COBRA payments, which the company may elect to pay as a lump sum payment.. In addition, the Company will pay me an additional cash severance payment in an amount equal to $217,350 (which is calculated as a prorated amount of my target bonus for 2026, which I acknowledge that I did not earn on or prior to the Separation Date), which will be paid to me in a lump sum, less all applicable deductions and withholdings, within 30 days after effective date of this release, as set forth below.

- I agree to make myself available, upon reasonable notice, to respond to questions from the Company regarding matters relating to my transition, including the location of files and documents, and to facilitate the orderly transfer of files and documents in my personal possession to the Company. In addition, I agree to respond in good faith to substantive questions from the Company in connection with matters relating to my employment with the Company that might be uniquely known by me as a result of my employment with the Company. I agree to provide this assistance for up to ten (10) hours following my separation from the Company at no charge. Any time I spend beyond ten (10) hours, however, will be compensated at a rate to be agreed upon between me and the Company considering my experience, both work and educational, and prevailing hourly or daily rates paid to someone with my experience and background.

- I agree to cooperate with the Company in connection with its defense, prosecution, or investigation of any claims or demands by or against third parties. Such cooperation includes continuing to abide by preservation notices and obligations I was under during my employment with the Company (including, without limitation, keeping - without altering or destroying - any image(s) of my hard drives made and provided to me by a third party vendor), as well as making myself available to the Company as needed, upon reasonable notice, to provide complete, truthful and accurate information in witness interviews, depositions, and trial testimony. I understand that, consistent with the Company's indemnification agreement with me, the Company will reimburse me for my time spent providing such assistance and cooperation to the Company at an agreed upon daily our hourly rate to be agreed on between me and the Company taking into account the factors specified in the paragraph above, as well as all reasonable pre-approved out-of-pocket expenses I incur with such witness interviews, depositions and trial testimony (excluding foregone wages but including any reasonable legal fees, travel and other related usual and customary costs and expenses), and will make reasonable efforts to accommodate my scheduling needs. The amount of my compensation for providing the assistance to the Company specified in this paragraph shall be agreed upon by the Company and I before any of the assistance specified in this paragraph is provided.

- The Company has agreed to provide reasonable assistance in filing Form 4s and similar filings with the Securities and Exchange Commission as required by Section 16 of the Securities Exchange Act of 1934, as amended, in connection with my future sales of Common Stock of the Company. I agree that the Company is providing this service as a courtesy to me and assumes no liability to me for any such filings or the information contained therein. I agree to provide notice to the Company of any sales of stock of the Company by me on the date of each such sale in order to facilitate such filings by the Company.

Eligible Employee:

By: /s/ Richard Lowenthal

Name: Richard Lowenthal

Date: July 15, 2026

ARS PHARMACEUTICALS, INC.

By: /s/ Donn Casale

Name: Donn Casale

Title: Chief Executive Officer

Date: July 15, 2026

Exhibit 10.3

RELEASE AGREEMENT

I understand and agree completely to the terms set forth in the ARS Pharmaceuticals, Inc. Change in Control and Severance Benefit Plan (the "*Plan*") and the Executive Employment Agreement between me and ARS Pharmaceuticals, Inc. (the "*Company*"), dated September 14, 2018, as amended (as amended, the "*Employment Agreement*").

I understand that this Release Agreement (the "***Release***"), together with the Plan and Employment Agreement, constitutes the complete, final and exclusive embodiment of the entire agreement between the Company, affiliates of the Company and me with regard to the subject matter hereof. I am not relying on any promise or representation by the Company or an affiliate of the Company that is not expressly stated therein, and I acknowledge and agree that any prior severance or other post-employment termination benefits offered to me are hereby withdrawn. Certain capitalized terms used in this Release are defined in the Plan.

I hereby represent that I have been paid all compensation owed and for all hours worked; I have received all the leave and leave benefits and protections for which I am eligible pursuant to the Family and Medical Leave Act (if applicable), or otherwise; and I have not suffered any on-the-job injury for which I have not already filed a workers' compensation claim.

I hereby acknowledge and agree to abide by my continuing obligations under my confidential information and invention assignment agreement with the Company and/or an affiliate of the Company.

I hereby confirm that, except for materials the Company has expressly authorized me to retain in writing, I have returned to the Company all Company property, including, but not limited to, all equipment, vehicles, product samples, computers, pass codes, keys, swipe cards, credit cards, documents, or other materials, in whatever form or format that I received, prepared, or helped prepare them; and that I have not retained, whether in hard copy or electronic form, any copies, duplicates, reproductions, computer disks, or excerpts thereof.

If I am an officer or director of the Company or any of its affiliated entities, effective immediately, I agree to (and hereby do) resign from any and all offices and directorships with any such entities, and agree to execute all documents reasonably requested by the Company to effectuate such resignation(s).

I understand that I may apply for unemployment insurance benefits after my employment with the Company ends and that the Company will not contest my eligibility for such benefits; *provided*, *however*, that I understand that the state agency responsible for administering unemployment insurance benefits, and not the Company, is ultimately responsible for determining my eligibility for such benefits. I further understand that, in response to any request for references from a prospective employer, the Company will only confirm my dates of employment and last job title.

I understand that if I timely sign this Release, and permit it to become effective and irrevocable in accordance with its terms, then the Company will provide me with the severance benefits to which
I am entitled in the event of a termination without Cause under my Employment Agreement or a
"Regular Termination" under the Plan, each as applicable and set forth under the Employment Agreement and Plan. In addition, as part of this Release I understand and agree to the additional terms set forth on the addendum attached hereto.

In consideration of the severance benefits and other consideration provided to me under the Plan and Employment Agreement that I am not otherwise entitled to receive, I hereby generally and completely release the Company and its affiliates and assigns, and their parents, subsidiaries, successors, predecessors and affiliates, and their current and former partners, members, directors, officers, employees, stockholders, shareholders, agents, attorneys, predecessors, successors, insurers, affiliates and assigns (collectively, the "***Releasees***"), from any and all claims, liabilities and obligations, both known and unknown, that arise out of or are in any way related to events, acts, conduct, or omissions occurring at any time prior to and including the date I sign this Release (collectively, the "***Released Claims***"). The Released Claims include, but are not limited to: (a) all claims arising out of or in any way related to my employment with the Company and any other Releasees, or their affiliates, or the termination of that employment; (b) all claims related to my compensation or benefits, including salary, bonuses, commissions, vacation pay, expense reimbursements, severance pay, fringe benefits, stock, stock options, or any other ownership, equity, or profits interests in the Company and any other Releasees; (c) all claims for breach of contract, wrongful termination, and breach of the implied covenant of good faith and fair dealing; (d) all tort claims, including claims for fraud, defamation, emotional distress, and discharge in violation of public policy; and (e) all federal, state, and local statutory claims, including claims for discrimination, harassment, retaliation, attorneys' fees, penalties, or other claims arising under the federal Civil Rights Act of 1964, the federal Americans with Disabilities Act of 1990, the federal Age Discrimination in Employment Act (as amended) ("***ADEA***"), the federal Employee Retirement Income Security Act of 1974, the California Fair Employment and Housing Act and the California Labor Code, all including any amendments and their respective implementing regulations, and any other federal, state, local, or foreign law (statutory, regulatory, or otherwise) that may be legally waived and released.

In releasing claims unknown to me at present, I am waiving all rights and benefits under the following provision of Section 1542 of the California Civil Code, and any law or legal principle of similar effect in any domestic or international jurisdiction: "**A general release does not extend to claims which the creditor or releasing party does not know or suspect to exist in his or her favor at the time of executing the release and that, if known by him or her, would have materially affected his or her settlement with the debtor or released party**."

Notwithstanding the foregoing, I understand that the following rights or claims are not included in the Released Claims: (a) any rights or claims for indemnification I may have pursuant to any written indemnification agreement with the Company or any other Releasees to which I am a party, the charter, bylaws, or operating agreements of the Company or any other Releasees, or under applicable law; or (b) any rights that cannot be waived as a matter of law. In addition, I understand that nothing in this Release prevents me from filing, cooperating with, or participating in any proceeding before the Equal Employment Opportunity Commission, the Department of Labor, the National Labor Relations Board, the Occupational Safety and Health Administration, the California Civil Rights Department, the Securities and Exchange Commission or any other federal, state or local governmental agency or commission (each a "***Government Agency***"). While this Release does not limit my right to receive an award for information provided to the Securities and Exchange Commission, I understand and agree that, to the maximum extent permitted by law, I am otherwise waiving any and all rights I may have to individual relief based on any claims that I have released and any rights I have waived by signing this Release. In addition, I understand that nothing in this Release Agreement prevents me from discussing or disclosing information about unlawful acts in the workplace, such as harassment, discrimination, retaliation, or any other conduct that I have reason to believe is unlawful. Furthermore, I understand that nothing in this Release Agreement waives any rights I may have under Section 7 of the National Labor Relations Act (subject to the release of claims set forth herein). In addition, nothing herein shall be interpreted or applied in a manner that limits my ability to challenge, under the Older Workers Benefit Protection Act ("***OWBPA***") (29 U.S.C. § 626), the knowing and voluntary nature of my release of any claims under the ADEA. I hereby represent and warrant that, other than the foregoing excluded claims I am not aware of any claims I have or might have that are not included in the Released Claims. (This paragraph may be referred to herein as the "***Protected Rights***" paragraph.)

I acknowledge that I am knowingly and voluntarily waiving and releasing any rights I may have under the ADEA and the OWBPA, and that the consideration given under the Plan for the waiver and release in this paragraph is in addition to anything of value to which I was already entitled. I further acknowledge that I have been advised by this writing, as required by the ADEA, that: (a) my waiver and release do not apply to any rights or claims that may arise after the date I sign this Release; (b) I should consult with an attorney prior to signing this Release (although I may choose voluntarily not do so); (c) I have twenty-one (21) days to consider this Release (although I may choose voluntarily to sign this Release earlier); (d) I have seven (7) days following the date I sign this Release to revoke the Release by providing written notice of such revocation to the Company's Human Resources department or the Company's General Counsel; and (e) this Release shall not be effective until the date upon which the revocation period has expired, which shall be the eighth day after I sign this Release, provided I have not earlier revoked it.

I understand and agree that nothing in this Release or in the Plan or in the Employment Agreement is to be construed as an admission of liability or wrongdoing by the Company or any other Releasees, and that the Company and other Releasees disclaim any such liability or wrongdoing.

I understand and agree that while the I may apply for future employment with the Company or its successor, I have no right to such future employment, and the Company or its successor may, in its sole discretion, deny my employment application. I further understand and agree that in the event I obtain employment with the Company or its successor, the Company or its successor may, in its sole discretion, terminate my employment. I also acknowledge and agree that my rehire may affect the amount of severance pay and benefits to which I am entitled under the Plan (as provided in Section 2 of the Plan).

I agree that except for disclosures made (i) in confidence to my attorneys, financial advisors, accountants, spouse, or registered domestic partner, (ii) to a Government Agency, or (iii) as allowed under the Protected Rights paragraph above, I will keep this Release and its terms confidential and will not reveal its contents to anyone, unless necessary to enforce my rights hereunder or as other otherwise required by law.

I further agree not to, at any time, take any action through any medium or in any forum, to directly or indirectly disparage the employees, products, business reputation, abilities, or capabilities of the Company or any other Releasees. This provision includes, without limitation, email, any electronic media, and any postings to the Internet. Notwithstanding the foregoing, it shall not be a breach of this paragraph for me to comply with the lawful orders or processes of any court, including the obligation to testify truthfully in any legal proceeding. Additionally, this paragraph does not apply to communications between me and any Government Agency, or between me and the Company or any other Releasee, or as allowed under the Protected Rights paragraph above.

This Release, together with the Plan and Employment Agreement, constitutes the entire understanding and agreement with respect to the subject matter hereof. The provisions of this Release and the Plan and Employment Agreement are severable and if any part is found to be unenforceable, the other portions shall remain fully valid and enforceable. Additionally, if any of the waivers and releases set forth in this Release are held to be invalid, illegal, void and/or unenforceable: (i) the remaining waivers and releases shall remain fully valid and enforceable; and (ii) upon request by the Company, I shall immediately execute and deliver to the Company a release and waiver that is legal and enforceable to the fullest extent of the law. The construction and interpretation of this Release shall be subject to the terms and conditions of the Plan and Employment Agreement, and no ambiguity in this Release, Employment Agreement or the Plan shall be construed against any party as the drafter. I acknowledge that I must sign and return this Release to the Company so that it is received not later than twenty-one (21) days following the date it is provided to me. By signing below, I represent that: I have read this Release, the Employment Agreement and the Plan; I have had adequate time to consider them; I have been advised to consult with an attorney before signing this Release; I understand the meaning and application of this Release and the Plan and Employment Agreement; and that I sign this Release knowingly and voluntarily and with the intent of being bound by it.

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Eligible Employee:

By: /s/ Sarina Tanimoto

Name: Sarina Tanimoto

Date: July 15, 2026

ARS PHARMACEUTICALS, INC.

By: /s/ Donn Casale

Name: Donn Casale

Title: Chief Executive Officer

Date: July 15, 2026

ADDENDUM

I hereby agree to this Addendum to the Release Agreement between me and **ARS Pharmaceuticals, Inc.** (the "***Company***") to which this Addendum is attached**.** Capitalized terms used but not defined herein shall have the meanings ascribed to them in the Release Agreement.

- I and the Company agree my separation from the Company is a Termination Without Cause or Resignation for Good Reason, as defined in Section 7.2. of my Employment Agreement and the Company will pay me the following severance benefits described in sections 7.2.1 through Section 7.2.3 of that Agreement, which include: 12 months' pay as severance, 12 months acceleration of outstanding stock option, and 12 months of COBRA payments, which the company may elect to pay as a lump sum payment. In addition, the Company will pay me an additional cash severance payment in an amount equal to $111,780 (which is calculated as a prorated amount of my target bonus for 2026, which I acknowledge that I did not earn on or prior to the Separation Date), which will be paid to me in a lump sum, less all applicable deductions and withholdings, within 30 days after effective date of this release, as set forth below.

- I agree to make myself available, upon reasonable notice, to respond to questions from the Company regarding matters relating to my transition, including the location of files and documents, and to facilitate the orderly transfer of files and documents in my personal possession to the Company. In addition, I agree to respond in good faith to substantive questions from the Company in connection with matters relating to my employment with the Company that might be uniquely known by me as a result of my employment with the Company. I agree to provide this assistance for up to ten (10) hours following my separation from the Company at no charge. Any time I spend beyond ten (10) hours, however, will be compensated at a rate to be agreed upon between me and the Company taking into account my experience, both work and educational, and prevailing hourly or daily rates paid to someone with my experience and background.

- I agree to cooperate with the Company in connection with its defense, prosecution, or investigation of any claims or demands by or against third parties. Such cooperation includes continuing to abide by preservation notices and obligations I was under during my employment with the Company (including, without limitation, keeping - without altering or destroying - any image(s) of my hard drives made and provided to me by a third party vendor), as well as making myself available to the Company as needed, upon reasonable notice, to provide complete, truthful and accurate information in witness interviews, depositions, and trial testimony. I understand that, consistent with the Company's indemnification agreement with me, to the extent not precluded by applicable rules and regulations, the Company will reimburse me for my time spent providing such assistance and cooperation to the Company at an agreed upon daily our hourly rate to be agreed on between me and the Company taking into account the factors specified in the paragraph above, as well as all reasonable pre-approved out-of-pocket expenses I incur with such witness interviews, depositions and trial testimony (excluding foregone wages but including any reasonable legal fees, travel and other related usual and customary costs and expenses), and will make reasonable efforts to accommodate my scheduling needs. The amount of my compensation for providing the assistance to the Company specified in this paragraph shall be agreed upon by the Company and I before any of the assistance specified in this paragraph is provided.

- The Company has agreed to provide reasonable assistance in filing Form 4s and similar filings with the Securities and Exchange Commission as required by Section 16 of the Securities Exchange Act of 1934, as amended, in connection with my future sales of Common Stock of the Company. I agree that the Company is providing this service as a courtesy to me and assumes no liability to me for any such filings or the information contained therein. I agree to provide notice to the Company of any sales of stock of the Company by me on the date of each such sale in order to facilitate such filings by the Company.

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Eligible Employee:

By: /s/ Sarina Tanimoto

Name: Sarina Tanimoto

Date: July 15, 2026

ARS PHARMACEUTICALS, INC.

By: /s/ Donn Casale

Name: Donn Casale

Title: Chief Executive Officer

Date: July 15, 2026

Exhibit 10.4

ARS PHARMACEUTICALS, INC.

EXECUTIVE EMPLOYMENT AGREEMENT

for

MARGARET SMITH

This Executive Employment Agreement (this "**Agreement**") is made and entered into effective as of August 12, 2026 (the "**Effective Date**"), by and between Margaret Smith ("**Executive**") and ARS Pharmaceuticals, Inc. (the "**Company**").

1. Employment by the Company.

1.1 Position. Executive's employment with the Company shall begin on August 17, 2026 or such date as otherwise agreed to by Executive and the Company (the actual date Executive's employment begins, the "**Start Date**"). Executive shall serve as the Company's Chief Commercial Officer, reporting to the Company's Chief Executive Officer. During the term of Executive's employment with the Company, Executive will devote Executive's best efforts and full-time attention to the business of the Company, except for approved vacation periods and reasonable periods of illness or other incapacities all in conformity with the Company's policies applicable to senior executives and general employment policies.

1.2 Duties and Location. Executive shall perform such duties as are customarily associated with the position of Chief Commercial Officer and such other duties as are assigned to Executive by the Company's Chief Executive Officer. Executive will primarily work from the Executive's home in Batesville, Indiana; provided that Executive shall be expected to engage in business travel as reasonably required by the Company for business purposes.

1.3 Policies and Procedures. The employment relationship between the parties shall be governed by the general employment policies and practices of the Company and applicable law, except that when the terms of this Agreement differ from or are in conflict with the Company's general employment policies or practices, this Agreement shall control.

2. Compensation.

2.1 Base Salary. Executive shall receive a base salary at the annual rate of $525,000, less standard payroll deductions and withholdings and payable in accordance with the Company's regular payroll schedule.

2.2 Annual Bonus. During Executive's employment, Executive will be eligible for an annual discretionary bonus with a target of 45% of Executive's annual base salary, subject to applicable payroll deductions and withholdings, and prorated for the number of days Executive remains continuously employed in a calendar year (the **"Annual Bonus"**). Whether Executive receives an Annual Bonus for any given year, and the amount of any such Annual Bonus, will be determined by the Company's Board of Directors (the "**Board**") or the Compensation Committee thereof in its discretion based upon the achievement of Company corporate and/or individual objectives and milestones that are determined in the sole discretion of the Board. Executive must continue to be employed through the date the Annual Bonus is paid in order to earn such bonus.

2.3 Equity Grant. Subject to approval by the Board or the Compensation Committee thereof and as a material inducement to Executive entering into employment with the Company, Executive will be awarded an option to purchase a number of shares of the Company's common stock ("**Shares**") with an approximate value of $4,250,000 (four million two hundred fifty thousand dollars) (the "**Option**") determined in accordance with the Company's equity grant policies in effect from time to time. The Option will be subject to the terms and conditions of the Company's 2020 Equity Incentive Plan (the "**Plan**") or another equity compensation plan maintained by the Company and a stock option agreement thereunder. The Option will vest over four years, with 25% of the Shares subject to the Option vesting on the first anniversary of the vesting commencement date of the Option and the remaining 75% of the Shares subject to the Option vesting in equal installments each month thereafter on the same day of the month as the vesting commencement date (and if there is no same day, the last day of the month), subject to Executive's continued employment with the Company through each applicable vesting date. The exercise price per Share subject to the Option will be equal to the fair market value of a share of Common Stock on the date of grant as determined by the Board or Compensation Committee thereof.

3. Standard Company Benefits. Executive shall, in accordance with Company policy and the terms and conditions of the applicable Company benefit plan documents, be eligible to participate in the benefit and fringe benefit programs provided by the Company to its executive officers and other employees from time to time. Any such benefits shall be subject to the terms and conditions of the governing benefit plans and policies and may be changed by the Company in its discretion.

4. Expenses. The Company shall pay or reimburse Executive, on a monthly basis, for reasonable travel, entertainment, promotional, professional and other expenses incurred by Executive in the performance of Executive's business-related obligations under this Agreement (collectively "**Expenses**"). To be eligible for reimbursement of any Expenses under this Agreement, Executive must submit timely detailed expense reports, receipts or other satisfactory evidence of payment for appropriate review within 30 days of incurring such expense. The Company shall reimburse Executive promptly, but in no event later than 30 days after Executive submits an expense report in accordance with the preceding sentence.

5. Confidential Information Obligations.

5.1 Confidential Information Agreement. As a condition of employment, and in consideration for the benefits provided for in this Agreement, Executive agrees to execute and abide by the Company's Employee Confidential Information and Inventions Assignment Agreement (the "**Confidential Information Agreement**") attached hereto as **Exhibit A**. In addition, Executive agrees to abide by the Company's policies and procedures, as may be modified from time to time within the Company's discretion.

5.2 Third-Party Agreements and Information. Executive represents and warrants that Executive's employment by the Company does not conflict with any prior employment or consulting agreement or other agreement with any third party, and that Executive will perform Executive's duties to the Company without violating any such agreement. Executive represents and warrants that Executive does not possess confidential information arising out of prior employment, consulting, or other third party relationships, that would be used in connection with Executive's employment by the Company, except as expressly authorized by that third party. During Executive's employment by the Company, Executive will use in the performance of Executive's duties only information that is generally known and used by persons with training and experience comparable to Executive's own, common knowledge in the industry, otherwise legally in the public domain, or obtained or developed by the Company or by Executive in the course of Executive's work for the Company.

6. Outside Activities and Non-Competition During Employment.

6.1 Outside Activities. Except with the prior written consent of the Company's Chief Executive Officer, Executive will not during the term of Executive's employment with the Company undertake or engage in any other employment, occupation or business enterprise, other than ones in which Executive is a passive investor. Executive may engage in civic and not-for-profit activities so long as such activities do not materially interfere with the performance of Executive's duties hereunder. Executive agrees not to acquire, assume or participate in, directly or indirectly, any position, investment or interest known to be adverse or antagonistic to the Company, its business or prospects, financial or otherwise.

6.2 Non-Competition During Employment. Throughout Executive's employment with the Company, Executive will not, without the express written consent of the Chief Executive Officer, directly or indirectly serve as an officer, director, stockholder, employee, partner, proprietor, investor, joint venture, associate, representative or consultant of any person or entity engaged in, or planning or preparing to engage in, business activity competitive with any line of business engaged in (or planned to be engaged in) by the Company or its affiliates; provided, however, that Executive may purchase or otherwise acquire up to (but not more than) one percent (1%) of any class of securities of any enterprise (without participating in the activities of such enterprise) if such securities are listed on any national or regional securities exchange.

7. Termination of Employment; Severance Benefits.

7.1 At-Will Employment. Executive's employment relationship is at-will. Either Executive or the Company may terminate the employment relationship at any time, with or without cause or advance notice.

7.2 Severance Benefits. Executive will be eligible for severance and change in control benefits under the terms and conditions of the Company's Change in Control and Severance Benefit Plan (the "**Severance Plan**"), pursuant to the Severance Plan terms as may be in effect and as may be amended from time to time, and Executive's Participation Agreement under the Severance Plan, if and as executed by and between Executive and the Company.

8. Section 409A. It is intended that all of the severance benefits and other payments payable under this Agreement or the Severance Plan satisfy, to the greatest extent possible, the exemptions from the application of Code Section 409A provided under Treasury Regulations 1.409A-1(b)(4), 1.409A-1(b)(5) and 1.409A-1(b)(9), and this Agreement will be construed to the greatest extent possible as consistent with those provisions, and to the extent not so exempt, this Agreement (and any definitions hereunder) will be construed in a manner that complies with Section 409A. For purposes of Code Section 409A (including, without limitation, for purposes of Treasury Regulation Section 1.409A-2(b)(2)(iii)), Executive's right to receive any installment payments under this Agreement (whether severance payments, reimbursements or otherwise) shall be treated as a right to receive a series of separate payments and, accordingly, each installment payment hereunder shall at all times be considered a separate and distinct payment. Notwithstanding any provision to the contrary in this Agreement, if Executive is deemed by the Company at the time of Executive's Separation from Service to be a "specified employee" for purposes of Code Section 409A(a)(2)(B)(i), and if any of the payments upon Separation from Service set forth herein and/or under any other agreement with the Company are deemed to be "deferred compensation", then to the extent delayed commencement of any portion of such payments is required in order to avoid a prohibited distribution under Code Section 409A(a)(2)(B)(i) and the related adverse taxation under Section 409A, such payments shall not be provided to Executive prior to the earliest of (i) the expiration of the six-month and one day period measured from the date of Executive's Separation from Service with the Company, (ii) the date of Executive's death or (iii) such earlier date as permitted under Section 409A without the imposition of adverse taxation. Upon the first business day following the expiration of such applicable Code Section 409A(a)(2)(B)(i) period, all payments deferred pursuant to this Section 8 shall be paid in a lump sum to Executive, and any remaining payments due shall be paid as otherwise provided herein or in the applicable agreement. No interest shall be due on any amounts so deferred. If the Company determines that any severance benefits constitute "deferred compensation" under Section 409A, for purposes of determining the schedule for payment of the severance benefits, the effective date of the Release will not be deemed to have occurred any earlier than the sixtieth (60^{th}) date following the Separation From Service, regardless of when the Release actually becomes effective. In addition to the above, to the extent required to comply with Section 409A and the applicable regulations and guidance issued thereunder, if the applicable deadline for Executive to execute (and not revoke) the applicable Release spans two calendar years, payment of the applicable severance benefits shall not commence until the beginning of the second calendar year. To the extent required to avoid accelerated taxation and/or tax penalties under Code Section 409A, amounts reimbursable to Executive under this Agreement shall be paid to Executive on or before the last day of the year following the year in which the expense was incurred and the amount of expenses eligible for reimbursement (and in-kind benefits provided to Executive) during any one year may not effect amounts reimbursable or provided in any subsequent year. The Company makes no representation that any or all of the payments described in this Agreement will be exempt from or comply with Code Section 409A and makes no undertaking to preclude Code Section 409A from applying to any such payment.

9. Section 280G.

If any payment or benefit Executive will or may receive from the Company or otherwise (a "**280G Payment**") would (i) constitute a "parachute payment" within the meaning of Section 280G of the Code, and (ii) but for this sentence, be subject to the excise tax imposed by Section 4999 of the Code (the "**Excise Tax**"), then any such 280G Payment pursuant to this Agreement or otherwise (a "**Payment**") shall be equal to the Reduced Amount. The "**Reduced Amount**" shall be either (x) the largest portion of the Payment that would result in no portion of the Payment (after reduction) being subject to the Excise Tax or (y) the largest portion, up to and including the total, of the Payment, whichever amount (i.e., the amount determined by clause (x) or by clause (y)), after taking into account all applicable federal, state and local employment taxes, income taxes, and the Excise Tax (all computed at the highest applicable marginal rate), results in Executive's receipt, on an after-tax basis, of the greater economic benefit notwithstanding that all or some portion of the Payment may be subject to the Excise Tax. If a reduction in a Payment is required pursuant to the preceding sentence and the Reduced Amount is determined pursuant to clause (x) of the preceding sentence, the reduction shall occur in the manner (the "**Reduction Method**") that results in the greatest economic benefit for Executive. If more than one method of reduction will result in the same economic benefit, the items so reduced will be reduced pro rata (the "**Pro Rata Reduction Method**").

Notwithstanding the foregoing, if the Reduction Method or the Pro Rata Reduction Method would result in any portion of the Payment being subject to taxes pursuant to Section 409A that would not otherwise be subject to taxes pursuant to Section 409A, then the Reduction Method and/or the Pro Rata Reduction Method, as the case may be, shall be modified so as to avoid the imposition of taxes pursuant to Section 409A as follows: (A) as a first priority, the modification shall preserve to the greatest extent possible, the greatest economic benefit for Executive as determined on an after-tax basis; (B) as a second priority, Payments that are contingent on future events (e.g., being terminated without Cause), shall be reduced (or eliminated) before Payments that are not contingent on future events; and (C) as a third priority, Payments that are "deferred compensation" within the meaning of Section 409A shall be reduced (or eliminated) before Payments that are not deferred compensation within the meaning of Section 409A.

Unless Executive and the Company agree on an alternative accounting firm, the accounting firm engaged by the Company for general tax compliance purposes as of the day prior to the effective date of the change in control transaction triggering the Payment shall perform the foregoing calculations. If the accounting firm so engaged by the Company is serving as accountant or auditor for the individual, entity or group effecting the change in control transaction, the Company shall appoint a nationally recognized accounting firm to make the determinations required hereunder. The Company shall bear all expenses with respect to the determinations by such accounting firm required to be made hereunder. The Company shall use commercially reasonable efforts to cause the accounting firm engaged to make the determinations hereunder to provide its calculations, together with detailed supporting documentation, to Executive and the Company within 15 calendar days after the date on which Executive's right to a 280G Payment becomes reasonably likely to occur (if requested at that time by Executive or the Company) or such other reasonable time as requested by Executive or the Company.

If Executive receives a Payment for which the Reduced Amount was determined pursuant to clause (x) of the first paragraph of this Section and the Internal Revenue Service determines thereafter that some portion of the Payment is subject to the Excise Tax, Executive shall promptly return to the Company a sufficient amount of the Payment (after reduction pursuant to clause (x) of the first paragraph of this Section so that no portion of the remaining Payment is subject to the Excise Tax). For the avoidance of doubt, if the Reduced Amount was determined pursuant to clause (y) in the first paragraph of this Section, Executive shall have no obligation to return any portion of the Payment pursuant to the preceding sentence

10. Indemnification. Executive shall be entitled to indemnification with respect to Executive's services provided hereunder pursuant to Delaware law, the terms and conditions of the Company's certificate of incorporation and/or by-laws, and the Company's standard indemnification agreement for directors and officers as executed by the Company and Executive. Executive shall be entitled to coverage under the Company's Directors' and Officers' ("**D&O**") insurance policies that it may hold now or in the future to the same extent and in the same manner (i.e., subject to the same terms and conditions) to which the Company's other executive officers are entitled to coverage under any of the Company's D&O insurance policies.

11. Dispute Resolution. To ensure the timely and economical resolution of disputes that may arise between Executive and the Company, both Executive and the Company mutually agree that pursuant to the Federal Arbitration Act, 9 U.S.C. §1-16 (the "**FAA**"), and to the fullest extent permitted by applicable law, Executive and the Company will submit solely to final, binding and confidential arbitration any and all disputes, claims, or causes of action arising from or relating to: **(i)** the negotiation, execution, interpretation, performance, breach or enforcement of this Agreement; or **(ii)** Executive's employment with the Company (including but not limited to all statutory claims); or **(iii)** the termination of Executive's employment with the Company (including but not limited to all statutory claims). **BY AGREEING TO THIS ARBITRATION PROCEDURE, BOTH EXECUTIVE AND THE COMPANY WAIVE THE RIGHT TO RESOLVE ANY SUCH DISPUTES THROUGH A TRIAL BY JURY OR JUDGE OR THROUGH AN ADMINISTRATIVE PROCEEDING.** The arbitrator shall have the sole and exclusive authority to determine whether a dispute, claim or cause of action is subject to arbitration under this Section and to determine any procedural questions which grow out of such disputes, claims or causes of action and bear on their final disposition. All claims, disputes, or causes of action under this Section, whether by Executive or the Company, must be brought solely in an individual capacity, and shall not be brought as a plaintiff (or claimant) or class member in any purported class or representative proceeding, nor joined or consolidated with the claims of any other person or entity. The arbitrator may not consolidate the claims of more than one person or entity, and may not preside over any form of representative or class proceeding. To the extent that the preceding sentences in this Section are found to violate applicable law or are otherwise found unenforceable, any claim(s) alleged or brought on behalf of a class shall proceed in a court of law rather than by arbitration. Any arbitration proceeding under this Section shall be presided over by a single arbitrator and conducted by JAMS, Inc. ("**JAMS**") in San Diego, California, or as otherwise agreed to by Executive and the Company, under the then applicable JAMS rules for the resolution of employment disputes (available upon request and also currently available at http://www.jamsadr.com/rules-employment-arbitration/). Executive and the Company both have the right to be represented by legal counsel at any arbitration proceeding, at each party's own expense. The arbitrator shall: **(i)** have the authority to compel adequate discovery for the resolution of the dispute; **(ii)** issue a written arbitration decision, to include the arbitrator's essential findings and conclusions and a statement of the award; and **(iii)** be authorized to award any or all remedies that Executive or the Company would be entitled to seek in a court of law. The Company shall pay all JAMS arbitration fees in excess of the amount of court fees that would be required of Executive if the dispute were decided in a court of law. This Section shall not apply to any action or claim that cannot be subject to mandatory arbitration as a matter of law, including, without limitation, sexual assault disputes and sexual harassment disputes as defined in the FAA, claims brought pursuant to the California Private Attorneys General Act of 2004, as amended, the California Fair Employment and Housing Act, as amended, and the California Labor Code, as amended, to the extent such claims are not permitted by applicable law to be submitted to mandatory arbitration and such applicable law is not preempted by the FAA or otherwise invalid (collectively, the "**Excluded Claims**"). In the event Executive intend to bring multiple claims, including one of the Excluded Claims listed above, the Excluded Claims may be filed with a court, while any other claims will remain subject to

mandatory arbitration. Nothing in this Section is intended to prevent either Executive or the Company from obtaining injunctive relief in court to prevent irreparable harm pending the conclusion of any such arbitration. Any final award in any arbitration proceeding hereunder may be entered as a judgment in the federal and state courts of any competent jurisdiction and enforced accordingly.

12. General Provisions.

12.1 Notices. Any notices provided must be in writing and will be deemed effective upon the earlier of personal delivery (including personal delivery by fax) or the next day after sending by overnight carrier, to the Company at its primary office location and to Executive at the address as listed on the Company payroll.

12.2 Severability. Whenever possible, each provision of this Agreement will be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Agreement is held to be invalid, illegal or unenforceable in any respect under any applicable law or rule in any jurisdiction, such invalidity, illegality or unenforceability will not affect any other provision or any other jurisdiction, but this Agreement will be reformed, construed and enforced in such jurisdiction to the extent possible in keeping with the intent of the parties.

12.3 Waiver. Any waiver of any breach of any provisions of this Agreement must be in writing to be effective, and it shall not thereby be deemed to have waived any preceding or succeeding breach of the same or any other provision of this Agreement.

12.4 Complete Agreement. This Agreement, together with the Confidential Information Agreement, constitutes the entire agreement between Executive and the Company with regard to the subject matter hereof and is the complete, final, and exclusive embodiment of the Company's and Executive's agreement with regard to this subject matter. This Agreement is entered into without reliance on any promise or representation, written or oral, other than those expressly contained herein, and it supersedes and replaces any other agreements or promises made to Executive by anyone concerning Executive's employment terms, compensation or benefits, whether oral or written. It cannot be modified or amended except in a writing signed by a duly authorized officer of the Company, with the exception of those changes expressly reserved to the Company's discretion in this Agreement.

12.5 Counterparts. This Agreement may be executed in separate counterparts, any one of which need not contain signatures of more than one party, but both of which taken together will constitute one and the same Agreement.

12.6 Headings. The headings of the sections hereof are inserted for convenience only and shall not be deemed to constitute a part hereof nor to affect the meaning thereof.

12.7 Successors and Assigns. This Agreement is intended to bind and inure to the benefit of and be enforceable by Executive and the Company, and their respective successors, assigns, heirs, executors and administrators, except that Executive may not assign any of Executive's duties hereunder and Executive may not assign any of Executive's rights hereunder without the written consent of the Company, which shall not be withheld unreasonably.

12.8 Tax Withholding. All payments and awards contemplated or made pursuant to this Agreement will be subject to withholdings of applicable taxes in compliance with all relevant laws and regulations of all appropriate government authorities. Executive acknowledges and agrees that the Company has neither made any assurances nor any guarantees concerning the tax treatment of any payments or awards contemplated by or made pursuant to this Agreement. Executive has had the opportunity to retain a tax and financial advisor and fully understands the tax and economic consequences of all payments and awards made pursuant to this Agreement.

12.9 Choice of Law. All questions concerning the construction, validity and interpretation of this Agreement will be governed by the laws of the State of California.

[*Signature Page Follows*]

IN WITNESS WHEREOF, this Agreement shall be effective as of the Effective Date.

ARS PHARMACEUTICALS, INC.

By: /s/ Donn Casale

Name: Donn Casale

Title: Chief Executive Officer

Date: August 12, 2026

EXECUTIVE

By: /s/ Margaret Smith

Name: Margaret Smith

Title: Chief Commercial Officer

Date: August 12, 2026

Exhibit A

Employee Confidential Information and Inventions Assignment Agreement

(separately attached)

Exhibit 10.5

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.

ARS Pharmaceuticals Operations, Inc.
11682 El Camino Real, Suite 300 San
Diego, CA 92130

To:

ALK-Abelló, Inc.
135 Route 202/206 Suite #16 Bedminster, New
Jersey 07921 Attention: President

Re: Side Letter to Co-Promotion Agreement, dated as of May 2, 2025, as amended October 23, 2025, and March 3, 2026 (as amended, the "**Agreement**"), by and between ARS Pharmaceuticals Operations, Inc. ("**ARS**") and ALK-Abelló, Inc. ("**ALK**").

Dear ALK:

This letter agreement (the "**Side Letter**") is entered into as of August 31, 2026 (the "**Side Letter Effective Date**"), by and between ARS and ALK (together, the "**Parties**") in connection with the Agreement. Capitalized terms used but not otherwise defined herein shall have the respective meanings given in the Agreement.

WHEREAS, the Parties desire to provide ARS with [***], with an adjusted Base Fee applicable for [***]; and

WHEREAS, [***].

NOW, THEREFORE, in consideration of the foregoing and the mutual covenants set forth herein, the Parties agree as follows:

(1) The undersigned agree that notwithstanding anything to the contrary in the Agreement, during the period commencing on [***], then ARS shall remain obligated to pay ALK all Base Fees [***], in accordance with the terms of the Agreement. However, a Fixed Fee of [***] per Quarter shall apply, pending [***], for any Base Fees [***], in lieu of the Base Fees stated in Section 6.1 of the Agreement. Following execution of the Amendment [***].

(2) [***].

Except for the consent set forth above, the existing terms and conditions of the Agreement shall continue to have full force and effect.

The governing law and dispute resolution provisions set forth in Sections 12.1 and 12.2, respectively, of the Agreement shall apply to this Letter Agreement, *mutatis mutandis*.

Sincerely,

/s/ Justin Chakma

Justin Chakma
Chief Business Officer
ARS Pharmaceuticals Operations, Inc.

Agreed for and on behalf of ALK-Abelló, Inc.:

By: /s/ Claus Steensen Sølje
Name: Claus Steensen Sølje
Title: CFO

By: /s/ Edward Jordan
Name: Edward Jordan
Title: EVP NA Commercial Operations

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Donn Casale, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the quarter ended September 30, 2026 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: November 5, 2026

By: /s/ Donn Casale
Donn Casale
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

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 September 30, 2026 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: November 5, 2026

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

Exhibit 32.1

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 September 30, 2026, 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: November 5, 2026

By: /s/ Donn Casale
Donn Casale
President and Chief Executive Officer
(Principal Executive Officer)

Date: November 5, 2026

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.