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, 2024

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 120 **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 6, 2024 there were 97,185,475 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:

- any statements regarding future economic conditions or performance;
- research and development plans, including planned clinical trials, for *neffy* (which includes *EURneffy*®, the trade name for *neffy* in the European Union ("EU")) for additional indications;
- the expected timing for reporting data;
- our expectations regarding the U.S. Food and Drug Administration's ("FDA") review of our supplemental new drug application ("sNDA") for *neffy* 1 mg;
- our plans to submit a post approval variation to the European Medicines Agency's ("EMA") for *neffy* 1 mg and the timing thereof;
- our plans to submit regulatory filings for *neffy* in Canada, the United Kingdom, China, Japan, Australia and New Zealand in collaboration with our partners and the timing thereof;
- the expected timing for regulatory review decisions for *neffy*;
- the commercial potential of and commercialization strategy for *neffy*;
- the size of the markets for *neffy* for its currently approved indications in the United States and the EU and any potential additional indications, the projected growth thereof, and our and our collaboration and marketing partners' ability to capture and grow those markets;
- the rate and degree of market acceptance of *neffy* or any future product candidate;
- our expected competitive position;
- our potential to become the standard in treatment and transform the treatment of allergic reactions;
- the likelihood of *neffy* attaining and maintaining favorable coverage;
- the expected intellectual property protection for *neffy*;
- legislative and regulatory developments in the United States and foreign countries;
- estimates regarding anticipated operating losses, capital requirements and needs for additional funds;
- our ability to obtain, maintain and successfully enforce adequate patent and other intellectual property protection for *neffy* or any future product candidate;
- our expected use of the remaining net proceeds from the Silverback Therapeutics, Inc. ("Silverback") initial public offering; 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.

SUMMARY OF RISKS ASSOCIATED WITH OUR BUSINESS

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

- We are highly dependent on the successful commercialization of *neffy* in the United States and in the EU for its currently approved indications in those jurisdictions. To the extent *neffy* is not commercially successful, our business, financial condition and results of operations would be materially adversely affected, and the price of our common stock would likely decline.
- *neffy* 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 become profitable.
- 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* for its current or future indications. 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* may be adversely affected.
- If we are unable to successfully develop *neffy* for additional indications, or experience significant delays in doing so, the commercial potential of *neffy* will be more limited.
- If the FDA does not conclude that potential additional indications for *neffy*, including urticaria, satisfy the requirements for the Section 505(b)(2) regulatory approval pathway, or if the requirements for additional indications under Section 505(b)(2) are not as we expect, the approval pathway for those product candidates 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*.
- 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*.
- We are dependent on international third-party licensees and assignees for the development and commercialization of *neffy* in several countries outside the United States. If these third parties are not successful in their development and commercialization efforts of if these third parties fail to meet their contractual, regulatory or other obligations, our business and results of operations could be adversely affected.
- We expect that our timing of sales and results of operations will fluctuate for the foreseeable future, which may make it difficult to predict our future performance from period to period.
- We have incurred significant losses since our inception.
- We may need additional funding, and if we are unable to raise capital when needed, we could be forced to delay, reduce or eliminate our product development activities or commercialization efforts.
- Our commercial success depends on our ability to obtain and maintain sufficient intellectual property protection for *neffy* and other proprietary technologies.
- Our success is highly dependent on our ability to attract and retain highly skilled executive officers and employees.

PART I – FINANCIAL INFORMATION

Item 1. Financial Statements

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

	September 30, 2024 (unaudited)	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 39,657	$ 70,971
Short-term investments	164,967	157,389
Accounts receivable, net	773	—
Inventories	715	—
Prepaid expenses and other current assets	2,677	3,366
Total current assets	208,789	231,726
Right-of-use asset	92	250
Fixed assets, net	843	574
Intangible assets, net	7,500	—
Other assets	377	638
Total assets	$ 217,601	$ 233,188
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued liabilities (including related party amounts of $133 and $178, respectively)	$ 16,521	$ 2,154
Lease liability, current	102	237
Total current liabilities	16,623	2,391
Lease liability, net of current portion	—	37
Total liabilities	16,623	2,428
Commitments and contingencies (Note 8)		
Stockholders' equity		
Preferred stock, $0.0001 par value per share; 10,000,000 shares authorized at September 30, 2024 and December 31, 2023; no shares issued and outstanding at September 30, 2024 and December 31, 2023	—	—
Common stock, $0.0001 par value per share; 200,000,000 shares authorized at September 30, 2024 and December 31, 2023; 97,147,442 and 96,414,963 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively	10	10
Additional paid-in capital	373,868	362,004
Accumulated other comprehensive gain, net	339	49
Accumulated deficit	(173,239)	(131,303)
Total stockholders' equity	200,978	230,760
Total liabilities and stockholders' equity	$ 217,601	$ 233,188

The accompanying notes are an integral part of these 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,	
	2024	2023	2024	2023
Revenue:				
Product revenue, net	$ 568	$ —	$ 568	$ —
Revenue under collaboration agreements	1,500	—	2,000	30
Total revenue	2,068	—	2,568	30
Operating expenses:				
Cost of goods sold	112	—	112	—
Research and development (including related party amounts of $406, $307, $1,651 and $1,382, respectively)	4,423	3,002	16,553	16,862
Selling, general and administrative (including related party amounts of $129, $322, $337 and $840, respectively)	19,281	14,976	36,183	40,462
Total operating expenses	23,816	17,978	52,848	57,324
Loss from operations	(21,748)	(17,978)	(50,280)	(57,294)
Other income, net	2,620	3,112	8,344	10,097
Net loss	$ (19,128)	$ (14,866)	$ (41,936)	$ (47,197)
Change in unrealized gains and losses on available-for-sale securities	484	19	290	(568)
Comprehensive loss	$ (18,644)	$ (14,847)	$ (41,646)	$ (47,765)
Net loss per share, basic and diluted	$ (0.20)	$ (0.16)	$ (0.43)	$ (0.50)
Weighted-average shares outstanding used in computing net loss per share, basic and diluted	97,032,331	95,576,627	96,782,818	94,910,012

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

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

	Common Stock					
	Shares	Amount	Additional Paid-in Capital	Accumulated Other Comprehensive (Loss) Gain, Net	Accumulated Deficit	Total Stockholders' Equity
Balance at December 31, 2023	96,414,963	$ 10	$ 362,004	$ 49	$ (131,303)	$ 230,760
Exercise of common stock options and release of restricted stock units	159,086	—	258	—	—	258
Stock-based compensation	—	—	3,315	—	—	3,315
Net loss and comprehensive loss	—	—	—	(173)	(10,292)	(10,465)
Balance at March 31, 2024	96,574,049	$ 10	$ 365,577	$ (124)	$ (141,595)	$ 223,868
Exercise of common stock options, shares issued under the employee stock purchase plan, and release of restricted stock units	365,748	—	545	—	—	545
Stock-based compensation	—	—	3,365	—	—	3,365
Net loss and comprehensive loss	—	—	—	(21)	(12,516)	(12,537)
Balance at June 30, 2024	96,939,797	$ 10	$ 369,487	$ (145)	$ (154,111)	$ 215,241
Exercise of common stock options and release of restricted stock units	207,645	—	680	—	—	680
Stock-based compensation	—	—	3,701	—	—	3,701
Net loss and comprehensive loss	—	—	—	484	(19,128)	(18,644)
Balance at September 30, 2024	97,147,442	$ 10	$ 373,868	$ 339	$ (173,239)	$ 200,978

	Common Stock					
	Shares	Amount	Additional Paid-in Capital	Accumulated Other Comprehensive Gain (Loss), Net	Accumulated Deficit	Total Stockholders' Equity
Balance at December 31, 2022	93,943,316	$ 9	$ 349,408	$ 407	$ (76,938)	$ 272,886
Exercise of common stock options and release of restricted stock units	504,712	—	1,319	—	—	1,319
Stock-based compensation	—	—	2,250	—	—	2,250
Net loss and comprehensive loss	—	—	—	(339)	(14,961)	(15,300)
Balance at March 31, 2023	94,448,028	$ 9	$ 352,977	$ 68	$ (91,899)	$ 261,155
Exercise of common stock options, shares issued under the employee stock purchase plan, and release of restricted stock units	874,925	—	2,854	—	—	2,854
Stock-based compensation	—	—	2,161	—	—	2,161
Net loss and comprehensive loss	—	—	—	(248)	(17,370)	(17,618)
Balance at June 30, 2023	95,322,953	$ 9	$ 357,992	$ (180)	$ (109,269)	$ 248,552
Exercise of common stock options	473,301	—	922	—	—	922
Stock-based compensation	—	—	2,657	—	—	2,657
Net loss and comprehensive loss	—	—	—	19	(14,866)	(14,847)
Balance at September 30, 2023	95,796,254	$ 9	$ 361,571	$ (161)	$ (124,135)	$ 237,284

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,	
	2024	2023
Cash flows from operating activities:		
Net loss	$ (41,936)	$ (47,197)
Non-cash adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	10,271	6,957
Depreciation	50	61
Amortization and accretion, net	(5,710)	(5,121)
Changes in operating assets and liabilities:		
Accounts receivable	(773)	—
Inventories	(183)	—
Prepaid and other assets	1,060	481
Donation of equipment	30	—
Accounts payable and accrued liabilities (including related party amounts of $(45) and $192, respectively)	8,749	6,104
Operating right-of-use assets and lease liabilities, net	(14)	(9)
Contract liability	—	(3,137)
Net cash used in operating activities	(28,456)	(41,861)
Cash flows from investing activities:		
Purchases of short-term investments, available-for-sale	(192,580)	(237,953)
Maturities of short-term investments, available-for-sale	191,000	125,000
Payments of milestone obligations under license agreements	(2,500)	—
Purchase of property and equipment	(261)	(266)
Net cash used in investing activities	(4,341)	(113,219)
Cash flows from financing activities:		
Proceeds from exercise of common stock options and employee stock purchase plan	1,483	5,094
Net cash provided by financing activities	1,483	5,094
Net change in cash and cash equivalents	(31,314)	(149,986)
Cash and cash equivalents at beginning of period	70,971	210,518
Cash and cash equivalents at end of period	$ 39,657	$ 60,532
Supplemental cash flow information:		
Intangible assets included in accounts payable	$ 5,000	$ —
Stock-based compensation capitalized into inventory	$ 110	$ —
Prepayment included in accrued expenses	$ 110	$ —
Purchases of inventories included in accounts payable	$ 422	$ —
Purchases of property and equipment included in accounts payable	$ 87	$ 91
Purchases of property and equipment reclassed from prepaid expenses and other current assets	$ —	$ 174

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* (previously referred to as ARS-1 and currently identified in the EU by the trade name *EURneffy*) for the needle-free intranasal delivery of epinephrine for the emergency treatment of Type I allergic reactions, including anaphylaxis. *neffy* is the first and only FDA and European Commission-approved needle-free epinephrine product, and the first new delivery method for epinephrine in more than 35 years.

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

Liquidity and Capital Resources

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. The Company has incurred net operating losses since its inception and had an accumulated deficit of $173.2 million as of September 30, 2024. The Company had cash, cash equivalents, and short-term investments of $204.6 million as of September 30, 2024 and has not generated positive cash flows from operations. To date, the Company has funded its operations primarily with proceeds from the merger with Silverback in November 2022 (the "Merger"), the issuance of convertible preferred stock, payments earned under collaboration agreements, bank debt, and product sales. The Company's currently available cash, cash equivalents, and short-term investments as of September 30, 2024 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, 2024, the Company has devoted substantially all of its efforts to developing intellectual property, conducting product development and clinical trials, organizing and staffing our company, business planning, raising capital, building infrastructure, pre-commercial and commercial activities, and providing general and administrative support for these operations. The Company has a limited operating history, and the sales and income potential of the Company's business and market are unproven. Management expects operating expenses to increase for the foreseeable future and there can be no assurance that the Company will ever achieve profitability, or if achieved, that it will be sustained on a continuing basis.

The Company's ability to raise additional capital may be adversely impacted should the global economic conditions worsen or as a result of further disruptions to, and volatility in, the credit and financial markets in the United States, including bank failures, future health epidemics or pandemics, geopolitical actions or other macroeconomic factors. If such further disruption occurs, the Company could experience an inability to access additional capital. If the Company is not able to secure adequate additional funding, it may be forced to make reductions in spending, extend payment terms with suppliers, liquidate assets where possible, and/or suspend or curtail planned programs. Any of these actions could materially harm the Company's business, results of operations, and future prospects.

2. Summary of Significant Accounting Policies

Basis of Presentation and Principles of Consolidation

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

Unaudited Interim Condensed Consolidated Financial Statements

The accompanying condensed consolidated balance sheet as of September 30, 2024, the condensed consolidated statements of operations and comprehensive loss for the three and nine months ended September 30, 2024 and 2023, the condensed consolidated statements of stockholders' equity for the nine months ended September 30, 2024 and 2023, and the condensed consolidated statements of cash flows for the nine months ended September 30, 2024 and 2023, are unaudited. The balance sheet as of December 31, 2023 was derived from the audited financial statements as of and for the year ended December 31, 2023. 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, 2023, 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, 2024, the condensed consolidated results of its operations for the three and nine months ended September 30, 2024 and 2023, and its cash flows for the nine months ended September 30, 2024 and 2023. The financial data and other information disclosed in these notes related to the three and nine months ended September 30, 2024 and 2023 are also unaudited. The condensed consolidated results of operations for the three and nine months ended September 30, 2024 are not necessarily indicative of the results to be expected for the full year ending December 31, 2024 or any other period.

Use of Estimates

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

Cash and Cash Equivalents

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

Trade Accounts Receivable and Allowance

Trade accounts receivable are amounts owed to the Company by its customers for product that has been delivered. Trade accounts receivable are recorded at wholesale acquisition cost ("WAC"), less purchase price discounts, prompt pay discounts, chargebacks, and an allowance for credit losses, if any. The allowance for credit losses is the Company's estimate of losses over the life of the receivables. The Company determines the allowance for credit losses based on each customer's trade accounts receivable balance and age, their financial condition, and the general economic environment. The Company must also use professional judgment because *neffy* was commercially launched in September 2024 and historical data is limited. The Company is currently operating under the Title Agreement (as defined in Note 3 - Revenue) with its 3PL Agent (as defined in Note 3 - Revenue) and the 3PL Agent retains all credit and collection risk on sales to the Company's wholesale distributors and pharmacy customers.

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

Investments

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

Fair Value of Financial Instruments

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

Concentrations of Credit Risk

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

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

The Company is also subject to credit risk related to its trade accounts receivable from product sales. *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 extends credit to its customers in the normal course of business after evaluating their overall financial condition. As stated above, the Company is currently operating under the Title Agreement with its 3PL Agent (as defined in Note 3 - Revenue) and the 3PL Agent retains all credit and collection risk on sales to the Company's wholesale distributors and pharmacy customers. For the three and nine months ended September 30, 2024, the Company's three largest customers combined made up approximately 81% of its gross product sales. As of September 30, 2024 the Company's three largest customers combined made up 83% of its trade accounts receivable balance. Historically, the Company has not experienced any credit losses from product sales.

Inventories

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

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

Property and Equipment

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

Impairment of Long-Lived Assets

Long-lived assets consist primarily of property and equipment and intangible assets. The Company reviews its long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. Recoverability is measured by comparison of the carrying amount to the future undiscounted net cash flows which the asset or asset group are expected to generate. 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, 2024.

Leases

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

Intangible Assets

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

Revenue Recognition

The Company's revenues consist of product sales of *neffy* and revenue derived from its collaboration and out-licensing agreements. See Note 3 - Revenue for more detail on product revenue, and Note 7 - Collaboration and Out-Licensing for more detail on revenue from collaboration and out-licensing agreements.

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

Cost of Goods Sold

Cost of goods sold consists primarily of direct and indirect costs related to the manufacture of *neffy* for commercial sale, including third-party manufacturing costs, raw material and component costs, packaging services, freight, storage costs, distribution fees, amortization of capitalized in-licensed costs, and royalties on product sales. Prior to the FDA approval of *neffy* in August 2024, costs incurred for the manufacture of *neffy* were recorded as research and development expenses and therefore will not be included in cost of goods sold. 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 is utilized and sold to customers.

Research and Development Costs

Research and development 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 our clinical studies, costs related to compliance with regulatory requirements, costs related to manufacturing the Company's product candidates (including *neffy* prior to FDA approval in August 2024) for clinical trials and other allocated expenses.

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

Advertising

Costs for producing advertising are expensed when incurred. Costs for communicating advertising, such as search engine marketing, banner advertisements, social media advertisements, and print advertisements, are recorded as prepaid expenses and then expensed when the advertisement occurs.

Patent Costs

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

License Fees

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

Acquired in-process research and development expense

Acquired in-process research and development expense ("IPR&D") is expensed on the acquisition date if there is no alternative future use. Contingent consideration payments in asset acquisitions are recognized when the contingency is resolved and the consideration becomes payable. Milestone payments made to third parties subsequent to regulatory approval will be capitalized as intangible assets and amortized over the estimated remaining useful life of the related product.

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 our 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 Common Share

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

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

	As of September 30,	
	2024	2023
Warrants to purchase common stock	45,456	45,456
Common stock options granted and outstanding	15,178,403	14,906,885
Unvested restricted stock units	2,763	5,082
Estimated shares to be purchased under the Employee Stock Purchase Plan	9,222	15,815
Total	15,235,844	14,973,238

Recently Issued Accounting Pronouncements — Not Yet Adopted

In November 2023, the FASB issued ASU 2023-07, Segment Reporting (ASU 2023-07), which requires issuers to make additional disclosures with respect to segment expenses, including required disclosure on an annual and interim basis for significant segment expenses and other segment items. ASU 2023-07 also permits the disclosure of more than one measure of a segment's profit or loss. ASU 2023-07 is effective for the Company as of January 1, 2024 for annual periods and as of January 1, 2025 for interim periods. The Company is evaluating the expected impact of ASU 2023-07 on the consolidated financial statements and related disclosures.

In December 2023, the FASB issued ASU 2023-09, Income Taxes (ASU 2023-09), which requires issuers to make additional disclosures on an annual basis related to specific categories in the rate reconciliation and provide additional information for reconciling items that meet a quantitative threshold on an annual basis, disclose additional information about income taxes paid as well as other disaggregated disclosures. ASU 2023-09 is effective for the Company as of January 1, 2025 for annual periods. The Company is evaluating the expected impact of ASU 2023-09 on the consolidated financial statements and related disclosures.

3. Revenue

The Company's revenues consist of product sales of *neffy* and revenue derived from its collaboration and out-licensing agreements. See Note 7 - Collaboration and Out-Licensing for further discussion related to those arrangements.

Product Revenue

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

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

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

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

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

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

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

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

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

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

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

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

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

4. Inventories

The Company began to capitalize the inventory costs associated with *neffy* upon FDA approval in August 2024 when future commercialization was considered probable and it was determined that the inventory had a probable future economic benefit. These inventory costs consist primarily of purchased materials, third-party manufacturing costs, and packaging and serialization services.

Capitalized inventories consisted of the following (in thousands):

	As of September 30,	
	2024	2023
Raw materials	$ 422	$ —
Work in process	293	—
Finished goods	—	—
Total	$ 715	$ —

Prior to FDA approval in August 2024, costs incurred for the manufacture of *neffy* were recorded as research and development expenses, which upon approval resulted in zero-cost inventory. The Company had $13.0 million in zero-cost inventory remaining as of September 30, 2024.

5. Fair Value Measurements

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

Level 1- Quoted prices (unadjusted) in active markets for identical assets or liabilities;

Level 2- Inputs other than quoted prices included within Level 1 that are either directly or indirectly observable; and

Level 3- Unobservable inputs in which little or no market activity exists, therefore requiring an entity to develop its own assumptions about the assumptions that market participants would use in pricing.

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

September 30, 2024	**Level**	**Amortized Cost**	**Gross unrealized gains**	**Gross unrealized losses**	**Estimated Fair Value**
Cash and cash equivalents - Money market mutual funds	1	$ 33,638	$ —	$ —	$ 33,638
Cash and cash equivalents - U.S. Treasury securities	2	4,977	2	—	4,979
Short-term investments - U.S. Treasury securities	2	164,630	337	—	164,967
Total		$ 203,245	$ 339	$ —	$ 203,584
December 31, 2023					
Cash and cash equivalents - Money market mutual funds	1	$ 69,938	$ —	$ —	$ 69,938
Short-term investments - U.S. Treasury securities	2	157,340	61	(12)	157,389
Total		$ 227,278	$ 61	$ (12)	$ 227,327

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, 2024, the Company purchased $41.5 million and $192.6 million, respectively, in short-term investments, and there was $61.0 million and $191.0 million, respectively, in maturities of short-term investments. During the three and nine months ended September 30, 2023, the Company purchased $106.6 million and $238.0 million, respectively, in short-term investments, and there was $60.0 million and $125.0 million, respectively, in maturities of short-term investments.

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

For the three and nine months ended September 30, 2024, there was a $0.5 million and $0.3 million unrealized gain on available-for-sale securities, respectively. For the three and nine months ended September 30, 2023, there was a negligible and $0.6 million unrealized loss on available-for-sale securities, respectively. For the nine months ended September 30, 2023, $0.3 million was reclassified from accumulated other comprehensive gain to other income. Management determined that the gross unrealized losses on the Company's available-for-sale securities as of September 30, 2024 were primarily attributable to current economic and market conditions and not credit risk. As of September 30, 2024 and December 31, 2023, no allowance for credit losses was recorded. It is neither management's intention to sell nor is it more likely than not that the Company will be required to sell any investments prior to recovery of its amortized cost basis, which is expected to be at maturity.

Accrued interest on the Company's available-for-sale securities was $0.5 million as of September 30, 2024 and is included in prepaid expenses and other current assets in the accompanying condensed consolidated balance sheet.

As of September 30, 2024 and December 31, 2023, the Company did not have any liabilities that were measured at fair value on a recurring basis.

6. Balance Sheet Details

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

	September 30, 2024	December 31, 2023
Prepaid expenses	$ 1,152	$ 1,124
Interest receivable	466	686
Capitalized software implementation costs	315	163
Deposits	192	—
Co-payment escrow	152	—
Prepaid insurance	137	904
Prepaid development costs	137	380
Other	126	109
Total	$ 2,677	$ 3,366

Fixed assets, net consisted of the following (in thousands):

	September 30, 2024	December 31, 2023
Equipment	$ 735	$ 590
Furniture and fixtures	255	81
Leasehold improvements	24	24
Less accumulated depreciation	(171)	(121)
Total	$ 843	$ 574

Depreciation expense was negligible and $0.1 million for the three and nine months ended September 30, 2024 and 2023, respectively.

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

	September 30, 2024	December 31, 2023
Capitalized software implementation costs	$ 377	$ 617
Security deposit	—	21
Total	$ 377	$ 638

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

	September 30, 2024	December 31, 2023
Accounts payable	$ 8,276	$ 759
Accrued compensation	2,584	315
Accrued marketing related expenses	2,187	42
Accrued legal and professional fees	1,414	174
Accrued research and development expenses	859	705
Other	1,201	159
Total	$ 16,521	$ 2,154

7. Collaboration and Out-Licensing

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

Licenses of Intellectual Property. If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, revenue is recognized from non-refundable, up-front 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 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, up-front fees. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

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

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.

Clinical and Commercial Supply. Arrangements that include a promise for the future supply of drug product for either clinical development or commercial supply at the licensee's discretion are generally considered as options. We assess if these options provide a material right to the licensee and if so, they are accounted for as separate performance obligations. The Company has not earned revenues for clinical or commercial supply sales as of September 30, 2024.

Royalty/Transfer Price Revenues. For arrangements that include sales-based royalties or transfer price, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). The Company has not received any royalty or transfer price revenues as of September 30, 2024.

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 for the rights pursuant to the LOI. Under the agreement, the Company delivered a license to *neffy* technology, completed a required clinical study, and remains obligated to use commercially reasonable efforts to develop and commercialize *neffy* in Japan. The parties agreed to share the cost of any additional clinical studies required for approval of *neffy* in Japan. Alfresa is solely responsible for regulatory and commercialization activities and may elect to assume responsibility for manufacturing and supplying drug product for commercial use in Japan. Either party may terminate the agreement for certain breaches of the agreement. Unless terminated earlier by either or both parties, the term of the agreement will continue until the later of (i) expiration of the last-to-expire patent in Japan; or (ii) 10 years after the commercial sale of *neffy* in Japan.

In addition to the $2.0 million received under the LOI, the Company is eligible to receive up to $13.0 million of milestone payments upon achievement of certain clinical and regulatory milestones. Further, the Company is eligible to receive a negotiable transfer price expected to be in the low double-digit percentage on net sales subject to the regulatory approval to commercialize *neffy* in Japan. In July 2020, the Company earned a $5.0 million milestone payment upon the completion of a clinical milestone in Japan.

At the commencement of this collaboration, the Company identified the following performance obligations: the license for *neffy* and research and development services, both of which have been completed. The Company determined the initial transaction price to be $7.0 million, which includes a clinical milestone as it was deemed not probable of significant reversal at the inception of the agreement. Due to the uncertainty in the achievement of the regulatory and commercial milestones, the variable consideration associated with these future milestone payments has been fully constrained and is excluded from the transaction price until such time that the Company concludes that it is probable that a significant reversal of previously recognized revenue will not occur. These estimates will be reassessed at each reporting period. The transaction price was allocated to the performance obligations based on the estimated stand-alone selling price of each performance obligation. The Company recognized no revenue and less than $0.1 million in revenue for the three and nine months ended September 30, 2024 and 2023, respectively, in the accompanying condensed consolidated statements of operations and comprehensive loss. There was no contract liability as of September 30, 2024.

Recordati Agreement

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

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

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

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

The Company determined that the Recordati Rights at the time of entering into the Recordati Termination Agreement had no alternative future use and therefore recorded the €3.0 million upfront payment to Recordati as an IPR&D expense presented within research and development expense. The Recordati Termination Agreement ended the Company's performance obligations pursuant to the Recordati Agreement and consequently the existing contract liability of $3.1 million previously received from Recordati was recorded against IPR&D expense presented within research and development expense in the accompanying condensed consolidated statements of operations and comprehensive loss. Accordingly, no revenue has been recognized subsequent to the Recordati Termination Agreement. In June 2024, the EMA regulatory milestone was met and a €2.0 million ($2.1 million in U.S. dollars) expense was recorded in research and development expense in the accompanying condensed consolidated statements of operations and comprehensive loss. The Company paid the EMA regulatory milestone in July 2024.

Pediatrix Agreement

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

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

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

Seqirus Agreement

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

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

At the commencement of this collaboration, the Company identified one performance obligation which is the delivery of the license for *neffy* in the Seqirus Territory in combination with the transfer of know-how. The Company determined that the option to purchase the commercial supply does not represent a material right. The Company determined the initial transaction price to be the $0.5 million upfront payment. Due to the uncertainty in the achievement of all the regulatory milestones, the variable consideration associated with these future milestone payments has been fully constrained and is excluded from the transaction price until such time that the Company concludes that it is probable that a significant reversal of previously recognized revenue will not occur. The variable consideration will be reassessed at each reporting period. In May 2024, the Company delivered the license for *neffy* in the Seqirus Territory in combination with the transfer of know-how and recognized $0.5 million in revenue. In August 2024, the first milestone event was met and the Company recognized $1.5 million in revenue. In summary, the Company recognized $1.5 million and $2.0 million in revenue for the three and nine months ended September 30, 2024, respectively, in the accompanying condensed consolidated statements of operations and comprehensive loss.

8. Commitments and Contingencies

Leases

In October 2021, the Company entered into a 38-month noncancelable lease for its current headquarters location consisting of 4,047 rentable square feet of office space in San Diego, California. Under the terms of the agreement, there is no option to extend the lease, and the Company is subject to additional charges for common area maintenance and other costs. Monthly rental payments due under the lease commenced on December 6, 2021 and escalate through the lease term. The Company prepaid the first month's rent upon execution of the lease, and the lease agreement provided full rent abatement for the second and third months of the rental term. As of September 30, 2024, the remaining lease term of the Company's operating lease was 5 months, and the discount rate on the Company's operating lease was 8%. As there was not an implicit rate within the lease, the discount rate was determined by using a set of peer companies incremental borrowing rates. The Company's operating lease expense was $0.1 million and $0.2 million for the three and nine months ended September 30, 2024 and 2023, respectively. The Company's variable lease expense was immaterial for the three and nine months ended September 30, 2024 and 2023. Cash paid for amounts included in the measurement of lease liabilities was $0.1 million and $0.2 million for the three and nine months ended September 30, 2024 and 2023, respectively.

As of September 30, 2024, future minimum noncancelable operating lease payments are as follows (in thousands):

Year ending December 31,	Amount
2024	$ 62
2025	42
Total lease payments	104
Less imputed interest	(2)
Lease liability	102
Less current portion of lease liability	(102)
Lease liability, net of current portion	$ —

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 August 12, 2021, Amphastar Pharmaceuticals, Inc. ("Amphastar") filed a Petition for Inter Partes Review with the United States Patent and Trademark Office ("USPTO"), seeking to invalidate claims 1-20 of United States Patent No. 10,682,414 (the "'414 patent"). The '414 patent issued on June 16, 2020 and is entitled "Intranasal Epinephrine Formulations and Methods for the Treatment of Disease." The claims of the '414 patent are directed to methods of treating a type-1 hypersensitivity reaction, including anaphylaxis, using an aqueous nasal spray pharmaceutical formulation containing epinephrine or a salt thereof in a single dose. On February 9, 2023, the USPTO issued a Final Written Decision finding claims 3-6 and 18-20, which encompass the Company's *neffy* product candidate, patentable, and claims 1-2 and 7-17 unpatentable. On April 12, 2023, Amphastar filed a notice of appeal with the United States Court of Appeals for the Federal Circuit. On May 15, 2023, the Company filed a motion to dismiss for lack of standing, which will be heard along with the merits of the case. Briefing on both the motion to dismiss and the merits is complete, and a decision from the Federal Circuit is expected in 2025. The results of any appeal proceedings are inherently unpredictable and uncertain, and could result in the Federal Circuit finding some or all of claims 1-20 of the '414 patent to be invalid or unenforceable.

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

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, 2024.

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, we enter into arrangements with suppliers, manufacturers, and various other companies that supply goods or services. These arrangements can include unconditional purchase obligations and commitments.

The total amount of unconditional purchase obligations related to the supply of raw materials is $34.1 million as of September 30, 2024. Payments by year are as follows: 2024 and 2025 ($6.8 million in the aggregate), 2026 ($7.6 million), 2027 ($8.9 million), and 2028 ($10.8 million).

The total amount of unconditional purchase obligations related to hosted software license subscription fees is $3.9 million as of September 30, 2024. Payments by year are as follows: 2024 ($0.6 million), 2025 ($1.4 million), 2026 ($1.5 million), and 2027 ($0.4 million).

The total amount of commitments related to a corporate sponsorship agreement with Food Allergy Research and Education, Inc. is $8.0 million as of September 30, 2024. Payments by year are as follows: 2024 ($1.0 million), 2025 ($4.0 million), 2026 ($3.0 million).

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

9. 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 condensed consolidated statement of operations.

The Company is required to make aggregate milestone payments of up to $20.0 million upon achievement of certain regulatory and commercial milestones. Regulatory milestone payments under the Aegis Agreement are recorded upon completion of the required events, as the triggering events are not considered to be probable until they are achieved. Prior to the FDA approval of *neffy* in August 2024, regulatory milestone payments were recorded as research and development expenses in the condensed consolidated statement of operations. The Company made a $0.5 million milestone payment to Aegis upon the achievement of a regulatory milestone during 2019, and a $1.0 million milestone payment to Aegis upon the FDA's acceptance of the Company's NDA submission for *neffy*, which occurred in the third quarter of 2022. Since the approval of *neffy* in August 2024, regulatory milestone payments have been capitalized as intangible assets in the accompanying condensed consolidated balance sheets. Amortization expense has been recorded to cost of goods sold, in the accompanying condensed consolidated statements of operations and comprehensive loss, on a straight-line basis over the estimated life of the intellectual property of 14.5 years. In August 2024, a $2.5 million milestone was met for achieving FDA approval of *neffy*. In September 2024, a $5.0 million milestone was met for the first commercial sale of *neffy*. As a result, the Company capitalized $7.5 million as intangible assets in the accompanying condensed consolidated balance sheets as of September 30, 2024. The Company paid the $2.5 million milestone for achieving FDA approval of *neffy* in September 2024, and paid the $5.0 million milestone for the first commercial sale of *neffy* in October 2024. The next milestone payment of $2.0 million is due upon the achievement of certain annual net sales.

The Company also pays royalties based on net product sales in the low to mid-single digits 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.

The Company is responsible for reimbursing Aegis for patent costs incurred in connection with prosecuting and maintaining patent rights that are specific to epinephrine or epinephrine products. There were no expenses recognized in connection with legal patent fees for the nine months ended September 30, 2024 and 2023.

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 "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 Supply Agreement unless this election is made. The parties may terminate the Supply Agreement at any time by mutual agreement. In addition, the parties may terminate the Supply Agreement in the event of certain breaches of the Supply Agreement or upon the earlier of the expiration or termination of the Aegis Agreement or June 2028. The Supply Agreement term may be extended by mutual written agreement. Under the Supply Agreement, $0.4 million and $0.7 million in expense was recognized in the three and nine months ended September 30, 2024, respectively, and no expense and $0.3 million in expense was recognized in the three and nine months ended September 30, 2023, respectively, in the accompanying condensed consolidated statements of operations and comprehensive loss.

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 and September 2024 (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 E.U., 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.

The initial term of the Renaissance Agreement commenced on September 17, 2024 and will terminate (a) for Renaissance Product designated for commercial sale in the U.S., on December 31 immediately following the fifth anniversary of the initial U.S. launch date ("U.S. Initial Term"), and (b) for Renaissance Product designated for commercial sale in the E.U., on December 31 immediately following the fifth anniversary of the initial E.U. launch date ("E.U. Initial Term"), in each case unless earlier terminated by one of the parties. The U.S. Initial Term and E.U. 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 E.U. 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.

10. 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

Common stock reserved for future issuance consisted of the following:

	September 30, 2024	December 31, 2023
Common stock options granted and outstanding	15,178,403	11,493,481
Restricted stock units granted and outstanding	2,763	4,144
Common stock reserved for future awards or option grants	6,669,273	6,220,866
Warrants to purchase common stock	45,456	45,456
Total	21,895,895	17,763,947

11. Stock-Based Compensation

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Research and development expense	$ 734	$ 656	$ 2,558	$ 1,916
Selling, general and administrative expense	2,857	1,953	7,713	5,041
Total stock-based compensation expense	$ 3,591	$ 2,609	$ 10,271	$ 6,957

During the nine months ended September 30, 2024 and 2023, $0.1 million and no stock compensation expense was capitalized into inventory, respectively.

As of September 30, 2024, the total unrecognized stock-based compensation expense related to outstanding employee options was $37.0 million, which is expected to be recognized over a remaining weighted-average period of approximately 2.57 years.

There were 4,144 restricted stock units outstanding as of December 31, 2023 and 2,763 restricted stock units outstanding as of September 30, 2024.

Equity Incentive Plans

In September 2018, ARS Pharma adopted the 2018 Equity Incentive Plan. As a result of the Merger, on November 8, 2022 ARS Pharma assumed Silverback's 2016 and 2020 Equity Incentive Plans, and Employee Stock Purchase Plan ("ESPP"). During the nine months ended September 30, 2024 and 2023, there were 43,679 and 21,899 shares of common stock purchased under the ESPP, respectively.

As of September 30, 2024, the 2016 and 2020 Equity Incentive Plans authorized a total of 20,839,408 shares, of which 6,371,928 shares are available for future grant, and 10,229,843 shares are outstanding. As of September 30, 2024, the 2018 Equity Incentive Plan authorized a total of 6,634,333 shares, of which 297,345 shares are available for future grant, and 4,951,323 shares are outstanding. The Company does not intend to grant future stock options or other equity awards under the 2016 or 2018 Equity Incentive Plans.

Stock Options

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

A summary of the Company's stock option activity for the nine months ended September 30, 2024 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, 2023	11,493,481	$ 5.32		
Granted	4,423,825	$ 7.16		
Exercised	(687,419)	$ 1.86		
Forfeited	(51,484)	$ 8.99		
Outstanding at September 30, 2024	15,178,403	$ 6.00	7.85	$ 134,144
Exercisable at September 30, 2024	8,604,390	$ 4.82	6.95	$ 88,428

The exercisable shares subject to options outstanding at September 30, 2024 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, 2024. The aggregate intrinsic value of options exercised during the nine months ended September 30, 2024 and 2023 was $5.5 million and $7.9 million, respectively.

The weighted-average grant date fair value per share of option grants for the nine months ended September 30, 2024 and 2023 was $5.57 and $6.31, respectively. The total fair value of shares vested during the nine months ended September 30, 2024 and 2023 was $12.0 million and $2.0 million, respectively.

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

	Nine Months Ended September 30,	
	2024	2023
Expected term (in years)	6.0	6.0
Expected volatility	93.9%	95.3%
Risk-free interest rate	3.9%	3.9%
Expected dividend yield	—	—

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

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

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

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

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

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

12. Employee Benefit Plans

In June 2022, the Company adopted a retirement plan, which is qualified under section 401(k) of the Internal Revenue Code of 1986, as amended, for the Company's U.S. employees. The plan allows eligible employees to defer, at the employee's discretion, pretax compensation up to the Internal Revenue Service (the "IRS") annual limits. The Company matches up to 5% of an employee's pay that they contribute to the plan, subject to IRS limitations. Expenses associated with the Company's matching contribution totaled $0.1 million and $0.3 million for the three and nine months ended September 30, 2024 and 2023, respectively.

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 President/Chief Executive Officer/director and his spouse, the Chief Medical Officer of the Company. The Company incurred consulting expense related to this agreement totaling $0.4 million and $1.7 million during the three and nine months ended September 30, 2024, respectively, and $0.4 million and $1.5 million during the three and nine months ended September 30, 2023, respectively.

In September 2018, the Company entered into a consulting agreement with Marlinspike Group, LLC ("Marlinspike Group") to provide management, business consulting services and business development support. The managing member of Marlinspike Group is the Chair of the Board of Directors of the Company and one of its stockholders. The Company incurred expenses related to this agreement totaling $0.1 million and $0.2 million for the three and nine months ended September 30, 2024 and 2023, respectively.

In April 2021, the Company entered into a consulting agreement, as amended in April 2022, with a member of the Board of Directors of the Company for general advice and assistance with the development of *neffy* and any future product candidates. As compensation for the consulting services the Company granted the member of the Board of Directors 590,950 stock options that vest over a four-year period. The Company incurred less than $0.1 million and $0.1 million in stock-based compensation expense related to this agreement for the three and nine months ended September 30, 2024 and 2023, respectively.

14. Subsequent Events

Ompi Supply Agreement

On October 8, 2024, the Company entered into a supply agreement ("Ompi Supply Agreement") with Nuova Ompi S.r.l. ("Ompi") pursuant to which Ompi has agreed to supply glass microvials to support the Company's manufacture and commercialization of *neffy.* Pursuant to the Ompi Supply Agreement, the Company has committed to purchase, and Ompi has committed to supply, specified annual minimum quantities of glass microvials. As partial consideration for the supply arrangement, the Company is obligated to pay Ompi an upfront payment of €3.0 million (approximately $3.3 million in U.S. dollars).

ALK Collaboration, License and Distribution Agreement

On November 9, 2024, the Company entered into a collaboration, license and distribution agreement (the "ALK Collaboration Agreement") with ALK-Abelló A/S to commercialize *neffy* in Europe, Canada and certain other geographies outside the U.S. Under the terms of the ALK Collaboration Agreement, the Company will receive an upfront payment of $145.0 million, and is eligible to receive up to an additional $20.0 million in regulatory and commercialization milestones and up to $300.0 million in sales-based milestones, provided that $55.0 million of such sales-based milestones are contingent upon the Company obtaining regulatory approval in Canada by a specified time. The Company will also receive tiered double-digit royalties in the teens on net sales in the licensed geographies.

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, 2023 included in our Annual Report on Form 10-K, filed with the Securities and Exchange Commission ("SEC"), on March 21, 2024. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. For a complete discussion of forward-looking statements, see the section above entitled "Forward Looking Statements." As a result of many factors, including those factors set forth in the under the caption "Item 1A. Risk Factors" of this Quarterly Report, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis. You should carefully read the "Risk Factors" section of this Quarterly Report to gain an understanding of the various factors that could cause actual results to differ materially from our forward-looking statements.

Overview

We are a biopharmaceutical company focused on the commercialization and development of *neffy* (previously referred to as ARS-1 and currently identified in the European Union ("EU") by the trade name *EURneffy*) for the needle-free intranasal delivery of epinephrine for the emergency treatment of Type I allergic reactions, including anaphylaxis. *neffy* is the first and only U.S. Food and Drug Administration ("FDA") and European Commission ("EC")-approved needle-free epinephrine product, and the first new delivery method for epinephrine in more than 35 years. *neffy* is a proprietary composition of epinephrine with an innovative absorption enhancer called Intravail®, which allows *neffy* to safely provide intranasal delivery of epinephrine at a low dose within the exposures of approved injectable products across a range of dosing conditions (including repeat dosing and allergen challenge).

We believe *neffy*'s "no needle, no injection" approach addresses a significant unmet need in the use of epinephrine, which, except for *neffy*, is currently approved only in injectable formulations for the emergency treatment of Type I allergic reactions. There are approximately 40 million people in the United States who experience Type I allergic reactions. Of this group, over the last three years, approximately 20 million people have been diagnosed and experienced severe Type I allergic reactions that may lead to anaphylaxis, and approximately 6.5 million were prescribed an epinephrine autoinjector. However (in 2023, for example), only 3.2 million filled their active epinephrine autoinjector prescription, and of those, only half consistently carry their prescribed autoinjector with them due to the many drawbacks of these devices. In aggregate, we estimate that up to 90% of patients prescribed an epinephrine device are not achieving an optimal treatment outcome today.

These drawbacks include the use of needles in the devices, which can result in patient and caregiver injury as well as hesitation and delays in administration due principally to apprehension and pain of needles, allowing the allergic reaction to progress in severity leading to symptoms that seriously impact patient quality of life, to potential need for emergency services and/or hospitalizations, and to life-threatening symptoms or events. Intra-muscular injections also are subject to dosing errors and risk of accidental blood vessel injections, which can cause a significant spike in the intravascular delivery of epinephrine potentially leading to serious cardiovascular complications or events. We believe *neffy*'s "no needle, no injection" delivery that eliminates apprehension, pain and safety concerns, small size allowing for ease of portability, ease of use, and high reliability provide it with a user-friendly profile that will increase prescriptions for epinephrine and make it more likely for patients and caregivers to administer epinephrine sooner, achieve more rapid symptom relief and prevent the allergic reaction from progressing to a level of severity that could lead to hospitalization or even death.

Data from our studies of *neffy* demonstrated nasally delivered epinephrine reached blood levels comparable to those of already approved epinephrine injectable products, and produced statistically significant responses compared to injection on pharmacodynamic surrogates for efficacy even one minute after dosing with *neffy*.

On August 9, 2024, the FDA approved *neffy* 2 mg for the treatment of type I allergic reactions, including anaphylaxis, in adults and children who weigh 30 kg or greater. As a result, we initiated commercial launch of *neffy* 2 mg in the United States, with product becoming available for shipment on September 23, 2024. A supplemental New Drug Application ("NDA") for *neffy* 1 mg dose for the treatment of type I allergic reactions, including anaphylaxis, in adults and children who weigh 15 to 30 kg was filed with the FDA on September 6, 2024. In November 2024, the FDA granted this supplemental NDA priority review and assigned a Prescription Drug User Fee Act target action date of March 6, 2025.

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

Our launch strategy for *neffy* in the United States involves direct sales force outreach to high-volume prescribers of epinephrine accounting for 40% to 45% of prescriptions in the last year through an efficient sales force comprised of 118 individuals serving as sales reps, virtual reps and areas sales managers that began field operations in early October 2024; active participation starting in November 2024 of more than 1,000 physician offices in our *neffy* experience program that allows healthcare professionals to use *neffy* firsthand as rescue therapy for anaphylaxis during in-clinic allergen challenge; extensive non-personal promotion including continuing medical education programs in collaboration with allergist societies, speaker bureaus, peer-to-peer programs and participation in regional and national medical conferences; engagement and contracting with payers to obtain timely coverage with favorable gross-to-net discounting; our *neffy*Connect program that provides support to physicians and patients including our $25 co-pay savings card, $199 cash price and patient assistance programs; a telemedicine service to conveniently obtain a prescription online; partnerships with patient advocacy organizations including disease awareness campaigns in 2025; and celebrity spokesperson-based direct to consumer advertising that is expected to commence in 2025.

On August 22, 2024, the EC granted marketing authorization in the EU for EUR*neffy* (the tradename for *neffy* in the EU), for the emergency treatment of allergic reactions (anaphylaxis), in adults and children who weigh 30 kg or greater. Through our collaboration with ALK (discussed below), we anticipate that EUR*neffy* will be made available to patients in certain EU member states in 2025. We anticipate additional regulatory filings for *neffy* in Canada, the United Kingdom, China, Japan, and Australia by the end of 2024.

We reported positive topline results demonstrating statistically significant and clinically meaningful improvements in treatment-refractory chronic urticaria patients at the American Academy of Allergy and Immunology medical conference in February 2024, and anticipate initiating a Phase 2b clinical trial in the outpatient urticaria setting in early 2025, followed by the potential initiation of a single pivotal efficacy study.

Since our inception in 2015 as ARS Pharmaceuticals, Inc., we have devoted substantially all of our efforts to developing intellectual property, conducting product development and clinical trials, organizing and staffing our company, business planning, raising capital, building infrastructure, pre-commercial and commercial activities, and providing general and administrative support for these operations. We began commercial operations in September 2024 and therefore have had limited net product sales. We have funded our operations primarily with proceeds from the Merger (see Note 1 to the notes to the condensed consolidated financial statements included in this report), private placement of convertible preferred stock, licensing, supply and distribution arrangements with our commercialization partners, and bank debt. From inception to September 30, 2024, we have raised $262.3 million in cash, cash equivalents and short-term investments, net of transaction costs, from the Merger; net proceeds of $76.3 million from the issuance of convertible preferred and common stock; $30.0 million from our collaboration, licensing, supply and distribution arrangements; and $10.0 million from bank debt. As of September 30, 2024, we had cash, cash equivalents, and short-term investments of $204.6 million.

We have incurred net losses from operations since our inception. Our net losses were $41.9 million and $47.2 million for the nine months ended September 30, 2024 and 2023, respectively. As of September 30, 2024, we had an accumulated deficit of $173.2 million. Until we consistently generate positive net income, if ever, our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our clinical trials, our expenditures on other development activities, the cost for regulatory filings, expenses for commercial activities to establish, maintain and enhance sales, marketing and distribution capabilities for *neffy*, the timing and volume of our product sales, and our ability to earn potential regulatory and commercial milestones under our license and collaboration arrangements.

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

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

ALK Agreement

In November 2024, we entered into a collaboration, license and distribution agreement (the "ALK Agreement") with ALK-Abelló A/S ("ALK"). Pursuant to the ALK Agreement, we granted to ALK a worldwide (other than the United States, Japan, mainland China, Hong Kong, Taiwan, Macau, Australia and New Zealand), exclusive license under certain of our patents and know-how to develop, manufacture and commercialize products containing epinephrine administered intranasally, including EUR*neffy* (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 we develop any new intranasally administered product that contains epinephrine and files a new drug application in the United States for such product, upon ALK's request such new product will be included as a Product under the ALK Agreement, subject to ALK bearing the costs of development of such new product for its licensed territory.

Under the ALK Agreement, we are obligated to transfer to ALK the existing marketing authorizations for the Products in ALK's territory. We are also required to conduct certain development and regulatory activities for Products in support of obtaining further regulatory approval of Products in ALK's 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 ALK's territory. Following such approval for a Product in each indication within specified countries within ALK's territory, ALK is obligated to use commercially reasonable efforts to commercialize such Product in such indication in such countries and to achieve first commercial sale of a Product in certain countries in accordance with a timeline specified in the ALK Agreement.

Under the ALK Agreement, ALK will make an upfront payment to us of $145.0 million in November 2024. We are eligible to receive regulatory and commercialization milestones of up to $20.0 million and sales-based milestones of up to $300.0 million, provided that $55.0 million of such sales-based milestones are contingent upon us obtaining regulatory approval for the Product in Canada by a specified time. We are entitled to receive tiered royalty payments on net sales in the mid- to high-teens, subject to certain standard reductions and offsets. Royalties will be payable, on a Product-by-Product and country-by-country basis, until the latest of the expiration of the licensed patents covering such Product in such country, 15 years from first commercial sale of such Product in such country, or expiration of regulatory exclusivity for such Product in such country.

Either we or ALK may terminate the ALK Agreement in the case of the other party's insolvency or in the event of an uncured material breach of the other party, except that we may not terminate the ALK Agreement for ALK's material breach of its commercial diligence obligations. ALK may terminate the ALK Agreement for convenience upon prior written notice or for a safety or regulatory concern. We may terminate the ALK Agreement in the event ALK makes certain challenges to certain of our patents. Prior to a change of control and outside of a set period of time after which we commence change of control negotiations, we may terminate the ALK Agreement with respect to all countries in the European Economic Area 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 European Economic Area at the time of such termination. We may also terminate the ALK Agreement if ALK commercializes a non-injectable epinephrine product or manufactures such a product in the United States.

ALK Supply Agreement

On November 9, 2024, in connection with the ALK Collaboration Agreement, ARS and ALK also entered into a commercial supply agreement (the "Supply Agreement"), under which ARS will supply ALK's requirements (and ALK will purchase from ARS its requirements) of Products for five years for a specified supply price, after which ALK may elect to transition to itself or its contract manufacturer the manufacture and supply of Products.

Seqirus Agreement

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

Under the Seqirus Agreement, we received an upfront payment of $0.5 million in May 2024. In August 2024, the first event milestone was met and we recorded a receivable for $1.5 million. We are also eligible to receive up to $3.0 million upon the achievement of the remaining event milestones. Subject to regulatory approval, we will also receive a per unit supply price for the sale of commercial supply to Seqirus. We recognized $1.5 million and $2.0 million in revenue in the three and nine months ended September 30, 2024, in the accompanying condensed consolidated statements of operations and comprehensive loss.

Financial Overview

Revenues

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

Cost of Goods Sold

Cost of goods sold consists primarily of direct and indirect costs related to the manufacture of *neffy* for commercial sale, including third-party manufacturing costs, raw material and component costs, packaging services, freight, storage costs, distribution fees, amortization of capitalized in-licensed costs, and royalties on product sales. Prior to the FDA approval of *neffy* in August 2024, costs incurred for the manufacture of *neffy* were recorded as research and development expenses, which resulted in zero-cost inventory. As a result, the cost of goods sold related to *neffy* will initially reflect a lower average per unit cost of materials, as previously expensed zero-cost inventory is utilized for commercial production and sold to customers. We expect the cost of goods sold for *neffy* to increase in relation to product revenues as we deplete these inventories. As of September 30, 2024, we had $13.0 million in zero-cost inventory remaining and based on our current forecast, we expect zero-cost inventory to be depleted by mid-2026.

The Company periodically evaluates zero-cost inventory for obsolescence. This evaluation considers the shelf life of raw materials, work in process, and finished goods as well as estimated sales trends. As of September 30, 2024, no zero-cost inventory was determined to be obsolete.

Research and Development Expenses

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

Research and development expenses include:

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

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

We expect our research and development expenses to increase in 2024 compared to 2023 based on our planned clinical development and manufacturing activities. We cannot determine with certainty the timing of initiation, the duration or the completion costs of current or future clinical trials and the manufacturing costs of *neffy* 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* 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;
- 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* for future indications;
- the cost to seek regulatory approvals for *neffy* 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*;
- 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* could significantly change the costs and timing associated with the development of that future product candidate. The process of conducting the necessary clinical research and manufacturing to obtain regulatory approval is costly and time-consuming. The actual probability of success for any future candidates may be affected by a variety of factors. Further, a number of factors, including those outside of our control, could adversely impact the timing and duration of our product's or any future candidates' development, which could increase our research and development expenses.

Selling, General and Administrative Expenses

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

We expect that our selling, general and administrative expenses will increase substantially in 2024 compared to 2023. The increase in expenses is due to our sales force which was established in the third quarter of 2024, the development and commencement of our marketing campaigns and initiatives, the hiring of additional sales and marketing personnel to support full commercialization activities, and the addition of infrastructure and programs to support commercialization activities. We expect to continue to incur audit, legal, regulatory and tax-related services associated with maintaining compliance with exchange listing and SEC requirements, director and officer insurance premiums, board of director fees, investor relations costs associated with operating as a public company, patent costs and defense, and general and administrative personnel.

Other Income, net

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

Results of Operations

Comparison of the Three Months Ended September 30, 2024 and 2023:

The following table summarizes our results of operations for the three months ended September 30, 2024 and 2023 (in thousands, except percentages):

	Three Months Ended September 30,		Dollar Change	% Change
	2024	2023		
Revenue:				
Product revenue, net	$ 568	$ —	$ 568	* %
Revenue under collaboration agreements	1,500	—	1,500	*
Total revenue	2,068	—	2,068	*
Operating expenses:				
Cost of goods sold	112	—	112	*
Research and development[(1)]	4,423	3,002	1,421	47
Selling, general and administrative[(1)]	19,281	14,976	4,305	29
Total operating expenses	23,816	17,978	5,838	32
Loss from operations	(21,748)	(17,978)	(3,770)	21
Other income, net	2,620	3,112	(492)	(16)
Net loss	(19,128)	(14,866)	(4,262)	29
Change in unrealized gains and losses on available-for-sale securities	484	19	465	*
Comprehensive loss	$ (18,644)	$ (14,847)	$ (3,797)	26 %

* Not meaningful

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

	Three Months Ended September 30,	
	2024	2023
Research and development	$ 734	$ 656
Selling, general and administrative	2,857	1,953
Total	$ 3,591	$ 2,609

Revenues. Revenues were $2.1 million and $0.0 million for the three months ended September 30, 2024 and 2023, respectively. Revenues for the three months ended September 30, 2024 include $0.6 million in net product revenues for sales of *neffy* and $1.5 million in revenue for the first event milestone under the Seqirus Agreement.

Cost of Goods Sold. Cost of goods sold were $0.1 million and $0.0 million for the three months ended September 30, 2024 and 2023, respectively. Since prior to August 2024 costs incurred for the manufacture of *neffy* were recorded as research and development expenses, the cost of goods sold for the three months ended September 30, 2024 utilized zero-cost inventory and therefore consisted primarily of distribution fees, royalties, and intangible assets amortization.

Research and Development Expenses. Research and development expenses were $4.4 million and $3.0 million for the three months ended September 30, 2024 and 2023, respectively. The increase of $1.4 million was primarily due to a $1.9 million increase in product development expenses and a $0.1 million increase in other operating expenses, partially offset by a $0.6 million decrease in clinical trial costs associated with *neffy*.

The following table summarizes our research and development expenses for the three months ended September 30, 2024 and 2023 (in thousands):

	Three Months Ended September 30,	
	2024	2023
Clinical and regulatory	$ 1,422	$ 1,513
Manufacturing and non-clinical development	3,001	1,489
Total research and development expenses	$ 4,423	$ 3,002

Selling, General and Administrative Expenses. Selling, general and administrative expenses were $19.3 million and $15.0 million for the three months ended September 30, 2024 and 2023, respectively. The increase of $4.3 million was primarily due to a $1.5 million increase in payroll-related expenses, a $1.5 million increase in pre-commercial launch activities related to *neffy*, a $0.9 million increase in stock-based compensation, a $0.7 million increase in legal fees, a $0.3 million increase in professional fees for accounting, auditing and tax, and a $0.3 million increase in other operating expenses. These aggregated increases were partially offset by a $0.6 million decrease in consulting fees and a $0.3 million decrease in general overhead expenses.

Other Income, Net. Other income, net was $2.6 million and $3.1 million for the three months ended September 30, 2024 and 2023, respectively. The decrease of $0.5 million was primarily due to a $0.8 million decrease in interest income from our cash, cash equivalents, and short-term investments, and a $0.1 million decrease in other items, partially offset by a $0.4 million increase in net amortization and accretion associated with our short-term investments.

Comparison of the Nine Months Ended September 30, 2024 and 2023:

The following table summarizes our results of operations for the nine months ended September 30, 2024 and 2023 (in thousands, except percentages):

	Nine Months Ended September 30,		Dollar	%
	2024	2023	Change	Change
Revenue:				
Product revenue, net	$ 568	$ —	$ 568	* %
Revenue under collaboration agreements	2,000	30	1,970	*
Total revenue	2,568	30	2,538	*
Operating expenses:				
Cost of goods sold	112	—	112	*
Research and development[(1)]	16,553	16,862	(309)	(2)
Selling, general and administrative[(1)]	36,183	40,462	(4,279)	(11)
Total operating expenses	52,848	57,324	(4,476)	(8)
Loss from operations	(50,280)	(57,294)	7,014	(12)
Other income, net	8,344	10,097	(1,753)	(17)
Net loss	(41,936)	(47,197)	5,261	(11)
Change in unrealized gains and losses on available-for-sale securities	290	(568)	858	(151)
Comprehensive loss	$ (41,646)	$ (47,765)	$ 6,119	(13) %

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* Not meaningful

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

	Nine Months Ended September 30,	
	2024	2023
Research and development	$ 2,558	$ 1,916
Selling, general and administrative	7,713	5,041
Total	$ 10,271	$ 6,957

Revenues. There was $2.6 million in revenues for the nine months ended September 30, 2024, and less than $0.1 million in revenues for the nine months ended September 30, 2023. The revenues for the nine months ended September 30, 2024 includes $0.6 million in net product revenues for sales of *neffy* and $2.0 million in revenues under the Seqirus Agreement. The revenues under the Seqirus Agreement consists of $1.5 million for the first event milestone and $0.5 million for the delivery of the license for *neffy* in the Seqirus Territory in combination with the transfer of know-how. The revenues for the nine months ended September 30, 2023 includes the recognition of revenue for the portion of upfront and clinical and regulatory milestone payments under our collaboration agreement with Alfresa that have been allocated to research and development services provided for during that period.

Cost of Goods Sold. Cost of goods sold were $0.1 million and $0.0 million for the nine months ended September 30, 2024 and 2023, respectively. Since prior to August 2024, costs incurred for the manufacture of *neffy* were recorded as research and development expenses, the cost of goods sold for the nine months ended September 30, 2024 utilized zero-cost inventory and therefore consisted primarily of distribution fees, royalties, and intangible assets amortization.

Research and Development Expenses. Research and development expenses were $16.6 million and $16.9 million for the nine months ended September 30, 2024 and 2023, respectively. The decrease of $0.3 million was primarily due to a $2.0 million decrease in product development expenses, a $1.2 million decrease in consulting fees, and a $0.5 million decrease in other operating expenses. These aggregated decreases were partially offset by a $2.1 million increase in in-process research and development expense related to an EMA regulatory milestone liability under the Recordati Termination Agreement, a $0.6 million increase in stock-based compensation, a $0.4 million increase in outside services, and a $0.3 million increase in clinical trial costs associated with *neffy.*

The following table summarizes our research and development expenses for the nine months ended September 30, 2024 and 2023 (in thousands):

	Nine Months Ended September 30,	
	2024	2023
Clinical and regulatory	$ 6,686	$ 6,721
Manufacturing and non-clinical development	9,867	10,141
Total research and development expenses	$ 16,553	$ 16,862

Selling, General and Administrative Expenses. Selling, general and administrative expenses were $36.2 million and $40.5 million for the nine months ended September 30, 2024 and 2023, respectively. The decrease of $4.3 million was primarily due to a $5.7 million decrease in pre-commercial launch activities related to *neffy*, a $1.4 million decrease in consulting fees, a $0.5 million decrease in recruiting fees, a $0.5 million decrease in insurance costs, and a $0.3 million decrease in other operating expenses. These aggregated decreases were partially offset by a $2.7 million increase in stock-based compensation, a $1.1 million increase in payroll-related expenses, and a $0.3 million increase in legal fees.

Other Income, Net. Other income, net was $8.3 million and $10.1 million for the nine months ended September 30, 2024 and 2023, respectively. The decrease of $1.8 million was primarily due to a $1.9 million decrease in interest income from our cash, cash equivalents, and short-term investments, a $0.3 million decrease from the sale of in-process research and development obtained in the Merger, which occurred in the nine months ended September 30, 2023, and a $0.3 million decrease in other items. These aggregated decreases were partially offset by a $0.7 million increase in net amortization and accretion associated with our 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 recognized limited net product sales since the commercial launch of *neffy* in September 2024. We have funded our operations to date primarily with proceeds from the Merger, the sale of preferred and common stock, revenue earned under collaboration, licensing, supply and distribution agreements and bank debt. From inception to September 30, 2024, we have raised $262.3 million in cash, cash equivalents and short-term investments, net of transaction costs, from the Merger, net proceeds of $76.3 million from the issuance of convertible preferred and common stock, $30.0 million from our collaboration, licensing, supply and distribution arrangements, and $10.0 million from bank debt. As of September 30, 2024, we had cash, cash equivalents, and short-term investments of $204.6 million.

Cash flows

The following table summarizes our cash flows for the nine months ended September 30, 2024 and 2023 (in thousands):

	Nine Months Ended September 30,	
	2024	2023
Net cash and cash equivalents used in operating activities	$ (28,456)	$ (41,861)
Net cash and cash equivalents used in investing activities	(4,341)	(113,219)
Net cash and cash equivalents provided by financing activities	1,483	5,094
Net decrease in cash and cash equivalents	$ (31,314)	$ (149,986)

Operating Activities

During the nine months ended September 30, 2024, net cash used in operating activities was $28.5 million. This consisted primarily of a net loss of $41.9 million, an increase in our operating liabilities of $8.7 million, a decrease in our operating assets of $0.1 million, and non-cash charges of $4.6 million. The increase in our operating liabilities was primarily due to an increase in accounts payable and accrued liabilities of $8.7 million. The decrease in our operating assets was primarily due to a decrease in prepaid and other assets of $1.1 million, partially offset by an increase in accounts receivable of $0.8 million and an increase in inventories of $0.2 million. The non-cash charges consisted of non-cash stock-based compensation of $10.3 million, partially offset by $5.7 million in net amortization of discounts on short-term investments.

During the nine months ended September 30, 2023, net cash used in operating activities was $41.9 million. This consisted primarily of a net loss of $47.2 million, an increase in our operating liabilities of $3.0 million, a decrease in our operating assets of $0.5 million, and non-cash charges of $1.9 million. The increase in our operating liabilities was primarily due to an increase in accounts payable and accrued liabilities of $6.1 million, partially offset by a decrease in contract liability of $3.1 million. The decrease in our operating assets was primarily due to a decrease in prepaid and other assets of $0.5 million. The non-cash charges consisted primarily of non-cash stock-based compensation of $7.0 million, partially offset by $5.1 million in net amortization of discounts on short-term investments.

Investing Activities

During the nine months ended September 30, 2024, the cash and cash equivalents used in investing activities was $4.3 million. This consisted primarily of purchases of short-term investments of $192.6 million, maturities of short-term investments of $191.0 million, payments of milestone obligations under license agreements of $2.5 million, and purchases of property and equipment of $0.3 million.

During the nine months ended September 30, 2023, the cash and cash equivalents used in investing activities was $113.2 million. This consisted primarily of purchases of short-term investments of $238.0 million, maturities of short-term investments of $125.0 million, and purchases of property and equipment of $0.3 million.

Financing Activities

During the nine months ended September 30, 2024, the cash and cash equivalents provided by financing activities was $1.5 million, which consisted of proceeds from stock option exercises and the employee stock purchase plan.

During the nine months ended September 30, 2023, the cash and cash equivalents provided by financing activities was $5.1 million, which consisted of proceeds from stock option exercises and the employee stock purchase plan.

Future Funding Requirements

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

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

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

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

Our ability to raise additional funds may be adversely impacted by potential worsening global economic conditions and disruptions to and volatility in the credit and financial markets in the United States, including due to bank failures, and worldwide resulting from macroeconomic factors. 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 ever be profitable or generate positive cash flow from operating activities.

Material Cash Requirements

The total amount of unconditional purchase obligations related to the supply of raw materials is $34.1 million as of September 30, 2024. Payments by year are as follows: 2024 and 2025 ($6.8 million in the aggregate), 2026 ($7.6 million), 2027 ($8.9 million), and 2028 ($10.8 million).

The total amount of unconditional purchase obligations related to hosted software license subscription fees is $3.9 million as of September 30, 2024. Payments by year are as follows: 2024 ($0.6 million), 2025 ($1.4 million), 2026 ($1.5 million), and 2027 ($0.4 million).

In August 2024, we entered into a corporate sponsorship agreement with Food Allergy Research and Education, Inc. pursuant to which we have payment obligations of $9.0 million over a 28-month period. Our remaining payment obligations have been reduced to $8.0 million as of September 30, 2024 due to a $1.0 million payment that was made in September 2024. Payments by year are as follows: 2024 ($1.0 million), 2025 ($4.0 million), and 2026 ($3.0 million).

Our remaining payment obligations to Aegis that are contingent upon our achievement of certain regulatory and commercial milestones have been reduced to $16.0 million as of September 30, 2024 due to the $2.5 million milestone payment that was made in August 2024 for achieving FDA approval of *neffy*.

Our remaining payment obligations to Recordati that are contingent upon our achievement of regulatory and certain commercial milestones have been reduced to €5.0 million as of September 30, 2024 due to the €2.0 million ($2.2 million in U.S. dollars) payment that was made in July 2024 for the EMA regulatory milestone.

There have been no other material changes in our material cash requirements from those disclosed in "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in our Annual Report on Form 10-K filed with the SEC on March 21, 2024.

Critical Accounting Policies and Significant Judgments and Estimates

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

We believe the following critical accounting policies involve significant areas where management applies estimates, assumptions and judgments in the preparation of our condensed consolidated financial statements. See our other additional critical accounting policies under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Policies and Significant Judgments and Estimates" in our Annual Report on Form 10-K filed with the SEC on March 21, 2024 and Note 2 - Summary of Significant Accounting Policies to our unaudited condensed consolidated financial statements appearing in Part I, Item 1 of this Quarterly Report on Form 10-Q.

Revenue Recognition and Trade Accounts Receivable

Our revenues generally consist of product sales of *neffy* and licenses and milestone revenue generated from license and collaboration agreements.

We recognize revenue in accordance with ASC Topic 606, Revenue from Contracts with Customers. 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) we satisfy each performance obligation. At contract inception, we assess the goods or services promised within each contract, determine whether each promised good or service is distinct and identify those that are performance obligations. We recognize 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 is recorded with each sale at wholesale acquisition cost, net of reserves for variable components, including but not limited to distribution service fees, prompt pay discounts, product returns, chargebacks, rebates, and co-payment assistance, which are collectively referred to as "Gross-to-Net Adjustments". In accordance with ASC 606, the Company must make significant judgments to determine the estimates for certain Gross-to-Net Adjustments. Estimates for Gross-to-Net Adjustments are reassessed each reporting period, and adjustments are recorded on a cumulative catch-up basis, which would affect product revenue and net income in the period of adjustment.

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

Recent Accounting Pronouncements

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

Emerging Growth Company and Smaller Reporting Company Status

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"). For so long as we remain an emerging growth company, we are permitted and intend to rely on certain exemptions from various public company reporting requirements, including not being required to have our internal control over financial reporting audited by our independent registered public accounting firm pursuant to Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and any golden parachute payments not previously approved.

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

We will remain an emerging growth company until the earliest to occur of: (i) the last day of the fiscal year in which we have at least $1.235 billion in annual revenue; (ii) the date upon which we are deemed to be a "large accelerated filer," as defined in Rule 12b-2 under the Exchange Act; (iii) the date on which we have issued more than $1.0 billion in nonconvertible debt securities during the prior three-year period; and (iv) December 31, 2025.

We are also a "smaller reporting company" as defined in the Exchange Act. We may continue to be a smaller reporting company if either (i) the market value of our stock held by non-affiliates is less than $250 million measured on the last business day of our second fiscal quarter or (ii) our annual revenue was less than $100 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $700 million measured on the last business day of our second fiscal quarter. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation and other matters.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

As a "smaller reporting company" as defined under Item 10(f)(1) of Regulation S-K of the Securities Act, we are not required to provide the information contemplated by this item.

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, 2024. 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, 2024, 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

In September 2024, we began product sales of *neffy* and in conjunction began recording product revenue, cost of goods sold, and inventory. We enhanced our internal control over financial reporting by adding new processes and controls in these areas. We did not identify any material adverse impacts on our internal control over financial reporting as a result of the implementation of these new processes and controls.

There have been no other changes in our internal control over financial reporting that occurred during the quarter ended September 30, 2024 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 8 - 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 21, 2024.

Risks Related to Our Business

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

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

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

We have built a sales force to commercialize *neffy* in the United States. In order to successfully commercialize *neffy*, we must 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;
- 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.

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

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

neffy 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 become profitable.*

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* in place of well-established epinephrine intra-muscular injectable devices. 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 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 may be smaller than we expect.*

We have focused our development of *neffy* 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 for which *neffy* is approved.

Third-party payors, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. The current environment is putting pressure on companies to price products below what they may feel is appropriate. Selling *neffy* at less than an optimized price could impact our revenues and overall success as a company. In addition, in the United States, no uniform policy of coverage and reimbursement for drug products exists among third-party payors. Therefore, coverage and reimbursement for *neffy* may differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of *neffy* to each payor separately, with no assurance that coverage will be obtained, or that payment levels will be adequate for *neffy* or any other products we may market. 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 for its current or future indications. 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 may be adversely affected.*

The clinical and commercial landscape for the emergency treatment of Type I allergic reactions is highly competitive and subject to significant technological change. We face competition with respect to our current indications for *neffy* and will face competition with respect to any future indications of *neffy* 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 indication 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. Amphastar Pharmaceuticals is reported to be developing an intranasal candidate with an undisclosed dose, and Aquestive Therapeutics is developing a sublingual candidate based on a prodrug of epinephrine. If *neffy* is approved for other indications, it 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* 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*, which could render such product candidates obsolete and noncompetitive.

We face competition based on many different factors, including the efficacy, safety and tolerability of *neffy*, the ease with which *neffy* can be administered, the scope of regulatory approval for *neffy*, 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 any future product candidate of ours that receives regulatory approval, or such authorities do not grant our products appropriate periods of non-patent exclusivity before approving generic versions of such products, the sales of such products could be adversely affected.*

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

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

Obtaining regulatory approval of neffy in one jurisdiction does not mean that we will be successful in obtaining regulatory approval in other jurisdictions.*

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

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

If we are unable to successfully develop neffy for additional indications, or experience significant delays in doing so, the commercial potential of neffy will be more limited.*

Successful continued development and ultimate regulatory approval of *neffy* in additional indications, including urticaria, is important to the future success of our business. The future regulatory and commercial success of *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 *neffy* 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 *neffy*;
- making arrangements or maintaining existing arrangements with third-party manufacturers, or establishing manufacturing capabilities, for both clinical and commercial supplies of *neffy*;
- entry into collaborations to further the development of *neffy* in other jurisdictions or for additional indications;
- establishing sales, marketing and distribution capabilities and commercializing any approved products, whether alone or in collaboration with others;
- successfully commercializing *neffy*;
- acceptance by patients, the medical community and third-party payors of *neffy*;
- 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, *neffy* 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 potential additional indications for neffy, including urticaria, satisfy the requirements for the Section 505(b)(2) regulatory approval pathway, or if the requirements for such product candidates under Section 505(b)(2) are not as we expect, the approval pathway for 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.*

Although we submitted a supplemental new drug application ("sNDA") for *neffy* 1 mg under Section 505(b)(2) ("Section 505(b)(2)") of the FDCA regulatory pathway for the emergency treatment of Type I allergic reactions, in children who weigh 15 to 30 kg, there can be no assurance that the FDA will approve any such application or agree that the Section 505(b)(2) pathway is appropriate for any additional indications.

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

If the FDA does not allow us to proceed under the Section 505(b)(2) regulatory pathway for any 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 potential additional indications, including urticaria, for *neffy*, 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 *neffy*, in any potential 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 potential additional indications, including urticaria, for *neffy*, which could delay approval of potential additional indications, including urticaria, for *neffy*.

We may incur unexpected costs or experience delays in completing, or ultimately be unable to complete, further development and the commercialization of neffy for additional indications.*

To obtain the requisite regulatory approvals to market and commercialize *neffy* for potential additional indications, including urticaria and *neffy* 1 mg dose for the treatment of type I allergic reactions, including anaphylaxis, in adults and children who weigh 15 to 30 kg, 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 *neffy* for potential additional indications, including urticaria, including:

- regulators, institution 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 contract research organizations ("CROs") and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- a delay in receiving study or clinical trial material from outside the United States;
- the number of subjects or patients required for clinical trials of *neffy* for potential additional indications, including 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 *neffy* or other materials necessary to conduct clinical trials of *neffy* for potential additional indications, including 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 *neffy* for potential additional indications, including urticaria. While data from our studies of *neffy* 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 *neffy* for potential additional indications, including urticaria. If later stage clinical trials do not produce favorable results that meet regulatory authority criteria, our ability to obtain regulatory approval for *neffy* for potential additional indications, including urticaria, may be adversely impacted.

Our failure to successfully initiate and complete clinical trials of *neffy* for potential additional indications, including urticaria, and to demonstrate the efficacy and safety necessary to obtain regulatory approval to market *neffy* for such potential additional indications, including 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 *neffy* for potential additional indications, including 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 *neffy* for potential additional indications, including urticaria.

We may not be successful in our efforts to expand our pipeline by identifying additional indications for which to investigate neffy 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 neffy and fail to capitalize on product candidates, indications or formulations that may be more profitable or for which there is a greater likelihood of success.*

Although *neffy* is approved in the United States for the emergency treatment of Type I allergic reactions, including anaphylaxis, in adults and children who weigh ≥30 kg and in the EU (under the name EUR*neffy*) for the emergency treatment of allergic reactions (anaphylaxis) due to insect stings or bites, foods, medicinal products and other allergens as well as idiopathic or exercise induced anaphylaxis, for adults and children with a body weight ≥30 kg, as part of our longer-term growth strategy, we are evaluating and plan to continue to evaluate *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 *neffy*, we do not currently have any other programs in development. Our development of *neffy* 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 *neffy*. As a result, we may fail to generate additional clinical development opportunities for *neffy* for a number of reasons, including, that *neffy* 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 *neffy* 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 *neffy* require substantial technical, financial and human resources. Additionally, any future potential indications for *neffy* 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 *neffy*, 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 *neffy*, we may not realize the full potential benefits from the sale of *neffy* 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 *neffy* for additional indications. 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 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* 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* 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 in the development of any potential additional indications for *neffy*, including urticaria, we, the FDA or comparable foreign regulatory authorities, the IRBs, or independent ethics committees at the institutions in which our trials are conducted, or the independent safety monitoring committee could suspend or terminate our clinical trials or regulatory authorities could order us to cease clinical trials, restrict us or *neffy*, including withdrawing the marketing approval of *neffy* for any approved indications, or deny approval for or all targeted indications. Treatment-emergent side effects and adverse events that are deemed to be drug-related could also affect subject recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims, an unwillingness of physicians to prescribe *neffy* for approved indications, patients' unwillingness to purchase *neffy*, or payors' willingness to cover *neffy*. Undesirable side effects or adverse events resulting from the use of *neffy* (whether by patients in our clinical studies or through the commercialization of *neffy*) could adversely affect enrollment in clinical trials, regulatory approval and commercialization of *neffy* in other indications. Additionally, there may be negative findings regarding components of *neffy* by other parties. Any negative findings by third parties may impact *neffy* for its initially approved indication and labeling, or the future approvability or labeling of *neffy* for potential additional indications, including 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* 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 *neffy* 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 *neffy* that is greater than the actual positive effect, if any, or alternatively fail to identify undesirable side effects.

Finally, *neffy* is 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 *neffy* has been used to deliver several drugs approved by the FDA and other regulatory authorities, including VALTOCO®, TOSYMRA® and NARCAN®. Even though *neffy* has received marketing approval for its initial indication, we are subject to the risks that the FDA, European Commission or similar regulatory authorities could revoke approval of intra-muscular epinephrine injection products, other drug formulations containing Intravail® or utilizing the same intranasal apparatus, or that efficacy, manufacturing or supply issues could arise with epinephrine API, Intravail® or our intranasal apparatus. This could result in our own products being removed from the market or being less commercially successful.

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

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

We may seek priority review by the FDA for potential additional indications, including urticaria, for neffy, 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 *neffy*, 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.*

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*. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for *neffy*;
- 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*.

We face an inherent risk of product liability as a result of the commercialization and clinical testing of *neffy*. 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* causes adverse events or side effects, we may be exposed to substantial liabilities. Physicians may not prescribe or patients may not use *neffy* for its approved indication or in accordance with *neffy*'s instructions or any warnings that identify known potential adverse effects, side effects, and patients who should not use *neffy*. We are highly dependent upon consumer perceptions of us regarding the safety and efficacy of *neffy*. 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 any future products, 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 process sensitive data, and, as a result, we and such third parties face a variety of evolving threats, including but not limited to ransomware attacks, which could cause security incidents. Cyber-attacks, malicious internet-based activity, online and offline fraud, and other similar activities threaten the confidentiality, integrity, and availability of our sensitive data and information technology systems, and those of the third parties with whom we work. Such threats are prevalent and continue to rise, are increasingly difficult to detect, and come from a variety of sources, including traditional computer "hackers," threat actors, "hacktivists," organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation-state-supported actors.

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

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

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

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

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

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

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

Any of the previously identified or similar threats could cause a security incident or other interruption that could 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. 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 clinical trials) to try to protect against security incidents. Additionally, certain data privacy and security obligations may require 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). We may not, 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 may 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 adverse consequences, such as government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing sensitive data (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; interruptions in our operations (including availability of data); financial loss; and other similar harms. Security incidents and attendant consequences may negatively impact our ability to operate our business. For example, the loss of clinical trial data from completed, ongoing or future clinical trials for *neffy* could result in delays in our development and regulatory approval efforts and significantly increase our costs to recover or reproduce the data. In addition, we may suffer reputational harm or face litigation or adverse regulatory action as a result of cyber-attacks or other data security breaches and may incur significant additional expense to implement further data protection measures.

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

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

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* 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*. 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*, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

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

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

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

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

Social media is increasingly being used to communicate about our clinical development activities and the indications *neffy* has been approved to treat and is being developed to treat, and we intend to utilize appropriate social media in connection with our commercialization efforts for *neffy*. Advertising and promotional materials must comply with FDA rules concerning the advertising and promotion of *neffy* 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 *neffy*. 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 timing of sales and our results of operations will fluctuate for the foreseeable future, which may make it difficult to predict our future performance from period to period.*

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

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

We have incurred significant losses since our inception.*

Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval and become commercially viable. We have one product approved for commercial sale and have generated only limited revenue from product sales to date, and we will continue to incur significant expenses related to our commercialization activities, clinical development and ongoing operations. As a result, we are not profitable and have incurred losses in each period 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 losses were $54.4 million for the year ended December 31, 2023 and $41.9 million for the nine months ended September 30, 2024. As of September 30, 2024, we had an accumulated deficit of $173.2 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 indications for which we may obtain regulatory approval;
- continue to develop and conduct nonclinical studies and clinical trials for *neffy* on a post-approval basis and for potential additional indications, including urticaria;
- seek regulatory approvals in the United States and in the EU for *neffy* for potential additional indications, including urticaria, and in other geographic regions for *neffy* for the emergency treatment of Type I allergic reactions and other indications that successfully complete clinical development;
- 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 a health epidemic or pandemic;
- add clinical, scientific, operational, sales, financial and management information systems and personnel, including personnel to support our product candidate development and commercialization efforts and help us comply with our obligations as a public company;
- maintain, expand and protect our intellectual property portfolio; and
- acquire or in-license other product candidates and technologies.

Our expenses could increase beyond our expectations if we are required by the FDA, the EMA or other regulatory authorities to perform clinical trials or conduct nonclinical studies in addition to those that we currently expect, or if there are any delays in completing our clinical trials or the development of *neffy*, or if we choose to develop or acquire any future product candidates.

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

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

Our future capital requirements depend on many factors, including:

- the costs of commercialization activities for *neffy* for its approved indication and any potential additional indications, including urticaria, and the similar costs of any other product candidate 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* for its approved indication and for any potential additional indications, including urticaria;
- the scope, progress, results and costs of researching and developing *neffy* for potential additional indications, including urticaria;
- the timing of, and the costs involved in, obtaining regulatory approval for the marketing of *neffy* for any potential additional indications, including urticaria;
- the amount and timing of potential royalty and milestone payments to our current or future licensing and collaboration partners;
- the receipt of licensing fees, royalties and potential milestone payments under our current or future out-licensing arrangements;
- the extent to which we in-license or acquire rights to other products, product candidates or technologies;
- our headcount growth and associated costs as we expand our personnel, including personnel to support our product development and commercialization efforts and help us comply with our obligations as a public company;
- the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights, including enforcing and defending intellectual property related claims; and
- the ongoing costs of operating as a public company.

We cannot be certain that additional funding will be available on acceptable terms, or at all. The global credit and financial markets have experienced extreme volatility and disruptions, including diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, inflation, bank failures and uncertainty about economic stability. If the equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly or more dilutive.

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

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

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

We expect our expenses to increase in connection with our planned operations. Based upon our current operating plan, we believe that our cash and cash equivalents will fund our operating and capital expenses for at least three years. However, unless and until we can generate a substantial amount of revenue from *neffy*, 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.

To the extent that we raise additional capital through the sale of common stock, convertible securities or other equity securities, stockholders' interests may be diluted, and the terms of these securities could include liquidation or other preferences and anti-dilution protections that could adversely affect our stockholders' rights. In addition, new debt financing, if available, may result in fixed payment obligations and may involve agreements that include restrictive covenants that further limit our ability to take specific actions, such as incurring additional debt, making capital expenditures, creating liens, redeeming stock or declaring dividends, which could adversely impact our ability to conduct our business. In addition, securing financing could require a substantial amount of time and attention from our management and may divert a disproportionate amount of their attention away from day-to-day activities, which may adversely affect their ability to oversee the commercialization of *neffy* and the development and potential future commercialization of *neffy* for additional indications.

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

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

The rules dealing with U.S. federal, state and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service, the U.S. Treasury Department, and state and local taxing authorities. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our common stock. In recent years, many such changes have been made and changes are likely to continue to occur in the future. Future changes in tax laws could have a material adverse effect on our business, cash flow, financial condition, realization of tax assets or results of operations.

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

We have incurred substantial losses during our history. Unused federal net operating losses ("NOLs") for the tax years beginning before January 1, 2018, will carry forward to offset future taxable income, if any, until such unused losses expire. Unused federal NOLs generated in tax years beginning after December 31, 2017, will not expire and may be carried forward indefinitely, but the deductibility of such federal NOL carryforwards is limited to 80% of taxable income. In addition, both current and future unused losses and other tax attributes may be subject to limitation under Sections 382 and 383 of the Code if we undergo an "ownership change," generally defined as a greater than 50 percentage point change (by value) in our equity ownership by certain stockholders over a three-year period. The Merger resulted in an ownership change of our company. The NOL carryforwards of pre-Merger, privately-held ARS Pharma may also be subject to limitation as a result of prior shifts in equity ownership and/or the Merger. Additional ownership changes in the future could result in additional limitations on our NOL carryforwards. Similar provisions of state tax law may also apply to limit our use of accumulated state tax attributes. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. For example, California recently imposed limits on the usability of California state NOL carryforwards and certain state tax credits in tax years beginning after 2023 and before 2027. Consequently, even if we achieve profitability, 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 is subject to ongoing obligations and continued regulatory review, which may result in significant additional expense. neffy 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, 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*, for only its approved indications, we, or they, may be subject to warnings or enforcement action for off-label marketing if it is alleged that we are doing so. Violation of laws and regulations relating to the promotion and advertising of prescription drugs may lead to investigations or allegations of violations of federal and state health care fraud and abuse laws and state consumer protection laws, including the False Claims Act and any comparable foreign laws. In the EU, the direct-to-consumer advertising of prescription-only medicinal products is prohibited. Violations of the rules governing the promotion of medicinal products in the EU could be penalized by administrative measures, fines and imprisonment. These laws may further limit or restrict the advertising and promotion of our products to the general public, and may also impose limitations on our promotional activities with health care professionals.

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

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

Recently enacted and future legislation may increase the difficulty and cost for us to commercialize neffy 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* for potential additional indications, including urticaria, restrict or regulate post-approval activities and affect our ability to profitably sell *neffy* for which we obtain marketing approval.

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

Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the ACA. For example, the Tax Cuts and Jobs Act of 2017 included a provision which repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." On June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the individual mandate was repealed by Congress. Prior to the U.S. Supreme Court ruling on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. In addition, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 ("IRA") into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges, and the healthcare reform measures of the Biden administration will impact the ACA and our business.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers of up to two percent per fiscal year pursuant to the Budget Control Act of 2011, which went into effect on April 1, 2013, and due to subsequent legislative amendments, will remain in effect until 2032, unless additional Congressional action is taken. In addition, the American Taxpayer Relief Act of 2012 was signed into law which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Recently there has also been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U.S. Presidential executive orders, congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. At the federal level, in July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, the U.S. Department of Health and Human Services ("HHS") released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. In addition, the IRA, among other things, (i) directs HHS to negotiate the price of certain high-expenditure, single-source drugs and biologics covered under Medicare, and subject drug manufacturers to civil monetary penalties and a potential excise tax by offering a price that is not equal to or less than the negotiated "maximum fair price" for such drugs and biologics under the law, and (ii) imposes rebates with respect to certain drugs and biologics covered under Medicare Part B or Medicare Part D to penalize price increases that outpace inflation. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has and will continue to issue and update guidance as these programs as implemented. These provisions took effect progressively starting in fiscal year 2023. On August 15, 2024, HHS announced the agreed-upon reimbursement prices of the first ten drugs that were subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. In response to the Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the Centers for Medicare & Medicaid Services Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. Further, on December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework.

At the state level, legislatures have become increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. For example, on January 5, 2024, the FDA approved Florida's Section 804 Importation Program (SIP) proposal to import certain drugs from Canada for specific state healthcare programs. It is unclear how this program will be implemented, including which drugs will be chosen, and whether it will be subject to legal challenges in the United States or EU, or Canada. Other states have also submitted SIP proposals that are pending review by the FDA. Any such approved importation plans, when implemented, may result in lower drug prices for products covered by those programs.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. As an example, the regulatory landscape related to clinical trials in the EU has evolved. The EU Clinical Trials Regulation (CTR), which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. The CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each EU Member State, leading to a single decision for each EU Member State. The assessment procedure for the authorization of clinical trials has been harmonized as well, including a joint assessment by all EU Member States concerned, and a separate assessment by each EU Member State with respect to specific requirements related to its own territory, including ethics rules. Each EU Member State's decision is communicated to the sponsor via the centralized EU portal. Once the clinical trial approved, clinical study development may proceed. The CTR foresees a three-year transition period. The extent to which ongoing and new clinical trials will be governed by the CTR varies. For clinical trials in relation to which application for approval was made on the basis of the Clinical Trials Directive before January 31, 2023, the Clinical Trials Directive will continue to apply on a transitional basis until January 31, 2025. By that date, all ongoing trials will become subject to the provisions of the CTR. The CTR will apply to clinical trials from an earlier date if the related clinical trial application was made on the basis of the CTR or if the clinical trial has already transitioned to the CTR framework before January 31, 2025. Compliance with the CTR requirements by us and our third-party service providers, such as CROs, may impact our developments plans.

In addition, on April 26, 2023, the European Commission adopted a proposal for a new Directive and Regulation to revise the existing pharmaceutical legislation and on April 10, 2024, the Parliament adopted its related position. If adopted in the form proposed, the recent European Commission proposals to revise the existing EU laws governing authorization of medicinal products may result in a decrease in data and market exclusivity opportunities for any additional indications for *neffy* in the EU and make them open to generic or biosimilar competition earlier than is currently the case with a related reduction in reimbursement status.

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

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

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

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

Healthcare professionals and third-party payors will play a primary role in the recommendation and prescription of *neffy* for which we obtain marketing approval. Our current and future arrangements with customers, healthcare professionals and third-party payors may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we conduct research, market, sell and distribute *neffy* 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 federal Health Insurance Portability and Accountability Act of 1996 ("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 or the payor (e.g., public or private), willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services; like the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- the federal Physician Payment Sunshine Act, which requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the government information related to payments or other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physician assistants and nurse practitioners) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH"), and their respective implementing regulations, which impose obligations on "covered entities," including certain healthcare providers, health plans, and healthcare clearinghouses, as well as their respective "business associates" and their covered subcontractors that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- federal price reporting laws require manufactures to calculate and report complex pricing metrics to government programs, where such reported prices may be used in the calculation of reimbursement and/or discounts on approved products;

- federal and state consumer protection and unfair competition laws broadly regulate marketplace activities and activities that potentially harm consumers; and

- analogous state and foreign laws and regulations of each of the laws described above, such as anti-kickback and false claims laws, that may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; laws that require biotechnology companies to comply with the industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; laws that require biotechnology companies to report information on the pricing of certain drug products; and laws require the registration or pharmaceutical sales representatives. For example, in the EU, interactions between pharmaceutical companies and healthcare professionals and healthcare organizations are also governed by strict laws, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct both at EU level and in the individual EU Member States.

Because of the breadth of these laws and the narrowness of available statutory exceptions and regulatory safe harbors, it is possible that some of our business activities, particularly any sales and marketing activities from *neffy* or from any future product candidate that has been approved for marketing in the United States or elsewhere, could be subject to legal challenge and enforcement actions. If our operations 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 are subject to stringent and evolving U.S. and foreign laws, regulations, rules, contractual obligations, policies and other obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation (including class claims) and mass arbitration demands; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse business consequences.*

In the ordinary course of business, we 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").

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). In the past few years, numerous U.S. states—including California, Virginia, Colorado, Connecticut, and Utah—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, as amended by the California Privacy Rights Act of 2020 (the "CCPA"), applies to personal information of consumers, business representatives, and employees, and requires businesses to provide specific disclosures in privacy notices and honor requests of California residents to exercise certain privacy rights. The CCPA provides for civil penalties of up to $7,500 per violation and allows private litigants affected by certain data breaches to recover significant statutory damages. Although the CCPA exempts some data processed in the context of clinical trials, the CCPA increases compliance costs and potential liability with respect to other personal data we maintain about California residents. Similar laws are being considered in several other states, as well as at the federal and local levels, and we expect more states to pass similar laws in the future.

Outside the United States, an increasing number of laws, regulations, and industry standards may 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 may be subject to new and emerging data privacy regimes in Asia, including China's Personal Information Protection Law, Japan's Act on the Protection of Personal Information, and Singapore's Personal Data Protection Act. China's PIPL imposes a set of specific obligations on covered businesses in connection with their processing and transfer of personal data and imposes fines of up to RMB 50 million or 5% of the prior year's total annual revenue of the violator.

In addition, we may be unable to transfer personal data from Europe and other jurisdictions to the United States or other countries due to data localization requirements or limitations on cross-border data flows. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the EEA and the UK have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it believes are inadequate. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross-border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA and UK's standard contractual clauses, the UK's International Data Transfer Agreement / Addendum, and the EU-U.S. Data Privacy Framework and the UK extension thereto (which allows for transfers for relevant U.S.-based organizations who self-certify compliance and participate in the Framework), these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States. If there is no lawful manner for us to transfer personal data from the EEA, the UK, or other jurisdictions to the United States, or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activities groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers of personal data out of Europe for allegedly violating the GDPR's cross-border data transfer limitations. Regulators in the United States are also increasingly scrutinizing certain personal data transfers and may impose data localization requirements, for example, the Biden Administration's executive order Preventing Access to Americans' Bulk Sensitive Personal Data and United States Government-Related Data by Countries of Concern.

In addition, we are contractually subject to industry standards adopted by industry groups and, we are, or may become directly subject to such obligations in the future. We are also bound by contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. Obligations related to data privacy and security (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 and may necessitate changes to our information technologies, systems, and practices and to those of any third parties that process personal data or sensitive data on our behalf.

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 on whom we rely may fail to comply with such obligations, which could negatively impact our business operations. If we or the third parties on which we rely fail, or are perceived to have failed, to address or comply with applicable data privacy and security obligations, we could face significant consequences, including but not limited to: government enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class-action claims) and mass arbitration demands; additional reporting requirements and/or oversight; bans on processing personal data; orders to destroy or not use personal data; and imprisonment of company officials. In particular, plaintiffs have become increasingly more active in bringing privacy-related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for monumental statutory damages, depending on the volume of data and the number of violations. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: loss of customers; interruptions or stoppages in our business operations (including clinical trials); inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or substantial changes to our business model or operations.

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

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

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

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

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

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

Risks Related to Our Dependence on Third Parties

We rely completely on third parties to manufacture and warehouse both our domestic and international supply of neffy.*

We do not currently have, nor do we plan to acquire, the infrastructure or capability to manufacture or warehouse commercial quantities of *neffy*. Our ability to commercially supply *neffy* depends, in part, on the ability of third-party manufacturers to supply, manufacture and warehouse the raw materials, active pharmaceutical ingredient ("API") and other important components related to the manufacture of *neffy*, 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 *neffy*, the raw materials and API for *neffy* 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*, 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*.

In particular, we rely on third parties for the supply of *neffy* 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 *neffy* in our clinical development, and we will continue to rely on Renaissance as the primary source for drug product manufacturing and final packaging. We have also entered into a supply agreement ("Ompi Supply Agreement") with Nuova Ompi S.r.l. ("Ompi") pursuant to which Ompi has agreed to supply glass microvials to support the Company's manufacture and commercialization of *neffy*. We will rely on Ompi as the primary source of glass microvials. Unless and until we can secure alternative sources for microvials, drug product manufacturing and final packaging, our dependence on Renaissance and Ompi will subject us to the possible risks of shortages, interruptions, and price fluctuations.

If we experience supply interruptions or delays, or if a supplier discontinues the sale of certain products, we may have to obtain substitute materials or products, which in turn would require us to obtain amended or additional regulatory approvals, subjecting us to additional expenditures of significant time and resources. In addition, changes in our raw material suppliers could result in significant delays in production, higher raw material costs and loss of sales and customers, because regulatory authorities must generally approve raw material sources for pharmaceutical products, which may be time consuming. Any significant supply interruption effect on our business, condition (financial and otherwise). For example, drug application processes require specification of raw material suppliers, if raw materials from a specified supplier were to become unavailable, FDA or comparable foreign regulatory authority approval of a new supplier would be required. The amount of time required for the FDA or a comparable foreign regulatory authority to qualify a new supplier and confirm that our manufacturing processes meet the necessary standards could cause delays in the manufacturing and marketing of *neffy* and 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* according to our schedule, or at all, including if our third-party contractors give greater priority to the supply of other products over *neffy* 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* 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 *neffy* or another product;
- the failure of the third party to manufacture *neffy*, 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*. 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 *neffy* 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*. 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* 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* may adversely affect our profit margins and our ability to successfully commercialize *neffy* on a competitive basis.

We are dependent on international third-party licensees and assignees for the development and commercialization of neffy 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* worldwide, excluding the United States. As a result, we are dependent on these parties to, at times, achieve regulatory approval of *neffy* for marketing and, if approval is obtained, commercialize *neffy* 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* in those regions outside of the United States, will depend on, among other things, the efforts, allocation of resources and successful commercialization of *neffy* 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* in those countries. They may take actions or fail to take actions that result in safety issues with *neffy* in their licensed territory, and such safety issues could negatively impact *neffy* 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*; to meet their obligations to us, including for future royalty and milestone payments; to adequately deploy business continuity plans in the event of a crisis; to adequately respond to the adverse impact of military action, sanctions and market disruptions; and/or to satisfactorily resolve significant disagreements with us or address other factors could have an adverse impact on our financial results and operations. In addition, if these third parties violate, or are alleged to have violated, any laws or regulations during the performance of their obligations for us, including with respect to safety, patient and data privacy, antitrust, and bribery and corruption, it is possible that we could suffer financial and reputational harm or other negative outcomes, including possible legal consequences and liabilities. We may not be successful in enforcing the terms and conditions of our licensing and collaboration agreements in court or via agreed upon dispute resolution mechanisms, and even if we were to prevail in any such dispute, the remedies may not be adequate to compensate us for the losses. Any termination, breach or expiration of any of these licensing or collaboration agreements could have a material adverse effect on our financial position by reducing or eliminating the potential for us to receive license fees, milestones and royalties. In such an event, we may be required to devote additional efforts and to incur additional costs associated with pursuing regulatory approval and commercialization of *neffy*. Alternatively, we may attempt to identify and transact with a new assignee or licensee, but there can be no assurance that we would be able to identify a suitable partner or transact on terms that are favorable to us. For example, in February 2023, we terminated the Recordati License and Supply Agreement, which eliminated the potential for us to receive milestone and royalty payments from Recordati under the Recordati License and Supply Agreement. Although we found a partner for the regions previously licensed to Recordati, under the Recordati Termination Agreement, we are obligated to pay certain milestone and royalty payments to Recordati.

neffy is 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 is 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 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 good clinic practice ("GCP") requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for any products or potential products in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs or trial sites fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable, and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. In addition, our clinical trials must be conducted with products produced under cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

There is no guarantee that any of our CROs, investigators or other third parties will devote adequate time and resources to such trials or studies or perform as contractually required. If any of these third parties fail to meet expected deadlines, adhere to our clinical protocols or meet regulatory requirements, or otherwise performs in a substandard manner, our clinical trials may be extended, delayed or terminated. In addition, many of the third parties with whom we contract may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other development activities that could harm our competitive position. In addition, principal investigators for our clinical trials are expected to serve as scientific advisors or consultants to us from time to time and may receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or the FDA or a comparable regulatory authority concludes that the financial relationship may have affected the interpretation of the study, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection by the FDA of any NDA we submit or of comparable applicable submitted to foreign regulatory authorities. Any such delay or rejection could prevent us from commercializing *neffy* 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 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 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*. If we are unable to obtain or maintain patent protection with respect to *neffy*, 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* that are important to our business, as appropriate. Our pending and future patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless, and until, patents issue from such applications, and then only to the extent the issued claims cover the technology. There can be no assurance that our patent applications will result in patents being issued or that issued patents will afford sufficient protection against competitors with similar technology, nor can there be any assurance that the patents issued will not be infringed, designed around or invalidated by third parties. Even issued patents may later be found invalid or unenforceable or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts. The degree of future protection for our proprietary rights is uncertain. Only limited protection may be available and may not adequately protect our rights or permit us to gain or keep any competitive advantage. This failure to obtain the intellectual property rights relating to our product could have a material adverse effect on our financial condition and results of operations.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our potential future collaborators will be successful in protecting our intellectual property by obtaining and defending patents. Obtaining and enforcing patents is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications, or maintain and/or enforce patents that may issue based on our patent applications, at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development results before it is too late to obtain patent protection.

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

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

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

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

Our patents or pending patent applications, or the patents or pending patent applications that we license, may be challenged in the courts or patent offices in the United States and other foreign jurisdictions. For example, we are currently a party to an appeal from a Final Written Decision in an Inter Partes Review of U.S. Patent No. 10,682,414 B2 and to an opposition proceeding at the European Patent Office with respect to EP 3678649, and we may be subject to new or additional 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, 2024 we co-own or exclusively license seven issued U.S. patents, granted patents in each of Australia, Canada, China, Hong Kong, Japan, Mexico, Singapore, South Korea, and member states of the European Patent Organization, including the United Kingdom, directed to *neffy* and its uses, among other things, two pending U.S. non-provisional patent applications, one pending U.S. provisional patent application and over fifteen pending foreign patent applications directed to *neffy* and its uses, among other things, filing, prosecuting and defending patents in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These competitor products may compete with our product, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

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

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

Further, geo-political actions in the United States and in foreign countries (such as the Russia and Ukraine conflict) 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. 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* 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* 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.*

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

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

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

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

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

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

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

Patent terms may be inadequate to protect our competitive position for neffy 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*. In particular, patent protection is important in the development and commercialization of our approved product candidates. Patents covering *neffy* normally provide market exclusivity, which is important in order for *neffy* to become profitable.

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

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

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

We co-own or exclusively license patent applications in our portfolio relating to *neffy* 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* 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* 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.*

As the pharmaceutical industry expands and more patents are issued, the risk increases that *neffy* 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* 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*.

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*. 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*. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market *neffy*.

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.*

Our commercial success depends, in part, on our ability to develop, manufacture, market and sell *neffy* 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. 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.

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*. 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 of use either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, and we may not be able to do this. Proving invalidity of third-party patents may be difficult and uncertain. Even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted in defending our rights in these proceedings, which could have a material adverse effect on our business and operations. In addition, we may not have sufficient resources to bring these actions to a successful conclusion.

If we are found to infringe a third party's intellectual property rights, we could be forced, including by court order, to cease developing, manufacturing or commercializing the infringing product candidate or product. Alternatively, we may be required to obtain a license from such third party in order to use the infringing technology and continue developing, manufacturing or marketing the infringing product candidate. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing *neffy* or 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.

We are currently a party to an appeal from a Final Written Decision in an Inter Partes Review of U.S. Patent No. 10,682,414 B2 and to an opposition proceeding at the European Patent Office with respect to EP 3678649. We may, in the future, be a party to other intellectual property litigation or administrative proceedings that are very costly and time-consuming and could interfere with our ability to sell and market our products. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations. In addition, patent holding companies that focus solely on extracting royalties and settlements by enforcing patent rights may target us, especially as we gain greater visibility and market exposure as a public company.

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

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

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

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

neffy may face competition from generic inhalable epinephrine products sooner than expected, and our patents may be challenged.*

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

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 as a result of questions regarding co-ownership of potential joint inventions. Litigation may be necessary to resolve these and other claims challenging inventorship and/or ownership. Alternatively, or additionally, we may enter into agreements to clarify the scope of our rights in such intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

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

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

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

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

- others may be able to make formulations that are similar to *neffy* 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 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*, 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 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. 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 may 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 may 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*, 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*. 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* 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* 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 recently expanded our organization following FDA approval of *neffy* in August 2024. Specifically, we added 108 people to 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 146 full-time employees and 5 part-time employees as of October 31, 2024. 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*, 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*;
- any inability to obtain adequate supply of *neffy* 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*;
- 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;
- sales of our common stock by us or our stockholders in the future;
- trading volume of our common stock;
- announcements by commercial partners or competitors of new commercial products, clinical progress or the lack thereof, significant contracts, commercial relationships or capital commitments;
- adverse publicity generally, including with respect to other products and potential products in such markets;
- the introduction of technological innovations or new therapies that compete with potential products of ours;
- changes in the structure of health care payment systems; and
- period-to-period fluctuations in our financial results.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We are an "emerging growth company" and we cannot be certain if the reduced disclosure requirements applicable to "emerging growth companies" will make our common stock less attractive to investors.

We are an "emerging growth company," as defined under the Jumpstart Our Business Startups Act (the "JOBS Act"). For so long as we are an "emerging growth company," we plan to take advantage of certain exemptions from reporting requirements that are applicable to other public companies that are not "emerging growth companies" including, but not limited to, compliance with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We cannot predict if investors will find our common stock less attractive, or us less comparable to certain other public companies because we will rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

Under the JOBS Act, "emerging growth companies" can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We have elected to use this extended transition period under the JOBS Act.

General Risk Factors

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

Use of Proceeds

On December 3, 2020, Silverback Therapeutics, Inc. ("Silverback") commenced its initial public offering ("IPO") pursuant to a registration statement on Form S-1 (File No. 333-250009) that was declared effective by the SEC on December 3, 2020, for 11,500,000 shares of its common stock for sale to the public at a price of $21.00 per share. In addition, in December 2020, the underwriters exercised their over-allotment option to purchase 1,725,000 additional shares of Silverback common stock in the initial public offering at the public offering price of $21.00 per share, such that the aggregate offering price of the IPO was $277.7 million. The net offering proceeds to Silverback, after deducting underwriting discounts and commissions and offering costs, were $255.3 million. No offering expenses were paid directly or indirectly to any of the Silverback directors or officers (or their associates) or persons owning 10% or more of any class of Silverback's equity securities or to any other affiliates. The underwriters for the Silverback initial public offering were Goldman Sachs & Co. LLC, SVB Leerink LLC, Stifel, Nicolaus & Company, Incorporated, and H.C. Wainwright & Co., LLC.

On November 8, 2022, Silverback completed its reverse merger with privately-held ARS Pharmaceuticals, Inc. On November 9, 2022, the combined company changed its name to ARS Pharmaceuticals, Inc.

The net proceeds from the IPO are held in cash and cash equivalents, primarily in treasury money market accounts, and investments, primarily in U.S. Treasury securities. Through September 30, 2024, approximately $194.9 million of the net proceeds from the IPO have been used, of which, (i) an estimated $51.7 million was used toward development of Silverback's product candidates, (ii) $0.8 million was used to repay outstanding indebtedness, (iii) $16.0 million was used for transaction costs related to the Merger, including $7.0 million in severance and change in control benefit payments made to Silverback's former officers, (iv) an estimated $60.4 million was used for development and commercial launch activities related to *neffy*, and (v) an estimated $66.0 million was used for working capital and general corporate purposes.

There have been no updates to the planned use of proceeds information from the IPO as described in our final prospectus filed with the SEC pursuant to Rule 424(b)(4) on December 4, 2020, except as otherwise disclosed in our Annual Report on Form 10-K, filed with the SEC on March 31, 2022, and our Quarterly Report on Form 10-Q, filed with the SEC on August 11, 2022. We intend to use the remaining net proceeds from the IPO, together with our existing cash and cash equivalents, to fund the manufacture and commercialization of *neffy* for the emergency treatment of Type I allergic reactions and other indications, if approved, as well as for working capital and other general corporate purposes. We may also use a portion of the net proceeds from the IPO to license, acquire or invest in complementary businesses, technologies, products or assets. However, we have no current commitments or obligations to do so.

Item 5. Other Information

During the quarter ended September 30, 2024, one of our executive officers terminated a Rule 10b5-1 trading plan as set forth in the table below.

			Type of Trading Arrangement			
Name and Position	**Action**	**Adoption/Termination Date**	**Rule 10b5-1[(1)]**	**Non-Rule 10b5-1[(2)]**	**Total Shares of Common Stock to be Sold**	**Expiration Date**
Brian Dorsey, Chief Operating Officer	Termination[(3)]	August 28, 2024	X		340,000	March 31, 2025

[(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 of a trading plan intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) adopted on March 31, 2023 and amended on December 8, 2023.

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).
4.1	Reference is made to Exhibit 3.1 and 3.2.
4.2	Amended and Restated Investors' Rights Agreement, by and between the registrant and certain of its stockholders, dated September 22, 2020 (incorporated by reference to Exhibit 4.2 to the registrant's Registration Statement on Form S-1 (File No. 333-250009), as amended, filed with the SEC on November 10, 2020).
4.3	Warrant to purchase stock issued to Silicon Valley Bank, dated as of September 30, 2019, as amended on December 7, 2020 (incorporated by reference to Exhibit 4.1 to the registrant's Current Report on Form 8-K, filed with the SEC on November 8, 2022).
10.1‡*	Second Amendment, dated September 17, 2024, to Manufacturing Agreement, dated September 9, 2020 and first amended July 25, 2023, by and between ARS Pharmaceuticals, Inc. and Renaissance Lakewood, LLC.
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Principal Executive and Financial Officers Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document–the instance document does not appear in the Interactive Data File as its XBRL tags are embedded within the Inline XBRL document
101.SCH	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents
104	Cover page formatted as Inline XBRL and contained in Exhibit 101

‡ Schedules have been omitted pursuant to Item 601(a)(5) of Regulation S-K. The registrant undertakes to furnish supplemental copies of any of the omitted schedules upon request by the SEC.

* 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.

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 13, 2024

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

Date: November 13, 2024

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 BECAUSE THE REGISTRANT HAS DETERMINED THE INFORMATION IS BOTH NOT MATERIAL AND IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

SECOND AMENDMENT TO MANUFACTURING AGREEMENT

This Second Amendment to Manufacturing Agreement (this "**Amendment**"), effective as of September 17, 2024 (the "**Second Amendment Effective Date**"), is made by and between ARS Pharmaceuticals Operations, Inc. formerly known as ARS Pharmaceuticals, Inc., a corporation organized under the laws of the State of California with an office at 11682 El Camino Real, Suite 120 San Diego CA 92130 ("**COMPANY**") and Renaissance Lakewood, LLC, a limited liability company organized under the laws of the State of Delaware with an office at 1200 Paco Way, Lakewood, New Jersey 08701 ("**RENAISSANCE**").

RECITALS

A. Reference is made to that certain Manufacturing Agreement, dated as of September 9, 2020, by and between COMPANY and RENAISSANCE, as amended July 25, 2023 (the "**Agreement**"). Capitalized terms used but not otherwise defined herein shall have the respective meanings given in the Agreement.

B. COMPANY and RENAISSANCE desire to enter into this Amendment for purposes of modifying the Agreement as set forth herein.

Now, therefore, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties agree as follows:

1. Amendment of the Agreement.

(a) The following new definition of "**E.U. Printed Material**" is hereby added to Article I (Definitions) of the Agreement: "**E.U. Printed Material**" means all printed materials for the E.U., including horseshoe labels, quick-start guides, physician inserts, blister lidding and cartons. An estimate of the Materials Fee for E.U. Printed Material to be used for COMPANY budgetary purposes is included in **Schedule G** attached hereto.

(b) The definition of "**Materials Fee**" is hereby deleted in its entirety and replaced with the following: "**Materials Fee**" means an amount, quoted in single final Product unit increments, equal to [***].

(c) The definition of "**Project Protocol**" is hereby deleted in its entirety and replaced with the following: "**Project Protocol**" means a precise and detailed plan that is mutually agreed and executed by RENAISSANCE and COMPANY, which describes the nature and scope of materials and/or out-of-scope services to be purchased and/or rendered and fees to be charged, which may include Additional Development.

(d) The definition of "**RENAISSANCE Material**" is hereby deleted in its entirety and replaced with the following: "**RENAISSANCE Material**" means all materials, other than the COMPANY Material and the E.U. Printed Material, necessary for the Manufacture of Product.

(e) The definition of "**Target E.U. Launch Date**" is hereby deleted in its entirety and replaced with the following: "**Target E.U. Launch Date**" means [***], the target Launch Date for the first Product in the E.U.

(f) The definition of "**Target U.S. Launch Date**" is hereby deleted in its entirety and replaced with the following: "**Target U.S. Launch Date**" means [***], the target Launch Date for the first Product in the U.S.

(g) The definition of "**Total Price per Unit of Product**" is hereby deleted in its entirety and replaced with the following: "**Total Price per Unit of Product**" means, with respect to a unit of a Product, the sum of its [***].

(h) The definition of "**U.S. Termination Event**" is deleted in its entirety and replaced with the following: **"U.S. Termination Event"** means the occurrence of any of the following events: (i) COMPANY's authorization and approval to distribute or sell Product in the U.S. is not granted on or before December 31, 2026, (ii) COMPANY's authorization and approval representing more than [***] Units of Product sold in the U.S. during the last calendar year is withdrawn by the FDA, or (iii) COMPANY at its sole discretion determines to cease commercializing all Product in the U.S.

(i) The following new definition of "**Unit**" is hereby added to Article I (Definitions) of the Agreement: "**Unit**" has the meaning set forth in **Schedule B**.

(j) Section 2.2(b) (Materials Supplied by RENAISSANCE) of the Agreement is hereby deleted in its entirety and replaced with the following:

> (i) RENAISSANCE shall be responsible for the supply of E.U. Printed Material. Within [***] business days following the receipt of COMPANY's Forecasted Needs in accordance with Section 2.6(b), the parties will meet to agree on the quantities of E.U. Printed Material including, but not limited to, the timing of orders, MOQ and Material Fee for each of E.U. Printed Material that should be ordered by RENAISSANCE, and which will be detailed in writing in a Project Protocol and executed by the parties. Such Project Protocol will be invoiced in accordance with Section 2.9. Upon RENAISSANCE's receipt of COMPANY's payment for such E.U. Printed Material, RENAISSANCE will order such E.U. Printed Material from its supplier.
>
> (ii) RENAISSANCE shall be responsible for the supply of RENAISSANCE Material. [***].

(k) The last sentence of Section 2.6(b) (Purchase Orders: Forecasted Needs) is hereby deleted in its entirety and replaced with the following:

> Any such material which is subsequently rendered in excess of that required to support up to [***] of COMPANY's Forecasted Needs may be subject to [***] and [***] which will be invoiced by RENAISSANCE in accordance with Section 2.9, and, in addition, should COMPANY subsequently reduce its Forecasted Needs such that the inventory of RENAISSANCE Material is in excess of an amount required to support [***] COMPANY's then current Forecasted Needs, then RENAISSANCE may invoice COMPANY for [***], also in accordance with Section 2.9.

(l) Section 2.8(a) (Product Price: Manufacturing Fee) of the Agreement is hereby deleted in its entirety and replaced with the following:

> Each initial Manufacturing Fee to be paid by COMPANY to RENAISSANCE is listed in **Schedule B**.
>
> (i) On the first day of [***] of each [***], the applicable Manufacturing Fee for Product set forth in **Table 1**, and (ii) on the first day of January of each calendar year beginning on January 1, 2027, the applicable Manufacturing Fee for Product set forth in **Table 2**, in each case ((i) and (ii)) [***] be adjusted upward by the change in the most recently-published monthly Producer Price Index for Pharmaceutical Preparation Manufacturing PCU 325412, issued by the Bureau of Labor Statistics, U.S. Department of Labor ("**PPI**"), or comparable successor index, in [***] of the immediately-preceding [***] as compared to [***] of the prior [***], provided that (i) the increase in Manufacturing Fee during the period commencing on the Effective Date and ending on the U.S. Launch Date (for **Table 1**) and/or E.U. Launch Date (for **Table 2**) may not exceed [***] during any [***], and (ii) the total increase after the U.S. Launch Date and the E.U. Launch Date, as applicable, until the end of the Initial Term may not exceed [***] (a "**PPI Adjustment**").
>
> (For example: [***])
>
> Further, the Manufacturing Fee for any new Product that is not yet included in **Schedule B** will be negotiated by the parties in good faith using their commercially reasonable efforts, and if the parties are able to agree on the Manufacturing Fee, the Agreement will be amended to reflect that pricing prior to the time of first production of such new Product.

(m) Section 2.9 (Payment) of the Agreement is hereby deleted in its entirety and replaced with the following:

> Payment for all deliveries of Product shall be made in U.S. Dollars (USD), net [***] after the date of RENAISSANCE's invoice therefor. Invoices for Product shall be generated upon [***] of Product from RENAISSANCE. Total invoice price shall be equal to [***], plus any other additional amounts listed in **Schedule B**, less any pre-payments made for excess RENAISSANCE Materials in accordance with Section 2.6(b). Payment for the purchase of any materials or services purchased under a Project Protocol shall be made in U.S. Dollars (USD), net thirty (30) days after the date of RENAISSANCE's invoice therefor. Payment shall be made by check, wire transfer, electronic fund transfer or through other instrument accepted by RENAISSANCE. Payment by wire or electronic fund transfer should be made to the following:
>
> [***]

(n) Section 4.1 (Term) of the Agreement is hereby deleted in its entirety and replaced with the following:

> The initial term of this Agreement shall commence on the Effective Date and will terminate (a) for Product designated for commercial sale in the U.S. on December 31st immediately following the five (5) year anniversary of the U.S. Launch Date (the "U.S. Initial Term"), and (b) for Product designated for commercial sale in the E.U., on December 31st immediately following the five (5) year anniversary of the E.U. Launch Date (the "E.U. Initial Term" and with the U.S. Initial Term, each an "Initial Term"); in each case, unless sooner terminated pursuant to Section 4.2.Thereafter, each of the U.S. Initial Term and the E.U. Initial Term shall automatically renew for periods of twenty-four (24) months (each a "U.S. Renewal Term" and an "E.U. Renewal Term " respectively and each a "Renewal Term" and collectively with each Initial Term, the "U.S. Term" and "E.U. Term" and collectively, the "Term"), unless either party shall give notice to the other to the contrary not later than twenty-four (24) months prior to the expiration of the Initial Term or the then-current Renewal Term. For clarity, each of the U.S. Term and the E.U. Term may be independently or collectively renewed pursuant to this Section 4.1.

(o) Section 8.3 (Obsolete Inventory and Raw Material) of the Agreement is hereby deleted in its entirety and replaced with the following:

> Any inventory procured or developed by RENAISSANCE specifically for the Manufacture of Product, [***]. At such time and as instructed by COMPANY, RENAISSANCE will either destroy such obsolete inventory or raw materials or ship such obsolete inventory or raw materials to COMPANY. [***] shall bear [***] of all shipping and destruction costs related to such obsolete inventory or raw materials. Any such destruction shall be in accordance with Applicable Law, and each party shall also provide the other party with all manifests and other applicable evidence of proper destruction as may be requested by the other party or required by Applicable Law. If RENAISSANCE does not receive disposition instructions from COMPANY within [***] from date of notification, obsolete inventory [***] shall be subject to [***] or destruction at RENAISSANCE's discretion and [***] for such costs under a Project Protocol.

(p) **Schedule B** of the Agreement is hereby deleted in its entirety and replaced with Schedule B attached hereto.

(q) A new **Schedule F** is hereby added to the Agreement as set forth in Schedule F attached hereto.

(r) A new **Schedule G** is hereby added to the Agreement as set forth in Schedule G attached hereto.

(s) Article II (Product Manufacture and Supply) of the Agreement is hereby amended by adding the following as new Section 2.14:

> **2.14 Expansion Generally**
> RENAISSANCE agrees to use Commercially Reasonable Efforts to increase its capacity to Manufacture and supply Product under this Agreement in order to accommodate the growth of the market for Product as set forth in the forecasts provided by COMPANY.

2. Miscellaneous.

(a) Except as expressly amended herein, the Agreement shall remain in full force and effect.

(b) This validity, interpretation and effect of this Amendment shall be governed by and construed under the laws of the State of Delaware without reference to principles of conflicts of laws.

(c) This Amendment may be executed in counterparts, including electronic counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same original.

(The remainder of this page is intentionally left blank. The signature page follows.)

Each of the parties has caused this Amendment to be duly executed on its behalf as of the Second Amendment Effective Date.

ARS PHARMACEUTICALS OPERATIONS, INC.

By: /s/ Richard Lowenthal

Name: Richard Lowenthal

Title: CEO and President

RENAISSANCE LAKEWOOD, LLC

By: /s/ Serge Maltais

Name: /s/ Serge Maltais

Title: President and CEO

Schedule B – Product Description; Manufacturing Fee; Materials Fee

[***]

Schedule F – Drawings

[***]

Schedule G
Estimated Materials Fee for E.U. Printed Material

[***]

Exhibit 31.1

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

I, Richard Lowenthal, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the quarter ended September 30, 2024 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 13, 2024

By: /s/ Richard Lowenthal, M.S., MSEL
Richard Lowenthal, M.S., MSEL
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, 2024 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 13, 2024

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 PURSURANT 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 period ended September 30, 2024, 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 herby 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 13, 2024

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

Date: November 13, 2024

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.