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

FORM 10-Q

☒ **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 001-41264

NUVECTIS PHARMA, INC.

(Exact name of registrant as specified in its charter)

Delaware	**86-2405608**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
1 Bridge Plaza, Suite 275 **Fort Lee, NJ 07024** (Address of Principal Executive Offices)	**07024** (Zip Code)

(201) 614-3150
(Registrant's telephone number, including area code)

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 $0.00001 per share	NVCT	**NASDAQ Capital Market**

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 (§ 232.405 of this chapter) 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, 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 Act). Yes ☐ No ☒

Indicate the number of shares outstanding of each of the registrant's classes of common stock, as of the latest practicable date.

Class of Common Stock	Outstanding Shares as of November 1, 2024
Common Stock, $0.00001 par value	19,320,973

NUVECTIS PHARMA, INC.
FORM 10-Q
FOR THE QUARTER ENDED SEPTEMBER 30, 2024
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SUMMARY OF RISK FACTORS

An investment in our common stock is subject to a broad range of risks and should only be made after a careful consideration of such risks. For a discussion of some of the risks you should consider before purchasing our common stock, you are urged to carefully review and consider the section entitled "Item 1A. Risk Factors."

Our business is subject to a number of risks, including risks that may prevent us from achieving our business objectives or may adversely affect our business, financial condition, results of operations, cash flows and prospects that you should consider before making a decision to invest in our common stock. These risks are discussed more fully in the section titled "Risk factors" beginning on page 26 of this report, and include the following:

Risks Related to our Financial Condition and Capital Requirements

- We have a limited operating history, have only initiated a limited number of clinical trials, and have only a limited number of patients currently enrolled in our ongoing trials and have not completed any clinical trials to date. We do not have any products approved for commercial sale and have not generated any revenue, which may make it difficult for investors to evaluate our current business and likelihood of success and viability.

- We have incurred losses since our inception and have not generated any revenue. We expect to incur continued losses for the foreseeable future and may never achieve or maintain profitability.

- Our ability to generate revenue and achieve profitability depends significantly on our ability to achieve several objectives relating to the discovery or identification, preclinical and clinical development, regulatory approval and commercialization of our current or future product candidates.

- We will require substantial additional capital to finance our operations and achieve our goals. If we are unable to raise capital when needed or on terms acceptable to us, we may be forced to delay, reduce or eliminate our research or product development programs, any future commercialization efforts or other operations.

- Policies implemented during the COVID-19 pandemic, which remain in place today, could adversely impact our business, including our preclinical development, clinical trials and clinical trial operations.

Risks Related to the Development of our Product Candidates

- We are substantially dependent on the success of our product candidates, NXP800, and NXP900.

- Clinical trials are very expensive, time consuming and difficult to design and implement, and involve uncertain safety, tolerability and efficacy outcomes. Furthermore, results of earlier preclinical studies and clinical trials may not be predictive of results of future preclinical studies or clinical trials. Our current or future product candidates may not have favorable results in early or later clinical trials, if any, or receive regulatory approval.

- If we fail to demonstrate safety and/or efficacy for any or all of our product candidates, we may need to terminate development programs, which may harm our reputation and the business.

- The development and commercialization of pharmaceutical products are subject to extensive regulation, and we may not obtain regulatory approvals for NXP800, NXP900, or any future product candidate.

- If we are unable to obtain or maintain regulatory approval for our product candidates and ultimately cannot commercialize one or more of them, or experience significant delays in doing so, our business will be materially harmed.

Risks Related to our Reliance on Third Parties

- The manufacture of our current and potentially of our future product candidates is complex. Our third-party manufacturers may encounter difficulties or interruptions for various reasons, which could delay or entirely halt their ability to make any of our current or future product candidates for clinical trials or, if approved, for commercial sale.

Risks Related to Managing Growth and Employee Matters

- Our future success depends on our ability to retain our executive officers and key employees and to attract, retain and motivate qualified personnel and manage our human capital.

- We currently have 13 full-time employees and will need to grow the size and capabilities of our organization. We may experience difficulties in managing this growth.

Risks Related to our Intellectual Property

- If we are unable to obtain and maintain patent protection or other necessary rights for our products and technology, or if the scope of the patent protection obtained is not sufficiently broad or our rights under licensed patents are not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to successfully commercialize our products and technology may be adversely affected.

PART I – FINANCIAL INFORMATION

Item 1. Financial Statements

NUVECTIS PHARMA, INC.
CONDENSED BALANCE SHEETS
(USD in thousands, except per share and share amounts)
(unaudited)

	September 30, 2024	December 31, 2023
Assets		
CURRENT ASSETS		
Cash and cash equivalents	$ 17,169	$ 19,126
Other current assets	138	59
TOTAL CURRENT ASSETS	17,307	19,185
TOTAL ASSETS	$ 17,307	$ 19,185
Liabilities and Stockholders' Equity		
CURRENT LIABILITIES		
Accounts payables	$ 2,261	$ 2,771
Accrued liabilities	282	415
Employee compensation and benefits	3,773	3,798
TOTAL CURRENT LIABILITIES	6,316	6,984
TOTAL LIABILITIES	6,316	6,984
COMMITMENTS AND CONTINGENCIES, see Note 3		
STOCKHOLDERS' EQUITY, see Note 4		
Common Shares, $0.00001 par value – 60,000,000 shares authorized as of September 30, 2024, and December 31, 2023, 18,985,324, and 17,418,886 shares issued and outstanding as of September 30, 2024 and December 31, 2023, respectively	*	*
Additional paid in capital	77,988	66,446
Accumulated deficit	(66,997)	(54,245)
TOTAL STOCKHOLDERS' EQUITY	10,991	12,201
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 17,307	$ 19,185

* Represents an amount lower than $1 USD.

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

NUVECTIS PHARMA, INC.
CONDENSED STATEMENTS OF OPERATIONS
(USD in thousands, except per share and share amounts)
(unaudited)

	Three Months Ended September 30		Nine Months Ended September 30	
	2024	2023	2024	2023
OPERATING EXPENSES				
Research and development	$ 2,819	$ 4,486	$ 8,422	$ 11,115
General and administrative	1,540	1,672	4,976	4,916
OPERATING LOSS	(4,359)	(6,158)	(13,398)	(16,031)
Finance income	206	277	646	393
NET LOSS	$ (4,153)	$ (5,881)	$ (12,752)	$ (15,638)
NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS	$ (4,153)	$ (5,881)	$ (12,752)	$ (15,638)
BASIC AND DILUTED NET LOSS PER COMMON SHARE OUTSTANDING, see Note 6	$ (0.24)	$ (0.37)	$ (0.75)	$ (1.02)
Basic and diluted weighted average number of common shares outstanding	17,230,559	16,104,446	16,898,040	15,341,685

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

NUVECTIS PHARMA, INC.
CONDENSED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
(USD in thousands, except share amounts)
(unaudited)

	Common shares $0.00001 Par Value		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
BALANCES AT DECEMBER 31, 2022	15,190,720	*	$ 46,204	$ (31,985)	$ 14,219
Share-based payments	—	*	1,402	—	1,402
Issuance of restricted share awards	585,499	*	—	—	—
Exercise of preferred investment options	4,000	*	39		39
Exercise of warrants	105,920	*	663		663
Net loss for the period	—	—	-	(4,049)	(4,049)
BALANCES AT MARCH 31, 2023	15,886,139	*	$ 48,308	$ (36,034)	$ 12,274
Share-based payments	—	*	950	—	950
Issuance of restricted share awards	63,000	—	—	—	—
Exercise of preferred investment options, net of offering costs of $770	997,091	*	8,852	—	8,852
Exercise of warrants	79,104	*	816	—	816
Issuance of common share, net of offering costs of $152 - At-the-market	188,970	*	3,110	—	3,110
Exercise of share options	6,809	*	38	—	38
Net loss for the period	—	—	-	(5,708)	(5,708)
BALANCES AT JUNE 30, 2023	17,221,113	*	$ 62,074	$ (41,742)	$ 20,332
Share-based payments	—	*	1,134	—	1,134
Issuance of restricted stock awards	15,000	*	—	—	—
Issuance of common stock, net of offering costs of $39 - At-the-market	73,798	*	1,101	—	1,101
Net loss for the period	—	—	-	(5,881)	(5,881)
BALANCES AT SEPTEMBER 30, 2023	17,309,911	*	$ 64,309	$ (47,623)	$ 16,686

* Represents an amount lower than $1 USD.

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

NUVECTIS PHARMA, INC.
CONDENSED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
(USD in thousands, except share amounts)
(unaudited)

	Common Stock $0.00001 Par Value		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
BALANCES AT DECEMBER 31, 2023	17,418,886	*	$ 66,446	$ (54,245)	$ 12,201
Share-based payments	—	—	1,296	—	1,296
Issuance of restricted share awards	434,527	—	—	—	—
Issuance of common shares, net of offering costs of $153 - At-the-market	502,647	*	4,696	—	4,696
Net loss for the period	—	—	—	(4,171)	(4,171)
BALANCES AT MARCH 31, 2024	18,356,060	*	$ 72,438	$ (58,416)	$ 14,022
Share-based payments	—	*	1,262	—	1,262
Issuance of restricted share awards	146,000	*	—	—	—
Issuance of common shares, net of offering costs of $55 - At-the-market	246,691	*	1,672	—	1,672
Net loss for the period	—	—	—	(4,428)	(4,428)
BALANCES AT JUNE 30, 2024	18,748,751	*	$ 75,372	$ (62,844)	$ 12,528
Share-based payments	—	*	1,159	—	1,159
Issuance of restricted share awards	20,000	*	—	—	—
Issuance of common shares, net of offering costs of $49 - At-the-market	216,573	*	1,457	—	1,457
Net loss for the period	—	—	—	(4,153)	(4,153)
BALANCES AT SEPTEMBER 30, 2024	18,985,324	*	$ 77,988	$ (66,997)	$ 10,991

* Represents an amount lower than $1 USD.

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

NUVECTIS PHARMA, INC.
CONDENSED STATEMENTS OF CASH FLOWS
(USD in thousands, except per share and share amounts)
(unaudited)

	Nine Months Ended September 30,	
	2024	2023
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (12,752)	$ (15,638)
Adjustments to reconcile loss to net cash used in operating activities:		
Cost of share-based payments	3,717	3,485
Changes in operating assets and liabilities:		
(Increase)/decrease in other current assets	(79)	209
(Decrease)/increase in accounts payable	(510)	582
Decrease in accrued liabilities	(133)	(287)
Decrease in accrued compensation and benefits	(25)	(455)
Net cash used in operating activities	$ (9,782)	$ (12,104)
CASH FLOWS FROM INVESTING ACTIVITIES		
Net cash provided by (used in) investing activities	—	—
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from issuance of common shares - At-the market offering	$ 8,083	$ 4,388
Issuance costs related to At-the-market offering	(258)	(190)
Issuance costs related to initial public offering	—	(341)
Proceeds from exercise of warrants, options, and preferred investment options	—	11,192
Issuance costs related to the exercise of warrants, and preferred investment options	—	(371)
Issuance costs related to private placement	—	(508)
Net cash provided by financing activities	$ 7,825	$ 14,170
(DECREASE)/INCREASE IN CASH AND CASH EQUIVALENTS	$ (1,957)	$ 2,066
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	$ 19,126	$ 19,993
CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 17,169	$ 22,059

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

NUVECTIS PHARMA, INC.

Notes to the Unaudited Condensed Financial Statements

NOTE 1 – GENERAL:

a. Nuvectis Pharma, Inc. (hereafter – the "Company") was incorporated under the laws of the State of Delaware on July 27, 2020 and commenced its principal operations in May 2021. The Company's principal executive offices are located in Fort Lee, New Jersey.

The Company is a biopharmaceutical company focused on the development of innovative precision medicines for the treatment of serious conditions of unmet medical need in oncology.

b. In May 2021, the Company entered into a worldwide, exclusive license agreement with the CRT Pioneer Fund ("CRT") (see Note 3a). In August 2021, the Company entered into a worldwide, exclusive license agreement with the University of Edinburgh, Scotland for the Company's second drug candidate (see Note 3a).

c. In February 2022, the Company's shares began trading on the NASDAQ under the symbol "NVCT".

d. Liquidity and Capital Resources

The Company has incurred net operating losses since its inception and had an accumulated deficit of $67.0 million as of September 30, 2024. The Company had cash and cash equivalents of $17.2 million as of September 30, 2024 and has not generated positive cash flows from operations. To date, the Company has been able to fund its operations primarily through the issuance and sale of common stock.

During the three months ended September 30, 2024, the Company sold a total of 216,573 common shares under its At-the-Market Program for aggregate total gross proceeds of approximately $1.5 million at an average selling price of $6.96 per share, resulting in net proceeds of approximately $1.5 million after deducting issuance costs.

During the nine months ended September 30, 2024, the Company sold a total of 965,911 common shares under its At-the-Market Program for aggregate total gross proceeds of approximately $8.1 million at an average selling price of $8.36 per share, resulting in net proceeds of approximately $7.8 million after deducting issuance costs.

Management believes that its existing cash and cash equivalents as of September 30, 2024 enable the Company to fund planned operations for at least 12 months following the issuance date of these condensed financial statements.

The Company will need to raise additional capital in order to complete the clinical trials aimed at developing the product candidates until obtaining its regulatory and marketing approvals. There can be no assurances that the Company will be able to secure such additional financing, or at terms that are satisfactory to the Company, and that it will be sufficient to meet its needs. In the event the Company is not successful in obtaining sufficient funding, this could force the Company to delay, limit, or reduce its products' development, clinical trials, commercialization efforts or other operations, or even close down or liquidate.

NUVECTIS PHARMA, INC.

Notes to the Unaudited Condensed Financial Statements (continued)

NOTE 2 – SIGNIFICANT ACCOUNTING POLICIES:

a. Basis of Presentation

The accompanying condensed financial statements are unaudited. The unaudited condensed financial statements of the Company have been prepared in accordance with generally accepted accounting principles in the United States ("U.S. GAAP"), are stated in U.S. dollars and follow the requirements of the Securities and Exchange Commission ("SEC") for interim financial reporting. Accordingly, they do not include all of the information and disclosures required by U.S. GAAP for complete financial statements as certain footnotes or other financial information that are normally required by U.S. GAAP can be condensed or omitted. The unaudited condensed financial statements have been prepared on the same basis as the audited financial statements. The unaudited condensed financial statements include the accounts of the Company. 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 Updates ("ASU") of the Financial Accounting Standards Board ("FASB").

In the opinion of management, the unaudited condensed financial statements include all normal and recurring adjustments that are considered necessary for the fair statement of results for the interim periods. The results for the period ended September 30, 2024 are not necessarily indicative of those expected for the year ending December 31, 2024 or for any future period. The condensed balance sheet as of December 31, 2023 included herein was derived from the audited financial statements as of that date but does not include all disclosures required by U.S. GAAP. These unaudited condensed financial statements should be read in conjunction with the Company's audited financial statements and the related notes thereto for the year ended December 31, 2023, included in the Company's Annual Report on Form 10-K filed with the SEC on March 5, 2024.

The significant accounting policies adopted and used in the preparation of the financial statements are consistent with those of the previous financial year.

b. Use of Estimates in the Preparation of Financial Statements

The preparation of the Company's financial statements requires management to make estimates and assumptions that impact the reported amounts of assets, liabilities and expenses in the Company's financial statements and accompanying notes. The most significant estimates in the Company's financial statements relate to accruals for research and development expenses, valuation of equity awards, and valuation allowances for deferred tax assets. These estimates and assumptions are based on current facts, future expectations, 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 expenses that are not readily apparent from other sources. Actual results may differ materially and adversely from these estimates.

c. Fair Value Measurement

The Company follows authoritative accounting guidance, which among other things, defines fair value, establishes a consistent framework for measuring fair value, and expands disclosure for each major asset and liability category measured at fair value on either a recurring or nonrecurring basis. Fair value is defined as the exchange price that would be received to sell an asset or paid to transfer a liability (at exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. The three levels of inputs that may be used to measure fair value include:

Level 1: Quoted prices (unadjusted) in active markets for identical assets or liabilities that are accessible at the measurement date for assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs. The Company's Level 1 assets consist of money market funds.

Level 2: Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities in active markets or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3: Unobservable inputs that are supported by little or no market activity. The fair value hierarchy gives the lowest priority to Level 3 inputs.

In determining fair value, the Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible and considers counterparty credit risk in its assessment of fair value.

The money market accounts included in cash and cash equivalents are considered Level 1.

During the three and nine months ended September 30, 2024 and 2023, there were no transfers between fair value measure levels. Other financial instruments consist mainly of cash and cash equivalents, other current assets, accounts payable and accrued liabilities. The fair value of these financial instruments approximates their carrying values.

d. Recently Issued Accounting Pronouncements Not Yet Adopted

Management does not believe that any recently issued, but not yet effective, accounting pronouncements, if currently adopted, would have a material effect on the Company's financial position or results of operations. No new accounting standards were adopted during the period.

NOTE 3 – COMMITMENTS AND CONTINGENCIES:

a. License Agreements

CRT Pioneer Fund License Agreement

There have been no material changes to the CRT Pioneer Fund License Agreement, as previously disclosed in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2023, filed with the SEC on March 5, 2024 (see Note 5a in the Notes to the Financial Statements in our Annual Report).

Any potential milestone or royalty payment amounts have not been accrued as of September 30, 2024 and December 31, 2023 due to the uncertainty related to the achievement of these events or milestones.

University of Edinburgh License Agreement

There have been no material changes to the University of Edinburgh ("UoE") License Agreement as previously disclosed in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2023, filed with the SEC on March 5, 2024 (see Note 5a in the Notes to the Financial Statements in our Annual Report).

Any potential future research support, milestone or royalty payment amounts have not been accrued as of September 30, 2024 and December 31, 2023, due to the uncertainty related to the achievement of these events, milestones or commitments to additional research. As of September 30, 2024, the Company has paid UoE $0.8 million of the total of up to $3.0 million related to the fund-raising commitment.

b. Related Party Transactions

There have been no related party transactions except for in the normal course of business as previously disclosed in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2023, filed with the SEC on March 5, 2024 (see Note 10 in the Notes to the Financial Statements in our Annual Report on Form 10-K).

c. Contingencies

As of September 30, 2024, and December 31, 2023, there are no contingent liabilities, therefore, no provision was made.

NOTE 4 – STOCKHOLDERS' EQUITY:

a. Private Placement in Public Entity

On July 29, 2022, the Company closed a private placement offering (the "July 2022 Private Placement"), pursuant to the terms and conditions of a Securities Purchase Agreement (the "Agreement"), dated July 27, 2022. In connection with the July 2022 Private Placement, the Company issued 1,015,598 shares of common stock, pre-funded warrants (the "Pre-Funded Warrants") to purchase an aggregate of 909,091 shares of common stock which were fully exercised as of December 31, 2022 and preferred investment options (the "Preferred Investment Options") to purchase up to an aggregate of 1,924,689 shares of common stock. The Company agreed to pay the placement agent fee and management fee equal to 7.0% and 1.0%, respectively, of the aggregate gross proceeds from the July 2022 Private Placement including the exercise of the Preferred Investment Options. The Preferred Investment Options became exercisable on January 23, 2023, and are exercisable through January 29, 2026, at an exercise price of $9.65 per share, subject to certain adjustments as defined in the Agreement. As of September 30, 2024, 1,001,091 Preferred Investment Options were exercised for $8.9 million, net of fees. In addition, as part of the July 2022 Private Placement, the Company issued warrants to the placement agent to purchase up to 115,481 shares of common stock. The placement agent warrants are in substantially the same form as the Preferred Investment Options, except that the exercise price is $10.31. As of September 30, 2024, 79,104 placement agent warrants were exercised for which the Company has received $0.8 million.

b. At-the-Market Program

During the nine months ended September 30, 2024, the Company sold a total of 965,911 common shares under our At-the-Market Offering Agreement with H. C. Wainwright & Co. (the "ATM Program") for aggregate total gross proceeds of approximately $8.1 million at an average selling price of $8.37 per share, resulting in net proceeds of approximately $7.8 million after deducting issuance costs.

During the three months ended September 30, 2024, the Company sold a total of 216,573 common shares under its ATM Program for aggregate total gross proceeds of approximately $1.5 million at an average selling price of $6.96 per share, resulting in net proceeds of approximately $1.5 million after deducting issuance costs.

As of September 30, 2024, approximately $26.6 million of securities remain available for sale under the ATM Program.

NUVECTIS PHARMA, INC.

Notes to the Unaudited Condensed Financial Statements (continued)

NOTE 5 – SHARE-BASED PAYMENTS:

a. 2021 Global Equity Incentive Plan ("Incentive Plan")

The following table summarizes the Company's stock option activity in the Incentive Plan for the nine months ended September 30, 2024:

	Number of shares under option	Weighted average exercise price per option	Weighted average remaining life	Aggregated intrinsic value (in thousands)
Balance, December 31, 2023	348,281	$ 4.59	7.94	$ 1,317
Granted	—	-		
Exercised	—	-		
Forfeited	—	-		
Outstanding – September 30, 2024	348,281	$ 4.59	7.19	$ 592
Exercisable – September 30, 2024	333,281			
Expected to vest – September 30, 2024	348,281	$ 4.59	7.19	$ 592

As of September 30, 2024, there was $15 thousand in unrecognized share-based compensation expense that is expected to be recognized over a weighted average period of 0.5 years.

Restricted Stock Awards

Restricted stock awards ("RSAs") have been granted to employees. The value of an RSA award is based on the Company's share price on the date of grant. The Company granted RSAs pursuant to the Incentive Plan.

The following table summarizes the Company's RSA activity for the nine months ended September 30, 2024, as described above from the Incentive Plan:

	Number of shares	Weighted average grant date fair value	Weighted average contractual term (in years)	Aggregated intrinsic value (in thousands)
Balance, December 31, 2023	941,496	$ 8.23	1.80	$ 7,852
Granted	600,527	8.09		
Forfeited	(23,850)	7.70		
Vested	(115,304)	7.50		
Outstanding – September 30, 2024	1,402,869	$ 8.16	1.34	$ 8,824
Expected to vest – September 30, 2024	1,402,869	$ 8.16	1.34	$ 8,824

There were 60,000,000 shares of common stock authorized as of September 30, 2024. As of September 30, 2024, and December 31, 2023, 18,985,324 and 17,418,886 shares were issued and outstanding, respectively, which includes 1,402,869 and 941,496 of unvested RSAs as of September 30, 2024, and December 31, 2023, respectively.

As of September 30, 2024, there was $3.8 million of total unrecognized compensation cost related to RSAs expected to be recognized over a weighted average period of 1.32 years.

On January 4, 2024, the Company issued 130,000 RSAs to each of Dr. Enrique Poradosu and Mr. Shay Shemesh. These RSAs vest over three years with one-third vesting on each anniversary of the date of the grant.

On January 12, 2023, the Company issued 210,000 RSAs to Mr. Ron Bentsur and 115,000 RSAs to each of Dr. Enrique Poradosu and Mr. Shay Shemesh (the "January 2023 Grants"). These RSAs vest over three years with one-

third vesting on each anniversary of the date of the grant. On January 4, 2024, the vesting of the first one-third of the January 2023 Grants were extended to July 15, 2024. On July 12, 2024, the vesting of the first one-third of the January 2023 Grants were extended to January 3, 2025.

On April 1, 2022, the Company issued 120,000 RSAs to Mr. Bentsur and 60,000 RSAs to each of Dr. Poradosu and Mr. Shemesh (the "April 2022 Grants"). These RSAs vest over three years with one-third vesting on each anniversary of the date of the grant. On January 4, 2024, the vesting of the first two-thirds of the April 2022 Grants were extended to July 15, 2024. On July 12, 2024, the vesting of the first two-thirds of the April 2022 Grants were extended to January 3, 2025.

On July 27, 2021, Mr. Bentsur, Dr. Poradosu, and Mr. Shemesh were granted 96,759 RSAs, 48,399 RSAs, and 48,399 RSAs, respectively, which were not part of the Incentive Plan and excluded from the table above. On January 4, 2024, the vestings of the July 2021 grants to Mr. Bentsur, Dr. Poradosu and Mr. Shemesh were extended to July 15, 2024. On July 12, 2024, the vestings of the July 2021 grants to Mr. Bentsur, Dr. Poradosu and Mr. Shemesh were extended to January 3, 2025.

Share Compensation Expense

For the three months ended September 30, 2024, the Company recognized expenses of $0.4 million as part of general and administrative expenses and $0.7 million as part of research and development expenses. For the three months ended September 30, 2023, the Company recognized expenses of $0.5 million as part of general and administrative expenses and $0.6 million as part of research and development expenses.

For the nine months ended September 30, 2024, the Company recognized expenses of $1.4 million as part of general and administrative expenses and $2.3 million as part of research and development expenses. For the nine months ended September 30, 2023, the Company recognized expenses of $1.6 million as part of general and administrative expenses and $1.9 million as part of research and development expenses.

NOTE 6 – NET LOSS PER SHARE:

a. Basic

Basic net loss per share is calculated by dividing the net loss attributable to the Company's stockholders by the weighted average number of common share outstanding.

	For the three months ended September 30, 2024	For the three months ended September 30, 2023	For the nine months ended September 30, 2024	For the nine months ended September 30, 2023
	in thousand U.S. dollars except per share and share amounts			
Loss attributable to common stockholders	$ (4,153)	$ (5,881)	$ (12,752)	$ (15,638)
Basic and diluted net loss per common share	(0.24)	(0.37)	(0.75)	(1.02)
Weighted average of common shares outstanding	17,230,559	16,104,446	16,898,040	15,341,685

NUVECTIS PHARMA, INC.

Notes to the Unaudited Condensed Financial Statements (continued)

Basic loss per share is calculated by dividing the result attributable to equity holders of the Company by the weighted average number of shares of common stock in issue during the period.

	For the three months ended September 30, 2024	For the nine months ended September 30, 2024
Weighted average of common shares	18,882,015	18,303,912
Weighted unvested RSAs	(1,651,456)	(1,405,872)
Weighted average of common shares outstanding	17,230,559	16,898,040

b. Diluted

The following potentially dilutive securities were excluded from the calculation of diluted net loss per common share because their effect would have been anti-dilutive for the periods presented:

	September 30,	
	2024	2023
Common shares issuable in relation to:		
Warrants	159,870	159,870
Options	348,281	348,281
Unvested RSAs *	1,596,426	1,145,726

* Includes 193,557 of RSAs granted outside of the Incentive Plan see explanation in Note 5.

NOTE 7 – RELATED PARTY TRANSACTIONS:

No related party transactions except for in the normal course of business.

NOTE 8 – SUBSEQUENT EVENTS:

a. See Note 5 regarding the extension of the vesting periods for Mr. Bentsur, Dr. Poradosu, and Mr. Shemesh.

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

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and related notes appearing elsewhere in this report. The following discussion and analysis contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 (the "Exchange Act"), including, without limitation, statements regarding our expectations, beliefs, intentions or future strategies that are signified by the words "expect," "anticipate," "intend," "believe," "may," "plan," "seek" or similar language. All forward-looking statements included in this document are based on information available to us on the date hereof and we assume no obligation to update any such forward-looking statements. For such forward-looking statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995. Our business and financial performance are subject to substantial risks and uncertainties. Actual results could differ materially from those projected in the forward-looking statements. In evaluating our business, you should carefully consider the information set forth under the heading "Risk Factors" herein and in our Annual Report on Form 10-K for the year ended December 31, 2023. As used below, the words "we," "us" and "our" may refer to Nuvectis Pharma, Inc.

Overview

We are a biopharmaceutical company focused on the development of innovative precision medicines for the treatment of serious conditions of unmet medical need in oncology.

NXP800 (GCN2 Kinase Activator)

We have licensed exclusive world-wide development and commercial rights to NXP800, an oral, small molecule discovered at the Institute of Cancer Research ("ICR") in London, England.

In preclinical studies, treatment with NXP800 inhibited tumor growth in xenograft models of human ovarian, endometrial and gastric cancers, in which, a genetic mutation in the AT-rich interactive domain-containing protein 1A ("ARID1a") gene was present, potentially rendering ARID1a as a biomarker for treatment sensitivity, thereby offering a potential strategy for patient enrichment. Based on this work, we have begun to clinically investigate NXP800 in platinum-resistant ARID1a-mutated ovarian carcinoma, a type of cancer which is primarily comprised of two histologies, ovarian clear cell carcinoma ("OCCC") and ovarian endometrioid carcinoma ("OEC"). We are investigating the utility of ARID1a deficiency as a patient selection marker in additional tumor types. The genetic screening for the mutations in ARID1a can be detected using a commercially available next generation sequencing-based in vitro diagnostic tests, which are routinely utilized in the clinic for cancer patients.

In December 2021, the Phase 1 study was initiated in the United Kingdom and is comprised of two parts: dose-escalation (Phase 1a), followed by an expansion phase (Phase 1b). In the Phase 1a, the safety, tolerability and pharmacokinetic properties of NXP800 were evaluated in patients with advanced solid tumors to identify a dose and dosing schedule for Phase 1b. The Phase 1b portion of the study, which was initiated in the second quarter of 2023, is evaluating the safety and preliminary anti-tumor activity of NXP800 in patients with platinum-resistant, ARID1a-mutated ovarian carcinoma.

In June 2022, the Investigational New Drug ("IND") application for NXP800 was cleared by the U.S. Food and Drug Administration ("FDA"), including the Phase 1 clinical trial protocol. In December 2022, we announced that the FDA granted Fast Track Designation status to the development program of NXP800 for the treatment of platinum-resistant, ARID1a-mutated ovarian carcinoma.

In August 2023, we announced that the FDA granted Orphan Drug Designation to NXP800 for the treatment of patients with cholangiocarcinoma.

In December 2023, we announced a collaboration with Mayo Clinic to conduct an investigator-sponsored clinical trial in patients with cholangiocarcinoma.

In August 2024, we announced that the FDA granted Orphan Drug Designation to NXP800 for the treatment of patients with ARID1a-deficient ovarian, fallopian tube, and primary peritoneal cancers.

NXP900 (SRC/YES1 Kinase Inhibitor)

We have licensed exclusive world-wide development and commercial rights to NXP900, a SRC Family Kinase ("SFK") inhibitor that potently inhibits the c-Src ("SRC") and YES1 kinases. NXP900 was discovered at the University of Edinburgh, Scotland.

SRC is aberrantly activated in many cancer types, including solid tumors such as breast, colon, prostate, pancreatic and ovarian, while remaining predominantly inactive in non-cancerous cells. Increased SRC activity is generally associated with late-stage cancers, metastatic potential and resistance to therapy, and correlates with poor clinical prognosis. YES1 gene amplification has been reported to be implicated in several tumors including lung, head and neck, bladder and esophageal cancers. In addition, YES1 directly phosphorylates and activates the Yes-associated protein ("YAP1"), the main effector of the Hippo pathway, which has been identified as a promoter of drug resistance, cancer progression, and metastasis in several cancer types, including squamous cell, mesothelioma and papillary kidney cancers.

In vivo, treatment with NXP900 inhibited primary and metastatic tumor growth in xenograft models of breast, cervical, esophageal, head and neck and medulloblastoma cancers, and demonstrated on-target pharmacodynamic effects. Furthermore, it has been found that YES1 gene amplification is a key mechanism of resistance to Epidermal Growth Factor Receptor ("EGFR"), Human Epidermal Growth Factor Receptor 2 ("HER2") and Anaplastic Lymphoma Kinase ("ALK"). A peer reviewed study published in Nature Communications (not sponsored by the Company) in April 2022 demonstrated that NXP900 was able to re-sensitize resistant non-small cell lung cancer ("NSCLC") cells to osimertinib (the active ingredient in Tagrisso®), the leading EGFR inhibitor used for the treatment of EGFR mutation-positive NSCLC, when used in combination with osimertinib. These findings were reproduced and expanded by us in cell line models, demonstrating statistically significant synergies in combination with osimertinib and, separately, with the ALK inhibitor alectinib, (the active ingredient in Alecensa®).

In May 2023, the FDA cleared our IND for NXP900, which includes the Phase 1 clinical trial protocol.

The Phase 1 study was initiated in September 2023 and is comprised of two parts: dose-escalation (Phase 1a), to be followed by an expansion phase (Phase 1b). In the ongoing Phase 1a, the safety, tolerability and pharmacokinetic properties of NXP900 in patients with advanced solid tumors are being assessed to identify a dose and dosing schedule for Phase 1b.

Results of Operations

From our inception on July 27, 2020, through September 30, 2024, we did not generate any revenue. *Since o*ur *inception through* September 30, 2024, our main activities have been development activities for our two drug candidates, NXP800 and NXP900, including completion of the in-license agreements, IND-enabling studies and the conduct of the ongoing Phase 1 clinical trials for each drug candidate and other organizational activities including capital raising. For NXP800, we conducted IND-enabling studies, which were followed by our Clinical Trial Application and acceptance by the Medicines and Healthcare Regulatory Agency in the UK, IND application and acceptance by the FDA, and Clinical Trial Application and acceptance by the Spanish Agency of Medicines and Medical Devices in Spain. The Phase 1a and Phase 1b clinical trials for NXP800 commenced in December 2021 and April 2023, respectively. For NXP900, we conducted IND-enabling studies, which were followed by our IND application and acceptance by the FDA, as well as preparations for the Phase 1a clinical trial, which commenced in September 2023.

Research and Development Expenses

Research and development expenses include costs directly attributable to the conduct of research and development programs, including licensing fees, cost of salaries, share-based compensation expenses, payroll taxes, and other employee benefits, subcontractors, and materials and services used for research and development activities, including clinical trials, manufacturing costs, and professional services. All costs associated with research and development are expensed as incurred.

Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect that our research and development expenses will increase substantially in connection with our ongoing and planned preclinical and clinical development activities in the near term and in the future. The successful development of our product candidates is highly uncertain. At this time, we cannot accurately

estimate or know the nature, timing and costs of the efforts that will be necessary to complete the preclinical and clinical development of any of our product candidates and we may never succeed in obtaining regulatory approval for any of our product candidates.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and personnel-related costs, including stock-based compensation, for our personnel in executive, finance and accounting, and other administrative functions. General and administrative expenses also include legal fees relating to patent and corporate matters; professional fees paid for accounting, auditing, consulting, and tax services; insurance costs; investor relations activities; travel expenses; and facility costs not otherwise included in research and development expenses.

We anticipate that our general and administrative expenses will increase in the future as we increase our headcount to support our continued research and development activities.

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

	Three Months Ended September 30, 2024	2023	Change
OPERATING EXPENSES:			
Research and development	$ 2,819	$ 4,486	$ (1,667)
General and administrative	1,540	1,672	(132)
OPERATING LOSS	(4,359)	(6,158)	1,799
Finance income	206	277	(71)
NET LOSS	$ (4,153)	$ (5,881)	$ 1,728

Research and Development Expenses

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

	For the three months ended September 30, 2024	2023	Increase/ (Decrease)
Clinical expenses	$ 1,058	$ 1,209	$ (151)
Employee compensation and benefits	1,414	1,219	195
Manufacturing	333	1,494	(1,161)
License fee	—	500	(500)
Professional services and other	14	65	(51)
Total research and development expenses	$ 2,819	$ 4,486	$ (1,667)

Research and development expenses decreased by $1.7 million, or 37% during the three months ended September 30, 2024, compared to the same period in 2023. The decrease in research and development expense during the three months ended September 30, 2024, was primarily driven by a $1.2 million decrease in manufacturing related costs due to a decrease in manufacturing campaigns, $0.5 million decrease in one-time licensing fees for NXP900, and $0.2 million decrease in clinical trial expenses due clinical trial start-up expenses in 2023, partially offset by a $0.2 million increase in employee compensation including $0.1 million increase related to employee stock compensation.

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

	For the three months ended September 30, 2024	2023	Increase/ (Decrease)
Professional and consulting services	$ 764	$ 831	$ (67)
Employee compensation and benefits	391	410	(19)

Insurance and other	385	431	(46)
Total general and administrative expenses	$ 1,540	$ 1,672	$ (132)

General and administrative expenses decrease by $0.1 million, or 8%, during the three months ended September 30, 2024, compared to the same period in 2023. The decrease in general and administrative expenses during the three months ended September 30, 2024, was primarily driven by the $0.1 million decrease in professional and consulting services related to public company related expenses.

As a result of the foregoing, our loss from operations for the three months ended September 30, 2024, decreased $1.7 million or 29%, compared to the same period in 2023 including a $0.2 million increase in finance income due to an increase in interest rates.

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

	Nine Months Ended September 30, 2024	2023	Change
OPERATING EXPENSES:			
Research and development	$ 8,422	$ 11,115	$ (2,693)
General and administrative	4,976	4,916	60
OPERATING LOSS	(13,398)	(16,031)	2,633
Finance income	646	393	253
NET LOSS	$ (12,752)	$ (15,638)	$ 2,886

Research and Development Expenses

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

	For the nine months ended September 30, 2024	2023	Increase/ (Decrease)
Employee compensation and benefits	$ 4,358	$ 3,805	$ 553
Clinical expenses	2,651	3,085	(434)
Manufacturing	1,382	3,094	(1,712)
License fee	—	1,001	(1,001)
Professional services and other	31	131	(100)
Total research and development expenses	$ 8,422	$ 11,115	$ (2,693)

Research and development expenses decreased by $2.7 million during the nine months ended September 30, 2024 compared to the same period in 2023. The decrease in research and development expenses during the nine months ended September 30, 2024 was primarily driven by a $1.7 million decrease in manufacturing related costs, $1.0 million decrease in one-time licensing fees for NXP900, and $0.4 million decrease in clinical trial expenses, partially offset by a $0.5 million increase in employee compensation including $0.4 million increase related to employee stock compensation.

General and Administrative Expenses

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

	For the nine months ended September 30, 2024	2023	Increase/ (Decrease)
Professional and consulting services	$ 2,609	$ 2,272	$ 337
Employee compensation and benefits	1,277	1,405	(128)
Insurance and other	1,090	1,239	(149)

Total general and administrative expenses	$ 4,976	$ 4,916	$ 60

General and administrative expenses increased $0.1 million during the nine months ended September 30, 2024 compared to the same period in 2023. The increase in general and administrative expenses during the nine months ended September 30, 2024, was primarily driven by the $0.3 million increase in professional and consulting services related to public company related expenses, partially offset by a $0.1 million decrease related to employee compensation and benefits along with a $0.1 million decrease in other expenses.

As a result of the foregoing, our loss from operations for the nine months ended September 30, 2024, decreased $2.9 million, compared to the same period in 2023, which was primarily driven by employee compensation and benefits, clinical trial expenses, manufacturing expenses, and an increase in finance income of $0.3 million.

Liquidity and Capital Resources

As of September 30, 2024, we had $17.2 million of cash and cash equivalents. For the three months ended September 30, 2024 and 2023, we reported net losses of $4.2 million and $5.9 million, respectively. For the nine months ended September 30, 2024 and 2023, our net losses were $12.8 million and $15.6 million, respectively.

On February 4, 2022, we announced the pricing of our initial public offering of common stock (the "IPO") of 3,200,000 shares of common stock for a price of $5.00 per share, less certain underwriting discounts and commissions. Under the UoE license agreement, we are required to pay UoE 2.5% of the gross amount of each of our future fund raisings up to a cumulative total of $3.0 million. Pursuant to the IPO, we paid UoE $0.4 million associated with this fundraising.

The IPO closed on February 8, 2022, with gross proceeds of $16.0 million, before deducting underwriting discounts and expenses (for net proceeds of $12.6 million).

In addition, on July 29, 2022, we completed the July 2022 Private Placement in which we received gross proceeds of $15.9 million before deducting fees and expenses (for net proceeds of $14.2 million) excluding payments required by our license agreements. As part of this transaction, we issued Preferred Investment Options which became exercisable on January 23, 2023, and are exercisable through January 29, 2026, at an exercise price of $9.65 per share, subject to certain adjustments as defined in the securities purchase agreement. As of December 31, 2023, 1,001,091 Preferred Investment Options were exercised for $8.9 million, net of fees. For the three and nine months ended September 30, 2024, zero Preferred Investment Options were exercised, and $0.0 million, net of fees, was received. In addition, as part of the July 2022 Private Placement, we issued warrants to the placement agent to purchase up to 115,481 shares of common stock. The placement agent warrants are in substantially the same form as the Preferred Investment Options, except that the exercise price is $10.31. As of September 30, 2024, 79,104 placement agent warrants were exercised, and $0.8 million, net of fees, was received.

On March 17, 2023, we filed a shelf registration statement on Form S-3 (the "Registration Statement"). Pursuant to the Registration Statement, we may offer and sell securities having an aggregate public offering price of up to $150.0 million. In connection with the filing of the Registration Statement, we also entered into a sales agreement with H. C. Wainwright & Co. (the "Sales Agent"), pursuant to which we may issue and sell shares of our common stock for an aggregate offering price of up to $40.0 million under an at-the-market offering program (the "ATM"), which is included in the $150.0 million of securities that may be offered pursuant to the Registration Statement. Pursuant to the ATM, we will pay the Sales Agent a commission rate of up to 3.0% of the gross proceeds from the sale of any shares of our common stock. We are not obligated to make any sales of shares under the ATM. As of September 30, 2024, we have sold 1,337,654 shares of our common stock and received $12.9 million in net proceeds under the ATM.

We believe that the proceeds from our IPO, private placement and ATM will enable us to fund our operating expenses and capital expenditures through at least the next 12 months from the issuance of our financial statements. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. Our future viability in the long term is dependent on our ability to raise additional capital to finance our operations.

We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we advance the clinical trials of our current or future product candidates, including payments of milestones and sponsored research commitments associated with our license agreements for NXP800 and NXP900. In addition, we expect to incur increasing costs associated with operating as a public

company as we continue to grow, including increased legal, accounting, investor relations, and other expenses. The timing and amount of our operating expenditures will depend largely on our ability to:

- advance development of our clinical and preclinical programs;
- manufacture, or procure the manufacturing of, our preclinical and clinical drug material and develop processes for late stage and commercial manufacturing;
- seek regulatory approvals for any current or future product candidates that successfully complete clinical trials;
- achieve milestones in accordance with our license agreements;
- establish a sales, marketing, medical affairs and distribution infrastructure to commercialize any current or future product candidates for which we may obtain marketing approval;
- hire additional clinical, quality control and scientific personnel;
- expand our operational, financial and management systems and increase personnel, including personnel to support our clinical development, manufacturing and commercialization efforts and our operations as a public company;
- obtain, maintain, expand and protect our intellectual property portfolio; and
- acquire additional product candidates.

We anticipate that we will require additional capital as we seek regulatory approval of our product candidates and if we choose to pursue in-licenses or acquisitions of other product candidates. If we receive regulatory approval for our current or future product candidates, we expect to incur significant commercialization expenses related to product manufacturing, sales, marketing and distribution, depending on where we choose to commercialize.

Because of the numerous risks and uncertainties associated with research, development and commercialization of our product candidates, we are unable to estimate the exact amount of our working capital requirements. Our future funding requirements will depend on and could increase significantly as a result of many factors, including:

- the scope, progress and costs of researching and developing our current or future product candidates, including the timing and safety, tolerability and efficacy results from our preclinical and clinical trials;
- the costs, timing and outcome of regulatory review of our current or future product candidates;
- the costs, timing and ability to manufacture our current or future product candidates to supply our preclinical development efforts and our clinical trials;
- the costs of future activities, including product sales, medical affairs, marketing, manufacturing and distribution, for any of our current or future product candidates for which we receive marketing approval;
- the costs of manufacturing commercial-grade products and necessary inventory to support commercial launch;
- the ability to receive additional non-dilutive funding, including grants from organizations and foundations;
- the revenue, if any, received from commercial sale of our products, should any of our current or future product candidates receive marketing approval;

- the costs of preparing, filing and prosecuting patent applications, obtaining, maintaining, expanding and enforcing our intellectual property rights and defending intellectual property-related claims;
- our ability to establish and maintain collaborations on favorable terms, if at all; and
- the extent to which we acquire or in-license other product candidates and technologies.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our operations through a combination of public or private equity offerings, debt financings, governmental funding, collaborations, strategic partnerships and alliances or marketing, distribution or licensing arrangements with third parties. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest may be materially diluted, and the terms of such securities could include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include restrictive covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. In addition, debt financing would result in fixed payment obligations.

If we raise additional funds through governmental funding, collaborations, strategic partnerships and alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed, we may be required to delay, limit, reduce or terminate our research, product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Cash Flows

The following table provides information regarding our cash flows for the periods presented: (in thousands)

	For the nine months ended September 30,	
	2024	2023
Net cash used in operating activities	$ (9,782)	$ (12,104)
Net cash used in investing activities	—	—
Net cash provided by financing activities	$ 7,825	$ 14,170

Operating Activities

During the nine months ended September 30, 2024, $9.8 million of cash was used in operating activities. This was primarily attributable to our net loss of $12.8 million, partially offset by non-cash charges of $3.7 million. The change in our operating assets and liabilities was primarily due to $0.6 million payments to vendors, and $0.1 million payment for our director and officer insurance.

During the nine months ended September 30, 2023, $12.1 million of cash was used in operating activities. This was primarily attributable to our net loss of $15.6 million, partially offset by non-cash charges of $3.5 million. The change in our operating assets and liabilities was primarily due to $0.5 million of payments for employee compensation and benefits.

Financing activities

During the nine months ended September 30, 2024, net cash provided by financing activities was $7.8 million, consisting primarily of net proceeds from the sale of common stock through the ATM.

During the nine months ended September 30, 2023, net cash provided by financing activities was $14.2 million, consisting primarily of $10.3 million in net proceeds from the exercise of warrants associated with our private placement along with $4.2 million of net proceeds from the sale of common stock through the ATM, offset by $0.4 million of deferred offering costs paid.

Contractual Obligations and Other Commitments

We enter into contracts in the normal course of business with clinical research organizations, contract manufacturing organizations, and other third parties for clinical trials, preclinical research studies, and testing and manufacturing services. These contracts are cancelable by us upon prior written notice. Payments due upon cancellation consist only of payments for services provided or expenses incurred, including noncancelable obligations of our service providers, up to the date of cancellation. The amount and timing of such payments are not known.

We have also entered into license and collaboration agreements with third parties, which are in the normal course of business. We have not included future payments under these agreements since obligations under these agreements are contingent upon future events such as our achievement of specified development, regulatory, and commercial milestones, or royalties on net product sales.

Pursuant to the NXP800 License Agreement, we are required to make payments to the ICR for certain development and regulatory milestones, including up to $22.0 million related to pre-approval milestones, up to $178 million (in addition to the $22.0 million) in regulatory and commercial sales milestones, and mid-single digit to 10% royalties on a tiered basis on net sales, unless development ceases. Additionally, we originally agreed to provide the ICR with up to an additional $0.5 million in research and development. On March 31, 2022, we agreed to provide the ICR with $0.4 million of additional research and development support ($0.9 million total).

Pursuant to the NXP900 License Agreement, we are required to make payments to the UoE for certain development and regulatory milestones, including up to $45.0 million related to pre-approval milestones, up to $279.6 million (in addition to the $45.0 million) in regulatory and commercial sales milestones, mid-single digit to 8% royalties on a tiered basis on net sales and 2.5% of the gross amount of each of our future fund raising up to a cumulative total of $3.0 million, unless development ceases. Additionally, we will provide UoE with up to an additional $754,000 in research and development support.

We do not currently have any long-term leases. We rent our office space in Fort Lee, New Jersey, based on a one-year agreement signed on May 1, 2024.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

Critical Accounting Policies and Significant Judgments and Estimates

Our condensed financial statements and the related notes thereto included elsewhere in this Quarterly Report on Form 10-Q are prepared in accordance with U.S. generally accepted accounting principles. The preparation of condensed financial statements also requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, costs, expenses, and related disclosures. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. Actual results could differ significantly from the estimates made by management. To the extent that there are differences between our estimates and actual results, our future financial statement presentation, financial condition, results of operations, and cash flows will be affected.

There have been no significant changes to our critical accounting policies and estimates as compared to those described in “Note 2 – Summary of Significant Accounting Policies” to our audited financial statements set forth in our Annual Report on Form 10-K filed with the SEC on March 5, 2024.

Recently Issued Accounting Pronouncements

See Note 2 to our condensed financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q for a discussion of recent accounting pronouncements.

Emerging Growth Company and Smaller Reporting Company Status

The Jumpstart Our Business Startups Act of 2012 permits an "emerging growth company" such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. We have elected to not "opt out" of this provision and, as a result, we will adopt new or revised accounting standards at the time private companies adopt the new or revised accounting standard and will do so until such time that we either (i) irrevocably elect to "opt out" of such extended transition period or (ii) no longer qualify as an emerging growth company.

We are also a "smaller reporting company" meaning that the market value of our stock held by non-affiliates plus the proposed aggregate amount of gross proceeds to us as a result of our initial public offering is less than $700 million and our annual revenue was less than $100 million during the most recently completed fiscal year. We will continue to be a smaller reporting company for as long as either (i) the market value of our stock held by non-affiliates is less than $250 million 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. 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.

Item 3. Quantitative and Qualitative Disclosures About Market Risks

Under SEC rules and regulations, because we are considered to be a "smaller reporting company," we are not required to provide the information required by this item in this report.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We maintain "disclosure controls and procedures," as defined in Rule 13a-15(e) and Rule 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, 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 our management, including our principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure.

As of September 30, 2024, management carried out, under the supervision and with the participation of our principal executive officer and principal financial officer, an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). Our disclosure controls and procedures are designed to provide reasonable assurance that information we are required to disclose in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in applicable rules and forms. Based upon that evaluation, our principal executive officer and principal financial officer concluded that, as of September 30, 2024, our disclosure controls and procedures were effective.

Changes in and Management's Report on Internal Control over Financial Reporting

There were no changes in our internal controls over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the nine months ended September 30, 2024, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls and Procedures

Our management, including our Chief Executive Officer and Vice President of Finance, believes that our disclosure controls and procedures and internal control over financial reporting are designed to provide reasonable assurance of achieving their objectives and are effective at the reasonable assurance level. However, management does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent or detect all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the company have been detected. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

PART II – OTHER INFORMATION

Item 1. Legal Proceedings.

From time to time, we may become involved in legal proceedings arising in the ordinary course of our business, the resolution of which we do not anticipate would have a material adverse impact on our financial position, results of operations or cash flows. However, there is no certainty that any such future litigation that may arise would not have a material financial impact on our business. As of the date of this report, we were not a party to any material legal matters or claims.

Item 1A. Risk Factors.

The following information sets forth risk factors that could cause our actual results to differ materially from those contained in forward-looking statements we have made in this report and those we may make from time to time. You should carefully consider the risks described below, in addition to the other information contained in this report and our other public filings, before making an investment decision. Our business, financial condition or results of operations could be harmed by any of these risks. The risks and uncertainties described below are not the only ones we face. Additional risks not presently known to us or other factors not perceived by us to present significant risks to our business at this time also may impair our business operations.

Risks Related to Our Finances and Capital Requirements

Our limited operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

We are a clinical stage biopharmaceutical company with a limited operating history. We were incorporated in Delaware in July 2020, and our operations to date have been limited to organizing and staffing our company, business planning, raising capital, identifying, investigating, licensing and evaluating potential product candidates, and establishing arrangements with third parties for the manufacture of initial quantities of our lead product candidate and component materials. Both of our product candidates are in early clinical development. We have not yet demonstrated our ability to successfully conduct or complete any clinical development program for our drug candidates, obtain marketing approvals, manufacture a commercial-scale product or arrange for a third party to do so on our behalf, or conduct sales, marketing and distribution activities necessary for successful product commercialization. Consequently, any predictions about our future success or viability may not be as accurate.

We may need to transition at some point from a company with a research and development focus to a company capable of supporting commercial activities related to the full product life cycle. We may not be successful in such a transition.

We have incurred losses since inception and anticipate that we will continue to incur losses for the foreseeable future. We may never achieve or maintain profitability.

Investment in biopharmaceutical product development is a highly speculative undertaking and entails substantial upfront capital expenditures and significant risk that our current or potential future product candidates will fail to demonstrate adequate efficacy or an

acceptable safety profile, gain regulatory approval and become commercially viable. We are still in the early stages of development of our product candidates and initiated our first clinical trial in December 2021. We have no products approved for commercial sale and have not generated any revenue from product sales to date. We continue to incur significant research and development and other expenses related to our ongoing operations. In addition, as a business with a limited operating history, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors, such as the COVID-19 pandemic.

We have incurred losses in each period since we commenced operations. Since inception through the end of September 30, 2024, we had an accumulated deficit of $67.0 million. We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase substantially if and as we continue our research and development efforts for our lead product candidate; conduct preclinical studies and clinical trials for our current and future product candidates; seek marketing approvals for any current or future product candidate that successfully completes clinical trials; experience any delays or encounter any issues with any of the above; establish a sales, marketing and distribution infrastructure and scale-up manufacturing capabilities to commercialize any current or future product candidates for which we may obtain regulatory approval; obtain, expand, maintain, enforce and protect our intellectual property portfolio; hire additional clinical, regulatory and scientific personnel; and operate as a public company.

Our pipeline product candidates, NXP800 and NXP900, are both in clinical development. Both product candidates will require additional preclinical and clinical studies, regulatory review and approval, substantial investment, access to sufficient clinical and commercial manufacturing capacity and significant marketing efforts before we can potentially generate any revenue from product sales. The Phase 1 study for NXP800 started in December 2021 and NXP900 started in September 2023. To date, we have not generated any revenue from our product candidates. Our ability to generate revenue will depend on a number of factors, including, but not limited to:

- Our ability to timely and successfully complete of our preclinical studies and clinical trials, which may be significantly slower or more costly than anticipated and will depend upon several factors including the performance of third-party contractors, our ability to enroll patients into the clinical trials and the safety, tolerability and efficacy results generated in clinical trials;
- successful submissions of IND applications to the FDA and any additional comparable applications;
- completion of nonclinical studies necessary for the IND or comparable submission, as appropriate;
- whether we are required by the FDA or similar foreign regulatory authorities to conduct additional clinical trials or other studies to support the approval and commercialization of our current or future product candidates;
- the FDA's and similar foreign regulatory authorities' acceptance of the safety, potency, purity, efficacy and risk to benefit profile of our current or future product candidates;
- the prevalence, duration and severity of side effects or other safety issues experienced with our current or future product candidates, if any;
- the timely receipt of necessary marketing approvals from the FDA and similar foreign regulatory authorities;
- the actual and perceived availability, cost, risk profile and safety and efficacy of our current or future product candidates, if approved, relative to existing and future alternative cancer therapies and competitive product candidates and technologies;
- our ability and the ability of third parties with whom we contract to manufacture adequate clinical and commercial supplies of our current or future product candidates, to remain in good standing with regulatory authorities and to develop, validate and maintain commercially viable manufacturing processes that are compliant with cGMP;
- our ability to successfully develop a commercial strategy and to commercialize any current or future product candidate in the United States and internationally, if approved for marketing, reimbursement, sale and distribution in such countries and territories, whether alone or in collaboration with others;

- patient demand for our current or future product candidates, if approved; and
- our ability to establish and enforce intellectual property rights in and to our current or future product candidates.

Many of the factors listed above are beyond our control and could cause us to experience significant delays or prevent us from obtaining regulatory approvals or commercializing our current and future product candidates. Even if we can commercialize any current or future product candidates, we may not achieve profitability soon after generating product sales, if ever.

We will require substantial additional funding. Raising additional capital may cause dilution to our existing stockholders, or require us to relinquish proprietary rights. If we are unable to raise capital as needed, we may be compelled to delay, reduce or eliminate our product development programs or commercialization efforts.

We expect our expenses to increase in parallel with our ongoing activities, particularly as we continue our activities to identify new product candidates and initiate clinical trials of, and seek marketing approval for, any of our current or future product candidates. In addition, if we obtain marketing approval for any of our current or future product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing, and distribution. Furthermore, we expect to incur significant additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. We cannot be certain that additional funding will be available on acceptable terms, or at all. Until such time, if ever, as we can generate substantial product revenue, we expect to finance our operations through a combination of public or private equity offerings, ATM facility, debt financings, governmental funding, collaborations, strategic partnerships and alliances or marketing, distribution or licensing arrangements with third parties. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a stockholder. Debt financing and preferred 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.

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

If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our discovery and preclinical development programs or any future commercialization efforts.

Major public health issues, and specifically the policies and procedures implemented during the COVID-19 pandemic which are still in place, could have an adverse effect on our clinical trials, financial condition, results of operations, and other aspects of our business.

The COVID-19 pandemic had, and continues to have, widespread, rapidly evolving, and unpredictable impacts on global society, economies, financial markets, and business practices. During 2020 and 2021, there were policies and procedures implemented, which remain in place today, including =a wide distribution of several vaccinations and medicines to overcome the pandemic. We have shifted our operations to co-exist along with the pandemic.

The uncertainty to which the COVID-19 pandemic impacts the Company's business in the future, affects management's judgment and assumptions relating to accounting estimates in a variety of areas that depend on these estimates and assumptions. COVID-19 did not have a material influence on these estimates and judgements since the Company began operations in 2021.

The Company continues to face relative uncertainty as to the policies and procedures remaining in place, intensity and duration of, and the nature and timeline for, recovery from the COVID-19 pandemic going forward, and how all of that impacts the Company, including the extent to which potentially permanent changes clinical trial operations have been caused by the pandemic. The Company has taken the approach of managing this uncertainty (to the extent that it continues to remain a significant factor) via strengthening its balance sheet and cash assets and avoiding debt while focusing on cost controls. Some factors from the COVID-19 outbreak or any outbreak

caused by any variant of COVID-19 that may delay or otherwise adversely affect our clinical trial programs, as well as adversely impact our business generally, include:

- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical sites, and delays enrolling patients in our clinical trials or increased rates of patients withdrawing from our clinical trials following enrollment as a result of contracting COVID-19 or any variant, being forced to quarantine, or not otherwise being able to complete study assessments, particularly for older patients or others with a higher risk of contracting COVID-19 or any variant;
- diversion of healthcare resources, including clinical trial investigators and staff, away from the conduct of clinical trials to focus on pandemic concerns which could result in delays to our partner companies' clinical trials;
- limitations on travel, including limitations on domestic and international travel, and government-imposed quarantines or restrictions imposed by key third parties that could interrupt key trial activities, such as clinical trial site initiations and monitoring;
- interruption of, or delays in receiving, supplies of our product candidates from our contract manufacturing organizations due to staffing shortages, or production slowdowns or stoppages;
- disruptions and delays caused by potential workplace, laboratory and office closures and an increased reliance on employees working from home across the healthcare system; and
- disruptions in or delays to regulatory approvals, inspections, reviews or other regulatory activities as a result of the spread of COVID-19 or any variant, affecting the operations of the FDA or other regulatory authorities.

We currently rely on third parties for certain functions or services in support of our clinical trials and key areas of our operations. If these third parties themselves are adversely impacted by restrictions resulting from the COVID-19 outbreak, we will likely experience delays and/or realize additional costs. As a result, our ability to commence and complete clinical trials in a timely fashion, obtain regulatory approvals for, and to commercialize, our current and future product candidates may be delayed or disrupted.

Risks Related to the Development of our Product Candidates

Our development approach may never lead to marketable products.

The patient populations for our product candidates and potential future product candidates may be limited to those with specific target mutations and may not be completely defined but are substantially smaller than the general treated cancer population and we will need to actively screen and identify these patients. Successful identification of patients is dependent on several factors, including achieving certainty as to how diseases with specific genetic alterations respond to our current product candidates or any future product candidates and, if necessary, developing companion diagnostics to identify such genetic alterations. Furthermore, even if we are successful in identifying patients, we cannot be certain that the resulting patient populations for our target indications will be large enough to achieve profitability. In addition, even if our approach is successful, we may never successfully identify additional diseases in which our product candidates may be effective. We do not know if our approach of treating patients with genetically defined cancers will be successful; and if our approach is unsuccessful, our business will suffer.

We are early in our development efforts and are substantially dependent on our ability to advance NXP800, NXP900 or any of our other future product candidates through preclinical and clinical development, identify safe and effective doses and dosing schedules for our drug candidates, obtain regulatory approval and ultimately commercialize NXP800, NXP900 or any of our other future product candidates; if we experience delays in doing so, our business will be materially harmed.

Our ability to generate product revenues from NXP800, NXP900 or any of our other future product candidates depends heavily on the successful clinical development and eventual commercialization. In addition, our drug development programs may contemplate the development of companion diagnostics, which are assays or tests to identify an appropriate patient population based on genetic mutations and other alterations. Companion diagnostics are subject to regulation as medical devices and must themselves receive marketing authorization from the FDA or certain other foreign regulatory agencies before they may be marketed. If a companion diagnostic is

essential to the safe and effective use of any of our current and future product candidates, the FDA must conclude that the companion diagnostic meets the applicable standard for safety and effectiveness or for substantial equivalence for use with our product candidates before either the product candidates or companion diagnostic may be marketed in the United States.

Negative preclinical or clinical results in the development of our product candidates may prevent or delay our ability to continue or conduct clinical programs or receive regulatory approvals. For example, although we believe, based on preclinical studies of ARID1a-muted ovarian carcinoma models that demonstrated tumor growth inhibition, that this cancer type might be particularly sensitive to treatment with NXP800, this may not prove true in clinical testing, due to safety and tolerability issues and/or insufficient efficacy, and this holds true for any or all of the potential target indications. Moreover, anti-tumor activity may be different in each tumor type that we plan to evaluate in clinical trials. As a result, we may be required to discontinue development of our drug candidates or invest significant additional resources and delay our clinical trials and ultimately the approval, if any, of any of our other future product candidates.

Our current or future product candidates may not have favorable results in early clinical trials due to safety, tolerability and/or insufficient efficacy findings. In addition, positive results of early clinical trials are not necessarily predictive of future results, and any product candidate that we advance may not have favorable results in later clinical trials or receive regulatory approval. In March 2024 we announced preliminary safety and efficacy results from the ongoing Phase 1b study of NXP800 in platinum-resistant ARID1a-mutated ovarian carcinoma. Any results observed in this preliminary analysis may not be predictive of future results.

We may experience setbacks that could delay or prevent regulatory approval of, or our ability to commercialize, our current or future product candidates, including:

- negative or inconclusive efficacy results and/or adverse safety findings from our preclinical studies or clinical trials or positive results from the clinical trials of others for product candidates similar to ours leading to their approval, and evolving to a decision or requirement to conduct additional preclinical testing or clinical trials or abandon a program;
- product-related side effects experienced by patients or subjects in our clinical trials or by individuals using drugs or therapeutics that we, the FDA, other regulators or others view as relevant to the development of our current or future product candidates;
- delays in submitting IND applications or comparable foreign applications or delays or failure in obtaining the necessary approvals from regulators to commence a clinical trial, or a suspension or termination of a clinical trial once commenced;
- conditions imposed by the FDA or comparable foreign authorities regarding the scope or design of our clinical trials, including our clinical endpoints;
- delays in enrolling subjects in clinical trials, including difficulty or delays in identifying appropriate patients, or due to health-related emergencies, such as the COVID-19 pandemic, and timely completion of clinical trials, including under GCP or good laboratory practice ("GLP") requirements;
- inability to maintain compliance with regulatory requirements, including cGMPs, and complying effectively with other requirements pertaining to the quality of our current or future product candidates;
- high drop-out rates of subjects from clinical trials due to safety and tolerability issues and/or insufficient efficacy;
- inadequate supply or quality of our current or future product candidates or other materials necessary for the conduct of our clinical trials;
- greater than anticipated clinical trial costs;
- inability to compete with other therapies;

- poor efficacy of or safety and/or tolerability issues observed with our current or future product candidates or the need for different doses or dosing schedules during clinical trials;
- trial results taking longer than anticipated;
- trials being subjected to fraud or data capture failure or other technical mishaps leading to the invalidation of our trials;
- the results of our trials not supporting application for conditional approval in the European Union;
- unfavorable FDA or other regulatory agency inspection and review of a clinical trial site;
- failure of our third-party contractors or investigators to comply with regulatory requirements or otherwise meet their contractual obligations in a timely manner, or at all;
- delays related to the impact of the spread of the COVID-19 pandemic, including the impact of COVID-19 on the FDA's ability to continue its normal operations;
- delays and changes in regulatory requirements, policy and guidelines, including the imposition of additional regulatory oversight around clinical development generally or with respect to our technology in particular; or
- varying interpretations of data by the FDA and similar foreign regulatory agencies.

In addition, because we have limited financial and personnel resources and are focusing primarily on developing NXP800 and NXP900, we may forgo or delay pursuit of other future product candidates that may prove to have greater commercial potential and may fail to capitalize on viable commercial products or profitable market opportunities. If we do not accurately evaluate the commercial potential or target market for a future product candidate, we may relinquish valuable rights to those future product candidates through collaboration, licensing, or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such future product candidates.

Clinical drug development involves a lengthy and expensive process with uncertain outcomes, clinical trials are difficult to design and implement, and any of our clinical trials could produce unsuccessful results or fail at any stage in the process.

Clinical trials are conducted on humans, are expensive, and can take many years to complete, and outcomes are inherently uncertain. Failure can occur at any time during the process. Additionally, any positive results of preclinical studies and early clinical data of a drug candidate may not be predictive of the final results of the early clinical trial or of later-stage clinical trials, such that drug candidates may not reach later-stages clinical trials based on results from an early-stage clinical trial or reach later stages of clinical trials and fail to show the desired safety and efficacy traits despite having shown indications of those traits in preclinical studies and early-stage clinical trials. A number of companies in the pharmaceutical industry have suffered significant setbacks in early and advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in preclinical studies or preliminary clinical findings. Therefore, the results of any existing and future clinical trials we conduct may not be successful. Clinical trials may be delayed, suspended or prematurely terminated because costs are greater than we anticipate or for a variety of reasons, such as:

- delay or failure in reaching agreement with the FDA or a comparable foreign regulatory authority on a trial design that we are able to execute;
- delay or failure in obtaining authorization to commence a trial, including approval from the appropriate independent review board ("IRB") to conduct testing of a candidate on human subjects, or inability to comply with conditions imposed by a regulatory authority regarding the scope or design of a clinical trial;
- delay in reaching, or failure to reach, agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;

- inability, delay or failure in identifying and maintaining a sufficient number of trial sites, many of which may already be engaged in other clinical programs;
- delay or failure in recruiting and enrolling suitable volunteers or patients to participate in a trial;
- delay or failure in developing and validating companion diagnostics, if they are deemed necessary, on a timely basis;
- failure of patients to complete a trial or return for post-treatment follow-up;
- inability to monitor patients adequately during or after treatment;
- clinical sites and investigators deviating from trial protocols, failing to conduct the trial in accordance with regulatory requirements or dropping out of a trial;
- failure to initiate or delay of or inability to complete a clinical trial as a result of a clinical hold imposed by the FDA or comparable foreign regulatory authority due to observed safety findings or other reasons;
- negative or inconclusive results in our clinical trials, and our decision to our regulators' requirement that we conduct additional preclinical studies, clinical trials or that we abandon one or more of our product development programs; or
- inability to manufacture sufficient quantities of a drug candidate of acceptable quality for use in clinical trials.

We rely and plan to continue to rely on CROs, contract manufacturing organizations ("CMOs") and clinical trial sites to ensure the proper and timely conduct of our clinical trials. Although we have and expect that we will have agreements in place with CROs and CMOs governing their contracted activities and conduct, we will have limited influence over their actual performance. As a result, we ultimately do not and will not have control over a CRO's or CMO's compliance with the terms of any agreement it may have with us, its compliance with applicable regulatory requirements, or its adherence to agreed-upon time schedules and deadlines, and a future CRO's or CMO's failure to perform those obligations could subject any of our clinical trials to delays or failure.

Further, we may also encounter delays if a clinical trial is suspended, is put on clinical hold or terminated by us, by any IRB or ethics committee, by a Data Safety Monitoring Board, or by the FDA or European Medicines Agency ("EMA"), or other regulatory authority. A suspension or termination may be due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements, inspection of the clinical trial operations or trial site by the FDA, EMA or other regulatory authorities, exposing participants to health risks caused by unforeseen safety issues or adverse side effects, development of previously unseen safety issues, failure to demonstrate a benefit from using a drug candidate, or changes in governmental regulations or administrative actions. Therefore, we cannot predict with any certainty the schedule for commencement or completion of any currently ongoing, planned or future clinical trials.

Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of marketing approval for our current or future product candidates.

If we experience delays in the commencement or completion of, or suspension, hold or termination of, any clinical trial for our drug candidates, the commercial prospects of the drug candidate could be harmed, and our ability to generate product revenues from the drug candidate may be delayed or eliminated. In addition, any delays in completing our clinical trials will increase our costs, slow down our drug candidate development and approval process and jeopardize regulatory approval of our drug candidates and our ability to commence sales and generate revenues. The occurrence of any of these events could harm our business, financial condition, results of operations and prospects significantly.

Difficulty in enrolling patients could delay or prevent clinical trials of our current or future product candidates.

Identifying and qualifying patients to participate in clinical studies of our current or future product candidates is critical to our success. The timing of completion of our clinical studies depends in part on the speed at which we can recruit patients to participate in testing our current or future product candidates and we may experience delays in our clinical trials if we encounter difficulties in enrollment.

Further, because we are currently focused on patients with specific and rare diseases, our ability to enroll eligible patients may be limited and may result in slower enrollment than we anticipate. Our clinical trials will compete with other clinical trials for current or future product candidates that are in the same therapeutic areas as our current or future product candidates, which may reduce the number and types of patients available to us.

Clinical trials may be subject to delays as a result of patient enrollment taking longer than anticipated or greater than anticipated subject withdrawal. We may not be able to initiate or continue clinical trials for our current or future product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or foreign regulatory authorities. We cannot predict how successful we will be at enrolling subjects in future clinical trials. The enrollment of patients depends on many factors, including:

- patient identification and eligibility and inclusion/exclusion criteria defined in the protocol;
- the size of the patient population required for analysis of the clinical trial's primary endpoints and the process for identifying patients;
- potential disruptions caused by the COVID-19 pandemic, including difficulties in initiating clinical sites, enrolling and retaining participants, diversion of health care resources away from clinical trials, travel or quarantine policies that may be implemented, and other factors;
- the proximity of patients to clinical trial sites;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and expertise;
- clinicians' and patients' perceptions as to the potential advantages and risks of the product candidate being studied in relation to other available therapies, including any new products that may be approved for the indications we are investigating;
- the availability of competing commercially available therapies and other competing product candidates' clinical trials;
- our ability to obtain and maintain clinical trial subject informed consents; and
- the risk that subjects enrolled in clinical trials will drop out of the trials before completion.

If we are unable to locate and enroll sufficient eligible patients to participate, as required by the FDA or similar regulatory authorities, we may be unable to initiate or continue clinical trials for our current or future product candidates. If necessary, we intend to engage third parties to develop companion diagnostics for use in our clinical trials. If such third parties are unsuccessful, our difficulty in identifying patients with the targeted genetic mutations for our clinical trials would be increased. If we are unable to include patients with the targeted genetic mutations or patients with well-defined serious unmet medical needs, we may be unable to participate in the FDA's expedited review and development programs, including breakthrough therapy designation and fast track designation, or otherwise seek to accelerate clinical development and regulatory timelines.

Our studies may fail to adequately demonstrate the safety, potency, purity, efficacy or any other necessary pharmacological properties of any of our current or future product candidates, which would prevent or delay development, regulatory approval and commercialization.

Before obtaining regulatory approvals for the commercial sale of our current or future product candidates, including NXP800 and NXP900, we must demonstrate through lengthy, complex and expensive studies that our current or future product candidates are both safe and effective for use in each target indication. Preclinical and clinical testing are expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the preclinical study and clinical trial processes, and, because our current product candidates are in an early stage of development, there is a high risk of failure.

The results of preclinical studies and early clinical trials of a drug candidate may not be predictive of the final results of later-stage clinical trials. Results of our trials could reveal a high and unacceptable severity and prevalence of adverse safety issues which may result in suspension or termination, and the FDA or comparable foreign regulatory authorities could, through a clinical hold or otherwise, order us to halt or cease further development of or deny approval. Drug-related side effects could also affect patient recruitment into the study or patient willingness to remain in the study and therefore affect our ability to complete clinical trials. Drug-related side effects could also result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

Moreover, our product or product candidates may cause undesirable side effects that could delay or prevent their regulatory approval or impact their availability and commercial potential after approval.

The FDA and comparable foreign regulatory authorities may not accept data from any preclinical or clinical trials we may conduct in foreign countries.

The FDA's acceptance of data generated for patients recruited outside the United States from clinical trials conducted in whole or in part outside the United States may be subject to certain conditions, if accepted at all.

Although the FDA has the authority to accept foreign data as part or even the sole basis for marketing approval, the FDA generally does not approve an application on the basis of foreign data alone unless (i) the data is applicable to the U.S. population and U.S. medical practice, (ii) the trials were performed by clinical investigators of recognized competence and pursuant to GCP regulations, and (iii) the FDA's clinical trial requirements were met. Many foreign regulatory authorities have similar approval requirements. In addition, any clinical study conducted in whole or in part outside of the United States would be subject to the applicable local laws of the jurisdiction where the trial was conducted. We cannot guarantee that the FDA or comparable foreign regulatory authority will accept data from trials conducted in whole or in part outside of the United States, which may result in the need for additional trials.

We may not be able to submit IND applications to commence additional clinical trials on the timelines we expect, and even if we are able to, the FDA may not permit us to proceed.

Our CTAs and INDs for NXP800 and NXP900, have been approved. However, we may be unable to submit additional CTAs, IND applications or other clinical research on our expected timelines. Moreover, while we have obtained CTA and IND approvals, we cannot be sure that issues will not arise that may lead to the delay, suspension or termination of such clinical trials. Any failure to file CTAs, IND applications or other clinical research authorizations will adversely impact our expected timelines to obtain regulatory acceptance for the commencement of our trials and may prevent us from completing our clinical trials or commercializing our products on a timely basis, if at all.

We currently have no marketing and sales organization and have limited experience in marketing products. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell any approved product candidates, we may not be able to generate product revenue.

We will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and sales personnel. If we are unable or decide not to establish internal sales, marketing, and distribution capabilities, we may pursue arrangements with third-party sales, marketing, and distribution collaborators regarding the sales and marketing of our products, if approved.

There can be no assurance that we will be able to develop in-house sales and distribution capabilities or establish or maintain relationships with third-party collaborators to commercialize any product in the United States or overseas.

We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.

While we believe that our scientific knowledge, technology, and development expertise provide us with competitive advantages, we face potential competition from many different sources, including major pharmaceuticals, specialty pharmaceuticals and biotechnology companies, academic institutions and government agencies, and public and private research institutes that conduct research, development, manufacturing, and commercialization. Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, regulatory approvals, and product marketing than we do. Our

competitors may compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient recruitment for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. As a result, our competitors may discover, develop, license, or commercialize products earlier or more successfully than we do.

If our product candidates, NXP800 and NXP900, are approved, they will likely compete with competitor drugs and other drugs that are currently in development. The availability of reimbursement from government and other third-party payors will also significantly affect the pricing and competitiveness of our products. Our competitors may also obtain FDA or other regulatory approval for their products more rapidly than we do, which could result in our competitors establishing a strong market position before we are able to enter the market.

Risks Related to Government Regulation

Denial of or delay in our receipt of required regulatory approvals may prevent or delay commercialization of our current or future product candidates and our ability to generate revenue may be materially impaired.

The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of drug products are, and will remain, subject to extensive regulation by the FDA in the United States and by the respective regulatory authorities in other countries where regulations differ. We will not be permitted to market our current or future product candidates in the United States until we receive the respective approval of an NDA from the FDA, or in any foreign countries until we receive the requisite approval from the respective regulatory authorities in such countries. The time required to obtain regulatory approval, if any, by the FDA, EMA and comparable foreign authorities is unpredictable, but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities and the type, complexity and novelty of the product candidates involved. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional nonclinical studies or clinical trials.

Obtaining regulatory approval requires the submission of extensive nonclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing regulatory approval also requires the submission of information about the product manufacturing process, and in many cases the inspection of manufacturing, processing, and packaging facilities by the regulatory authorities. Our current or future product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use, or there may be deficiencies in cGMP compliance by us or by our CMOs that could result in the candidate not being approved. Moreover, we have not obtained regulatory approval for any drug candidate in any jurisdiction and it is possible that none of our existing drug candidates or any drug candidates we may seek to develop in the future will ever obtain regulatory approval.

Our drug candidates could fail to receive, or could be delayed in receiving, regulatory approval for many reasons, including any one or more of the following:

- the FDA, EMA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA, EMA or comparable foreign regulatory authorities that a drug candidate is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA, EMA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a drug candidate's clinical and other benefits outweigh its safety risks;
- the FDA, EMA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;

- the data collected from clinical trials of our drug candidates may not be sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the United States or elsewhere;
- upon review of our clinical trial sites and data, the FDA or comparable foreign regulatory authorities may find our record keeping or the record keeping of our clinical trial sites to be inadequate;
- the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies may fail to meet the requirements of the FDA, EMA or comparable foreign regulatory authorities;
- the FDA, EMA or comparable foreign regulatory authorities may fail to approve the companion diagnostics we contemplate developing internally or with partners; and
- the change of the medical standard of care or the approval policies or regulations of the FDA, EMA or comparable foreign regulatory authorities may significantly change in a manner that renders our clinical data insufficient for approval.

The time and expense of the approval process, as well as the unpredictability of future clinical trial results and other contributing factors, may result in our failure to obtain regulatory approval to market NXP800, NXP900 or any other drug candidates we may seek to develop in the future, which would significantly harm our business, results of operations and prospects. In such case, we may also not have the resources to conduct new clinical trials and/or we may determine that further clinical development of any such drug candidate is not justified and may discontinue any such programs.

In addition, even if we were to obtain regulatory approval in one or more jurisdictions, regulatory authorities may approve any of our drug candidates for fewer or more limited indications than we request, may not approve prices we may propose to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials (referred to as "conditional" or "accelerated" approval depending on the jurisdiction), or may approve a drug candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that drug candidate. Any of the foregoing circumstances could materially harm the commercial prospects for our drug candidates.

Obtaining and maintaining regulatory approval of our current or future product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our current or future product candidates in other jurisdictions.

Obtaining and maintaining regulatory approval of any of our current or future product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in other jurisdictions. For example, even if the FDA grants regulatory approval of a product candidate, similar foreign regulatory authorities must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Drug product approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical 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, 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 may also submit marketing applications in other countries. 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. Obtaining similar foreign regulatory approvals and compliance with similar foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. We do not have any product candidates approved for sale in any jurisdiction, including international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with the regulatory requirements in international markets and/or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our current or future product candidates will be harmed.

Even if we receive regulatory approval of our current or future product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our current or future product candidates.

If any of our current or future product candidates are approved, activities such as the manufacturing, labeling, packaging, storage, advertising, promotion, sampling, and record keeping for the products will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as ongoing compliance with cGMP regulations. Drug manufacturers and any CMOs responsible for any product manufacturing processes are required to comply with extensive FDA and comparable foreign regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to cGMP regulations and any applicable foreign equivalents. As such, we and our CMOs will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any NDA, other marketing application, and previous responses to inspection observations. Accordingly, we and others with whom we work must continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production and quality control.

The FDA or a comparable foreign regulatory authority may also impose requirements for costly post-marketing nonclinical studies or clinical trials (often called "Phase 4 trials") and post-marketing surveillance to monitor the safety or efficacy of the product. If we or a regulatory authority discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, production problems or issues with the facility where the product is manufactured or processed, such as product contamination or significant not-compliance with applicable cGMP regulations, a regulator may impose restrictions on that product, the manufacturing facility or us. If we or our third-party providers, including our CMOs, fail to comply fully with applicable regulations, then we may be required to initiate a recall or withdrawal of our products.

Later discovery of previously unknown problems with our current or future product candidates, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in the following, among other things:

- restrictions on the manufacturing of the product, the approved manufacturers or the manufacturing process;
- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- withdrawal of the product from the market;
- product recalls;
- warning or untitled letters from the FDA or comparable notice of violations from foreign regulatory authorities;
- refusal of the FDA or other applicable regulatory authority to approve pending applications or supplements to approved applications;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- suspension of any of our ongoing clinical trials;
- product seizure or detention or refusal to permit the import or export of products; and

- consent decrees, injunctions or the imposition of civil or criminal penalties.

In addition, regulatory authorities' policies (such as those of the FDA or EMA) may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our current or future product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are otherwise not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

Non-compliance with European Union requirements regarding safety monitoring or pharmacovigilance can also result in significant financial penalties. Similarly, failure to comply with the European Union's requirements regarding the protection of personal information can also lead to significant penalties and sanctions.

The FDA's policies may change and additional government regulations may be enacted that could prevent, limit or delay marketing approval of our current or future product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, this may adversely affect, or even lead to the rescission of, the marketing approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

A variety of risks associated with marketing our current or future product candidates internationally could materially adversely affect our business.

We plan to seek regulatory approval of our current or future product candidates outside of the United States and expect that we will be subject to additional risks related to operating in foreign countries including: differing regulatory requirements; unexpected changes in tariffs, trade barriers, price and exchange controls; economic weakness, including inflation, or political instability in particular foreign economies and markets; compliance with tax, employment, immigration and labor laws for employees living or traveling abroad; foreign currency fluctuations that result in increased operating expenses, reduced revenue, and other obligations incident to doing business in another country; potential liability under the Foreign Corrupt Practices Act of 1977 or comparable foreign regulations; and challenges enforcing our contractual and intellectual property rights, especially in countries that do not recognize intellectual property rights to the same extent as the United States.

The insurance coverage and reimbursement status of newly approved products is uncertain. Our current or future product candidates may become subject to unfavorable pricing regulations, third-party coverage and reimbursement practices, or healthcare reform initiatives, which would harm our business. Failure to obtain or maintain adequate coverage and reimbursement for new or current products could limit our ability to market those products and decrease our ability to generate revenue.

Adverse pricing limitations may hinder our ability to recoup our investment in one or more of our current or future product candidates, even if any such current or future product candidate we may develop obtains marketing approval.

Our ability to successfully commercialize any current or future product candidates will depend in part on the coverage and reimbursement for the products and related treatments from government health administration authorities and third-party payors, such as private health insurers and health maintenance organizations. These organizations decide which medications they will pay for and establish reimbursement levels. If coverage and adequate reimbursement is not available, or the approved reimbursement amount is not high enough, we may be unable to establish or maintain pricing sufficient to generate a return on our investment and may be unable to successfully commercialize our current or future product candidates. Reimbursement by a third-party payor may depend upon a number of factors, including, but not limited to, the third-party payor's determination that use of a product is a covered benefit under its health plan, safe, effective and medically necessary, appropriate for the specific patient, cost-effective, and neither experimental nor investigational. If coverage and adequate reimbursement is not available, or the approved reimbursement amount is not high enough, we may be unable to establish or maintain pricing sufficient to generate a return on our investment and may be unable to successfully commercialize our current or future product candidates.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. In general, the prices of medicines under such systems are substantially lower than in the United States.

There is also significant uncertainty related to the insurance coverage and reimbursement of newly approved products, and coverage may be more limited than the purposes for which the medicine is approved by the FDA or comparable foreign regulatory authorities. In the United States, the principal decisions about reimbursement for new medicines are typically made by CMS. As a result, the coverage determination process is often a time consuming and costly process that may require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. It is difficult to predict what CMS will decide with respect to reimbursement for fundamentally novel products such as ours. Reimbursement agencies in Europe may be more conservative than CMS. Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payors for any approved products we may develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize our current or future product candidates, and our overall financial condition.

Healthcare legislative measures and changes in policies, funding, staffing and leadership at the FDA and other agencies could hinder or prevent the commercial success of our products.

In the United States, there have been a number of legislative and regulatory changes to the healthcare system that could affect our future results of operations and the future results of operations of our potential customers.

In recent years, there has been heightened governmental scrutiny over the manner in which biopharmaceutical manufacturers set prices for their marketed products, which has resulted in several recent government inquiries as well as federal and state legislation designed to, among other things, increase drug price transparency, review the relationship between pricing and manufacturer patient programs, reduce the cost of drugs under Medicare, and reform government reimbursement for drug products. Congress and the executive branch have each indicated that they will continue to seek new legislative and/or administrative measures to control drug costs, making this area subject to ongoing uncertainty. At the state level in the United States, legislatures have also increasingly passed legislation and implemented regulations designed to control drug product pricing.

While we cannot predict what impact these laws or policies will have in general or specifically on any product we may commercialize in the future, such efforts by the government and payors may result in downward pressure on reimbursement, which could negatively affect market acceptance of new products. Any rebates, discounts, taxes costs or regulatory or systematic changes on healthcare may have a significant effect on our profitability in the future.

Given recent federal and state government initiatives directed at lowering the total cost of healthcare, the executive branch, Congress and state legislatures will likely continue to focus on healthcare reform and the reform of the Medicare and Medicaid programs. While we cannot predict the full outcome of any such government action or legislation, it may harm our ability to market our products and generate revenues.

Furthermore, regulatory authorities' assessment of the data and results required to demonstrate safety and effectiveness can change over time and can be affected by many factors, such as the emergence of new information, including on other products, changing policies and agency funding, staffing and leadership. We cannot be sure whether future changes to the regulatory environment will be favorable or unfavorable to our business prospects.

Our future relationships with customers and third-party payors in the United States and elsewhere may be subject to applicable anti-kickback, fraud and abuse, false claims, transparency, health information privacy and security and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings.

Healthcare providers, physicians and third-party payors in the U.S. and elsewhere will play a primary role in the recommendation and prescription of any current or future product candidates for which we obtain marketing approval. Our future arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act, which may constrain the business or financial arrangements and relationships through which we sell, market and distribute any current or future product candidates for which we obtain marketing approval. In addition, we may be subject to transparency laws and patient privacy regulation by the federal and state

governments and by governments in foreign jurisdictions in which we conduct our business. The applicable federal, state and foreign healthcare laws and regulations that may affect our ability to operate include, but are not necessarily limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal and state healthcare programs, such as Medicare and Medicaid;

- federal civil and criminal false claims laws and civil monetary penalty laws, including the federal False Claims Act, which impose criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government; the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and their respective implementing regulations, which impose obligations on covered healthcare providers, health plans, and healthcare clearinghouses, as well as their business associates 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;

- the federal Open Payments program, which requires manufacturers of certain drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to CMS, information related to "payments or other transfers of value" made to "covered recipients," which include physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors, and teaching hospitals) and applicable manufacturers. Applicable group purchasing organizations also are required to report annually to CMS the ownership and investment interests held by the physicians and their immediate family members. The SUPPORT for Patients and Communities Act added to the definition of covered recipient practitioners including physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists and certified nurse-midwives effective in 2022. Data collection began on August 1, 2013 with requirements for manufacturers to submit reports to CMS by March 31, 2014 and 90 days after the end of each subsequent calendar year. Disclosure of such information was made by CMS on a publicly available website beginning in September 2014; and

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state and foreign data privacy or data protection laws and regulations, such as state health data privacy legislation, state data breach legislation, or general state privacy legislation such as California's Consumer Privacy Act (CCPA) and its implementing regulations; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

In November 2020, HHS finalized significant changes to the regulations implementing the Anti-Kickback Statute, as well as the Physician Self-Referral Law and the civil monetary penalty rules regarding beneficiary inducements, with the goal of offering the healthcare industry more flexibility and reducing the regulatory burden associated with those fraud and abuse laws, particularly with respect to value-based arrangements among industry participants.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations may involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our

operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, including, without limitation, damages, fines, imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations, which could have a material adverse effect on our businesses. If any of the physicians or other healthcare providers or entities with whom we expect to do business, including our collaborators, is found not to be in compliance with applicable laws, it may be subject to criminal, civil or administrative sanctions, including exclusions from participation in government healthcare programs, which could also materially affect our businesses.

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 have a material adverse effect on the success of 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. Our operations may involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Our operations also may produce hazardous waste products. We currently contract with third parties for the conduct of our manufacturing efforts and preclinical studies and clinical trials and such third parties are responsible for disposal of these materials and wastes. However, we cannot eliminate our risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of 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.

Although we maintain workers' compensation insurance to cover us for costs and expenses, we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

Risks Related to our Intellectual Property

We currently hold a license to certain intellectual property rights relating to our lead product candidate, NXP800 and to NXP900, as well as intellectual property rights relating to other compounds that modulate HSF1 and the SRC and YES1 kinases. If we are unable to maintain patent and other intellectual property protection for NXP800 and NXP900, and to obtain and maintain patent and other intellectual property protections for our other current or future product candidates and technology, or if the scope of intellectual property protection obtained or maintained is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to commercialize NXP800, NXP900 or any other current or future product candidates or technology may be adversely affected.

Our success depends in large part on our ability to obtain and maintain patent and other intellectual property protection in the United States and other countries with respect to our current or future product candidates, including NXP800 and NXP900, their respective components, formulations, combination therapies, methods used to manufacture them and methods of treatment and development that are important to our business, as well as successfully defending these patents against third-party challenges. If we do not adequately protect our intellectual property rights, or if the intellectual property rights we are able to obtain are insufficiently broad and exclusive, competitors may be able to erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability.

We intend to rely upon a combination of patents, patent applications, confidentiality agreements, trade secret protection and license agreements to protect the intellectual property related to our current or future product candidates and technologies. Any disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in our market. We, or any current or future partners, collaborators, or licensees, may fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. We may be also unable to exclusively license relevant technology and associated intellectual property developed by others. Therefore, we may miss potential opportunities to establish our patent position.

If we are unable to secure additional patent protection or maintain existing or future patent protection with respect to NXP800, NXP900, or any other proprietary products and technology we develop, our business, financial condition, results of operations, and prospects would be materially harmed.

We currently hold a license to certain intellectual property rights relating to NXP800, including its composition of matter and to other compounds that modulate HSF1 (activate the GCN2 kinase). In addition, we hold a license to certain intellectual property relating to NXP900, including its composition of matter and to other compounds that inhibit the SRC and YES1 kinases.

We have licensed one patent family covering the composition of matter for NXP800, including two issued U.S. patents covering the composition of matter for NXP800, as well as methods for using and making NXP800. Additionally, patents have been issued in major markets, including the U.S., the European Union, and Japan. The statutory expiration for the issued U.S. patents in this family is October 2034, without considering any patent extensions that may or may not be possible.

We have licensed a patent family directed to additional compounds that modulate HSF1. A patent from this family has been granted in the U.S., and has a statutory expiration of April 2036, without considering any patent extensions that may or may not be possible.

We have also licensed a patent family directed to deuterated compounds that modulate HSF1. Any U.S. patent that grants from this family would have a statutory expiration of October 2037, without considering any patent extensions or patent disclaimers that may or may not be possible.

We have licensed one patent family covering the composition of matter for NXP900, which has been granted in the U.S., EU, Japan, China and is pending in the United Kingdom and Canada. The statutory expiration for patents in this patent family is April 2036, without considering any possible patent term extension.

If the scope of our patent protection, whether now or in the future, with respect to NXP800, NXP900 or our future product candidates and technology is not sufficiently broad, we will be unable to prevent others from using our technology or from developing or commercializing technology and products similar or identical to ours or other competing products and technologies. Any failure to obtain or maintain patent protection, through our own patents or through in-licensing, with respect to NXP800, NXP900 and our future product candidates would have a material adverse effect on our business, financial condition, results of operations and prospects.

Even if they are unchallenged, our patent applications, if issued, and any patents we may own or in-license now or in the future, may not provide us with any meaningful protection or prevent competitors from designing around our patent claims to circumvent any patents we may own or in-license in the future by developing similar or alternative technologies or therapeutics in a non-infringing manner. If the patent protection provided by our patent applications or any patents we may pursue with respect to our current or future product candidates is not sufficiently broad to impede competition, our ability to successfully commercialize our current or future product candidates could be negatively affected, which would harm our business.

Additionally, we cannot be certain that the claims in our patent applications covering composition of matter (or other related aspects) of our current or future product candidates or technology will be considered patentable by the USPTO, or by patent offices in foreign countries, or that the claims in any issued patents we may own or in-license in the future will be considered patentable by courts in the United States or foreign countries.

The issuance of a patent does not foreclose challenges to its inventorship, scope, validity or enforceability. Therefore, our owned and in-licensed patents may be challenged in the courts or patent offices in the United States and elsewhere. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated, or held unenforceable, in whole or in part. Successful patent challenges 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 product candidates might expire before or shortly after such product candidates are commercialized. As a result, our owned and in-licensed patents may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Moreover, patents or patent applications owned or filed by us, or by our licensors or other collaborators, may be challenged or narrowed by third-party pre-issuance submissions of prior art to the USPTO, or by opposition, derivation, reexamination, inter parties review, post-grant review or interference proceedings. An adverse determination in any such submission, Patent Trial and Appeal Board trial, proceeding or litigation could reduce the scope of, render unenforceable, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third party patent rights. In addition, if the breadth or strength of protection provided by

our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

If we fail to comply with our obligations in our current license agreements, or in any future agreements under which we may license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our current or future licensors, we could lose license rights that are important to our business.

We are currently party to a license which grants us certain intellectual property rights relating to our lead product candidate, NXP800, as well as other related compounds, and to a license which grants us certain intellectual property rights relating to our second drug candidate, NXP900, as well as other compounds that inhibit the SRC and YES1 kinases. These agreements impose numerous obligations on us to maintain our licensing rights, including development, diligence, payment, commercialization, funding, milestone, royalty, sublicensing, insurance, patent prosecution, enforcement and other obligations. In spite of our efforts, our licensor might conclude that we have materially breached our license agreement and might therefore terminate the license agreement, thereby removing or limiting our ability to develop and commercialize NXP800 or NXP900 (and other compounds covered by the licenses).

Additionally, in the future, we may be party to other license or collaboration agreements with third parties to advance our research or allow commercialization of current or future product candidates. Such future agreements may impose numerous obligations, such as development, diligence, payment, commercialization, funding, milestone, royalty, sublicensing, insurance, patent prosecution, enforcement and other obligations on us and may require us to meet development timelines, or to exercise commercially reasonable efforts to develop and commercialize licensed products, in order to maintain the licenses. In spite of our efforts, our future licensors might conclude that we have materially breached our future license agreements and might terminate the license agreements, thereby removing or limiting our ability to develop and commercialize products and technologies covered by these license agreements.

Any termination of these current or future licenses, or failure of the underlying patents to provide the intended exclusivity, could result in the loss of significant rights and could harm our ability to commercialize our current or future product candidates, and competitors or other third parties would have the freedom to seek regulatory approval of, and to market, products identical to ours and we may be required to cease our development and commercialization of certain of our current or future product candidates. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, 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 the protection afforded by patents we may own or in-license in the future, we seek to rely on trade secret protection, confidentiality agreements, and license agreements to protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce, and any other elements of our product discovery and development processes that involve proprietary know-how, information, or technology that is not covered by patents. Although we require all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information, or technology to enter into confidentiality agreements, trade secrets can be difficult to protect and we have limited control over the protection of trade secrets used by our collaborators and suppliers.

If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, financial condition, results of operations and future prospects.

Third-party claims of intellectual property infringement, misappropriation or other violations may be costly and time consuming and may prevent or delay our product discovery and development efforts.

The intellectual property landscape around precision medicine is crowded, and third parties may initiate legal proceedings alleging that we are infringing, misappropriating, or otherwise violating their intellectual property rights; the outcome of which would be uncertain and could have a material adverse effect on the success of our business. We or any of our future licensors or strategic partners may be party to, exposed to, or threatened with, future adversarial proceedings or litigation by third parties having patent or other intellectual property rights alleging that our current or future product candidates and/or proprietary technologies infringe, misappropriate or otherwise violate their intellectual property rights. Thus, because of the large number of patents issued and patent applications filed in our fields, there may be a risk that third parties may allege they have patent rights encompassing our current or future product candidates, technologies or methods.

Third parties may assert that we are employing their proprietary technology without authorization. In addition, because some patent applications in the United States may be maintained in secrecy until the patents are issued, patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, and publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications covering our current or future product candidates or technology. If any such patent applications issue as patents, and if such patents have priority over patent applications or patents we own or in-license, we may be required to obtain rights to such patents owned by third parties which may not be available on commercially reasonable terms or at all, or may only be available on a non-exclusive basis.

In the event of a successful claim of infringement, misappropriation or other violation against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure.

Changes to patent law in the United States and in foreign jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products.

Our success is heavily dependent on intellectual property, particularly patents. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened 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. Laws and regulations governing patents could further change in unpredictable ways that could weaken our ability to obtain new patents or to enforce patents that we own or in-license now, or that we might obtain or in-license in the future.

We may be subject to claims challenging the inventorship or ownership of our intellectual property, including any patents we may own or in-license currently or in the future.

We may be subject to claims that former employees, collaborators or other third parties have an interest in any patents we may own or in-license currently or in the future, trade secrets, or other intellectual property as an inventor or co-inventor. Litigation may be necessary to defend against these and other claims challenging inventorship of any patents we may own or in-license in the future, trade secrets or other intellectual property, which may require substantial time and monetary expenditure.

We may be subject to claims that we or our employees, consultants or independent contractors have wrongfully used or disclosed confidential information or alleged trade secrets of third parties or competitors or breached non-competition or non-solicitation agreements with our competitors.

We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information or trade secrets of third parties or competitors or our employees' former employers or our consultants' or contractors' current or former clients or customers. Litigation or arbitration may be necessary to defend against these claims, which may require substantial time and monetary expenditure.

If we do not obtain patent term extension and data exclusivity for any of our current or future product candidates we may develop, our business may be materially harmed.

Depending upon the timing, duration and specifics of any FDA marketing approval of any of our current or future product candidates we may develop, one or more U.S. patents we may own or in-license in the future may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act. If we are unable to obtain patent term extension or the term of any such extension is shorter than what we request, our competitors may obtain approval of competing products following expiration of any patents that issue from our patent applications, and our business, financial condition, results of operations, and prospects could be materially harmed.

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

Our trademarks or trade names may be challenged, infringed, diluted, circumvented or declared generic or determined to be infringing on other marks. We intend to rely on both registration and common law protection for our trademarks. 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. If we are unable to obtain a registered trademark or 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.

Risks Related to our Reliance on Third Parties

We plan to rely on third parties to conduct our preclinical studies and clinical trials. If these third parties do not properly and successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval of or commercialize our current or future product candidates.

We plan to utilize and depend upon independent investigators and collaborators, such as medical institutions, CROs, CMOs, and strategic partners to conduct and support our preclinical studies and clinical trials under agreements with us. We rely upon, and plan to continue to rely upon, such third-party entities to execute our clinical trials and preclinical studies and to monitor and manage data produced by and relating to those studies and trials. However, in the future we may not be able to establish arrangements with CROs when needed or on terms that are acceptable to us, or at all, which could negatively affect our development efforts with respect to our drug candidates and materially harm our business, operations and prospects. As a result of the use of third-party contractors, we will have only limited control over certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies, including each of our clinical trials, is conducted in accordance with the applicable protocol, legal and regulatory requirements as well as scientific standards, and our reliance on any third-party entity will not relieve us of our regulatory responsibilities.

Based on our present expectations, we and our third-party contractors will be required to comply with GCP regulations for the clinical development of all of our drug candidates. If we or any of these third parties fail to comply with applicable GLP or GCP regulations, the clinical data generated in our preclinical and 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, which we may not have sufficient cash or other resources to support and which would delay our ability to generate revenue from future sales of such drug candidate. Any agreements governing our relationships with CROs or other contractors with whom we currently engage or may engage in the future may provide those outside contractors with certain rights to terminate a clinical trial under specified circumstances. If such an outside contractor terminates its relationship with us during the performance of a clinical trial, we would be forced to seek an engagement with a substitute contractor, which we may not be able to do on a timely basis or on commercially reasonable terms, if at all, and the applicable clinical trial would experience delays or may not be completed.

Large-scale clinical trials require significant additional financial and management resources and reliance on third-party clinical investigators, CROs, and consultants, which may cause us to encounter delays that are outside of our control. We may be unable to identify and contract with sufficient investigators, CROs, or consultants on a timely basis, if at all.

If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, legal and regulatory requirements or for other reasons, our preclinical or clinical trials may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval for, or successfully commercialize, our current or future product candidates. In addition, we will be unable to control whether or not they devote sufficient time and resources to our preclinical and clinical programs. These outside contractors may not assign as great a priority to our programs or pursue them as diligently as we would if we were undertaking such programs ourselves. As a result, our operations and the commercial prospects for the effected drug candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed. These contractors may also have relationships with other commercial entities, some of whom may compete with us. If our contractors assist our competitors to our detriment, our competitive position would be harmed.

If our relationships with any third parties conducting our studies are terminated, we may be unable to enter into arrangements with alternative third parties on commercially reasonable terms, or at all. Switching or adding third parties to conduct our studies involves substantial cost and requires extensive management time and focus. In addition, there is a natural transition period when a new third party commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Although we carefully manage our relationships with third parties conducting our studies, we cannot assure you that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material and adverse effect on our business, financial condition and results of operations.

We rely, and expect to continue to rely, on the third-party manufacturers to manufacture our current or future product candidates. Reliance on third parties increases the risk that we will not have sufficient quantities of our products or such quantities at an acceptable quality and cost, which could delay, prevent or impair our development or commercialization efforts.

We do not currently own any facility that may be used as our clinical-scale manufacturing and processing facility and must rely on outside vendors to manufacture our current or future product candidates. We rely on a single CMO to make the NXP800 drug substance and finished drug product, each performed at a different manufacturing facility. We rely on a single CMO to manufacture NXP900 drug substance and another single CMO to manufacture NXP900 drug product. There is no assurance that we will be able to retain these relationships, and if we are unable to maintain these relationships, we could experience delays in our development efforts. There is no assurance that our CMOs will be successful in manufacturing NXP800 and/or NXP900 drug substance or product. If NXP800, NXP900 or any other drug candidate we may develop or acquire in the future receives regulatory approval, we will likely rely on one or more CMOs to manufacture the commercial supply of such drugs.

Our anticipated reliance on a limited number of third-party manufacturers exposes us to a number of risks, including:

- due to the limited number of potential manufacturers, and because the FDA requires inspection of any manufacturers' cGMP compliance as part of our marketing application, we may be unable to identify manufacturers on acceptable terms, if at all;
- a new manufacturer would have to be educated in and develop substantially equivalent processes for, the production of our current or future product candidates;
- our third-party manufacturers might be unable to timely manufacture our current or future product candidates or produce the quantity and quality required to meet our clinical and commercial needs due to a variety of potential reasons including failure to achieve drug substance or drug product specifications, batch to batch inconsistencies, site or equipment contaminations, failure to scale up as needed in a cost-efficient manner, failed regulatory inspections, competition for production capacity and availability from other customers;
- we may not own, or may have to share, the intellectual property rights to any improvements made by our third-party manufacturers in the manufacturing process for our current or future product candidates;
- our third-party manufacturers could breach or terminate their agreements with us;
- our third-party manufacturers might be unable to formulate and manufacture our drugs in the volume and of the quality required to meet our clinical and commercial needs, if any;
- our third-party manufacturers may not perform as contractually agreed or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store and distribute our products;
- drug manufacturers are subject to ongoing periodic unannounced inspection by the FDA and some state agencies in the United States, as well as foreign regulatory authorities, to ensure strict compliance with cGMP regulations and other regulatory requirements; and
- raw materials and components used in the manufacturing process, particularly those for which we have no other source or supplier, may not be available or may not be suitable or acceptable for use due to material or component defects.

Each of these risks could delay or prevent the completion of our preclinical or clinical trials or the approval of any of our current or future product candidates by the FDA or another foreign regulatory authority, result in higher costs or adversely impact commercialization of our current or future product candidates.

Although our agreements with our CMOs require them to perform according to certain cGMP requirements such as those relating to quality control, quality assurance and qualified personnel, we cannot control the conduct of our CMOs to implement and maintain these standards. If any of our CMOs cannot successfully manufacture material that conforms to our specifications and the regulatory

requirements of the FDA, EMA or other comparable foreign authorities, we could be prevented from obtaining regulatory approval for our drug candidates unless and until we engage a substitute CMO that can comply with such requirements, which we may not be able to do. Any such failure by any of our CMOs would significantly impact our ability to develop, obtain regulatory approval for or market our drug candidates, if approved.

If our third-party manufacturers use hazardous and biological materials in a manner that causes injury or violates applicable law, we may be liable for damages.

Although we believe that our manufacturers' procedures for using, handling, storing, and disposing of hazardous and biological materials comply with legally prescribed standards, we cannot completely eliminate the risk of contamination or injury. In the event of an accident, local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations. Further, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. We do not have any insurance for liabilities arising from medical or hazardous materials.

Risks Related to Managing Growth and Employee Matters

We are highly dependent on our key personnel and anticipate hiring new key personnel. If we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our management, scientific and medical personnel, including our Chairman, Chief Executive Officer and President, our Chief Scientific and Business Officer and our Chief Development and Operations Officer. While we expect to engage in an orderly transition process as we integrate newly appointed officers and managers, we face a variety of risks and uncertainties relating to management transition, including diversion of management attention from business concerns, failure to retain other key personnel or loss of institutional knowledge.

We will need to grow the size of our organization, and we may experience difficulties in managing this growth.

As of November 1, 2024, we had 13 full-time employees. We also contract for various services through consulting and vendor agreements. We intend to hire new employees to conduct our research and development activities in the future. Any delay in hiring such new employees could result in delays in our research and development activities and would harm our business. As our development and commercialization plans and strategies develop, and as we transition into operating as a public company, we expect to need additional managerial, operational, sales, marketing, financial and other personnel, as well as additional facilities to expand our operations.

If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, or we are not able to effectively build out new facilities to accommodate this expansion, we may not be able to successfully implement the tasks necessary to further develop and commercialize our current or future product candidates and, accordingly, may not achieve our research, development and commercialization goals.

We will incur significant increased costs as a result of operating as a public company, and our management will be required to devote substantial time to compliance activities and initiatives.

As a public company, we will incur significant legal, accounting, and other expenses that we did not incur as a private company. We are now subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, which requires, among other things, that we file with the SEC, annual, quarterly, and current reports with respect to our business and financial condition. In addition, the Sarbanes-Oxley Act of 2002 ("SOX"), as well as rules subsequently adopted by the SEC and the Nasdaq Capital Market to implement provisions of SOX, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices.

Moreover, these rules and regulations will increase our legal and financial compliance costs and make some activities more time-consuming and costly. For example, these rules and regulations make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified persons to serve on our Board of Directors, our Board committees or as executive officers.

SOX requires, among other things, that we maintain effective internal control over financial reporting and disclosure controls and procedures. As a result, we are required to periodically perform an evaluation of our internal control over financial reporting to allow management to report on the effectiveness of those controls, as required by Section 404 of SOX. These efforts to comply with Section 404 will require the commitment of significant financial and managerial resources. While we anticipate maintaining the integrity of our internal control over financial reporting and all other aspects of Section 404, we cannot be certain that a material weakness will not be identified when we test the effectiveness of our control systems in the future. If a material weakness is identified, we could be subject to sanctions or investigations by the SEC or other regulatory authorities, which would require additional financial and management resources, costly litigation or a loss of public confidence in our internal control, which could have an adverse effect on the market price of our stock.

Our business and operations would suffer in the event of computer system failures, cyber-attacks, or deficiencies in our or third parties' cybersecurity.

We are increasingly dependent upon information technology systems, infrastructure, and data to operate our business. In the ordinary course of business, we may collect, store, and transmit confidential information, including, but not limited to, information related to our intellectual property and proprietary business information, personal information, and other confidential information. We have outsourced elements of our operations to third party vendors, who each have access to our confidential information, which increases our disclosure risk. Although we have implemented internal security and business continuity measures, our information technology and other internal infrastructure systems may breakdown, incur damage or be interrupted by system malfunctions, natural disasters, terrorism, war, or telecommunication and electrical failures, as well as by inadvertent or intentional security breaches by our employees, contractors, consultants, business partners, and/or other third parties, or from cyber-attacks by malicious third parties, each of which could compromise our system infrastructure or lead to the loss, destruction, alteration, disclosure, or dissemination of, or damage or unauthorized access to, our data or other assets. Such a security breach may cause loss, damage, or disclosure of proprietary or confidential information, which could in turn result in significant legal and financial exposure and reputational damage that could adversely affect our business. Furthermore, the loss or corruption of clinical trial data from future clinical trials may result in delays in our regulatory approval efforts and could significantly increase our costs to recover or reproduce the data.

The costs related to significant security breaches or disruptions could be material and our insurance policies may not be adequate to compensate us for the potential losses arising from any such security breach. In addition, such insurance may not be available to us on economically reasonable terms, if at all, may not cover all claims made against us, and may have high deductibles. Furthermore, if the information technology systems of our third-party vendors and other contractors and consultants become subject to disruptions or security breaches, we may have insufficient recourse against such third parties and we may have to expend significant resources to mitigate the impact of such an event, and to develop and implement protections to prevent future events of this nature from occurring.

Risks Related to Commercial Activities

If any of our current or future product candidates do not achieve broad market acceptance among physicians, patients, healthcare payors and the medical community, the revenues from any such current or future product candidate may be limited.

The use of precision medicines as a potential cancer treatment is a recent development and may not become broadly accepted by physicians, patients, hospitals, cancer treatment centers, and others in the medical community. We cannot predict whether physicians, patients, hospitals, cancer treatment centers, and government agencies or third-party payors will determine that our product is safe, therapeutically effective, and cost effective as compared with competing treatments. If our current or potential future product candidates do not achieve an adequate level of market acceptance, we may not generate significant product revenues and may not become profitable. Factors influencing acceptance of our current or future product candidates in the market, include: the clinical indications for which our product candidates are licensed; whether our product candidates are viewed as a safe and effective treatment; our ability to demonstrate our product's advantages, including cost advantages, over alternative treatments; the prevalence and severity of any side effects of our products and of other precision medicines; product labeling or product insert requirements of the FDA or other regulatory authorities and limitations or warnings contained in the labeling; the timing of market introduction of our product candidates and competitive products; patient willingness to pay out-of-pocket in the absence of coverage by third-party payors and government authorities; and the effectiveness of our sales and marketing efforts.

If our current or future product candidates are licensed but fail to achieve market acceptance among physicians, patients, hospitals, cancer treatment centers or others in the medical community, we will not be able to generate significant revenue. In addition, although

our current or future product candidates may differ in certain ways from other precision medicine approaches, serious adverse events or deaths in other preclinical or clinical trials involving precision medicines, even if not ultimately attributable to our current or future products or product candidates, could result in increased government regulation, unfavorable public perception and publicity, potential regulatory delays in the testing or licensing of our current or future product candidates, stricter labeling requirements for those product candidates that are licensed, and a decrease in demand for any such product candidates.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our current or future product candidates.

We face an inherent risk of costly and time-consuming product liability lawsuits as a result of the planned clinical testing of our current or future product candidates and will face an even greater risk if we commercialize any products. For example, we may be sued if our current or future product candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our current or future product candidates. Failure to obtain or retain sufficient product liability insurance at an acceptable cost may prevent or inhibit the commercialization of products we may develop. Although we have clinical trial insurance, our insurance policies have various exclusions, and we may be subject to a claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that are not covered by or which exceed our insurance coverage, and we may not have sufficient capital to pay such amounts.

Risks Related to Ownership of our Common Stock

We do not know whether an active, liquid and orderly trading market will develop for our Common Stock or what the market price of our Common Stock will be and, as a result, it may be difficult for you to sell your shares of our Common Stock.

Prior to the pricing of our initial public offering on February 4, 2022, there was no public trading market for shares of our Common Stock and after our IPO the trading price of our Common Stock has been volatile. Although our Common Stock is listed on the Nasdaq Capital Market, an active trading market for our shares is still developing and may not be sustained in the future. The lack of an active market for our Common Stock creates volatility in the price of the stock and may impair investors' ability to sell their shares at the time they wish to sell them or at a price that they consider reasonable and may reduce the fair market value of their shares. Further, an inactive market may impair our ability to raise capital by selling shares of our Common Stock and to enter into strategic partnerships or acquire companies or products using our shares of common stock as consideration.

Our growth is subject to economic and political conditions.

Our business is affected by global and local economic and political conditions as well as the state of the financial markets, inflation, recession, financial liquidity, currency volatility, growth, and policy initiatives. There can be no assurance that global economic conditions and financial markets will not worsen and that we will not experience any adverse effects that may be material to our consolidated cash flows, results of operations, financial position or our ability to access capital, such as the adverse effects resulting from a prolonged shutdown in government operations both in the United States and internationally. Political changes, including war or other conflicts, some of which may be disruptive, could interfere with our supply chain, our customers and all of our activities in a particular location.

We do not intend to pay dividends on our Common Stock in the foreseeable future, so any returns will be limited to the value of our stock, which may be volatile.

We plan to retain future earnings for the development, operation, and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will be limited to the appreciation of their stock, which may never occur. Further, the trading price of our common stock is likely to be highly volatile and may be subject to wide fluctuations in response to various factors, some of which are beyond our control. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance.

If equity research analysts do not publish research or reports about our business or if they publish negative evaluations of or downgrade our Common Stock, the price of our Common Stock could decline.

The trading market for our Common Stock relies in part on the research and reports that equity research analysts publish about us or our business. We do not control these analysts. We may never obtain research coverage by industry or financial analysts. If no or few analysts publish research reports on the Company or if analysts publish negative research reports about the Company, our stock price may significantly decline.

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

We may seek additional capital through a combination of public and private equity offerings, ATM facility, debt financings, strategic partnerships and alliances and licensing arrangements. Any equity or equity-related financing may dilute our stockholders may subject us to restrictive covenants and interest costs. If we obtain funding through a strategic collaboration or licensing arrangement, we may be required to relinquish our rights to our current product candidates or any future product candidates that we may develop.

Additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our operations. If we are unable to raise additional capital as needed or on acceptable terms, we may be required to delay or discontinue any research, development or commercialization programs and may be unable to expand our operations or otherwise capitalize on our business opportunities. Further, we may be required to seek collaborators for potential product candidates earlier, or on less favorable terms, than might otherwise be desired, or to relinquish or license our rights to potential product candidates in markets where we otherwise would seek to pursue development or commercialization. Any of the above events could significantly harm our business, prospects, financial condition and results of operations and cause the price of our common stock to decline.

Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant influence over matters subject to stockholder approval.

As of November 1, 2024, our executive officers, directors, and 5% stockholders beneficially owned approximately 56.9% of our voting stock and anticipate that the same group will hold a significant portion of our outstanding voting stock for the foreseeable future. These stockholders will have the ability to influence us through their ownership position. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock.

Our failure to meet the continuing listing requirements of the NASDAQ Capital Market could result in a de-listing of our securities.

If we fail to satisfy the continuing listing requirements of NASDAQ, such as the corporate governance, stockholders' equity or minimum closing bid price requirements, NASDAQ may take steps to delist our common stock. Such a delisting would likely have a negative effect on the price of our common stock and would impair our stockholders' ability to sell or purchase our common stock. In the event of a delisting, we would likely take actions to restore our compliance with NASDAQ's listing requirements, but we can provide no assurance that any such action taken by us would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our securities, prevent our common stock from dropping below the NASDAQ minimum bid price requirement or prevent future non-compliance with NASDAQ's listing requirements.

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

We are an emerging growth company, as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including: exemption from the auditor attestation requirements of Section 404 of SOX, as amended; being permitted to provide only two years of our audited financial statements and correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations"; exemption from any Public Company Accounting Oversight Board requirement regarding audit firm rotation or an auditor report supplement providing additional information about the audit and financial

statements; reduced disclosure obligations regarding executive compensation; and exemption from the nonbinding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We have elected to take advantage of certain of the reduced reporting obligations. We cannot predict whether investors will find our common stock less attractive if we 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 reduced or more volatile.

Provisions in our certificate of incorporation, our bylaws, and Delaware law may discourage, delay, or prevent a change in control of our Company or changes in our management and, as a result, depress the trading price of our stock.

Provisions of our certificate of incorporation, our bylaws and Delaware law may deter unsolicited takeovers and/or delay or prevent a change in control of our Company, including transactions in which our stockholders might otherwise receive a premium for their shares.

In addition, the Delaware General Corporation Law prohibits a publicly held Delaware corporation from engaging in a business combination with an interested stockholder, defined as a person who owns, or within the last three years has owned, 15% of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner.

The foregoing provisions and anti-takeover measures may limit the price that investors might be willing to pay in the future for shares of our Common Stock and may deter potential acquirers of our Company.

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

During the period covered by this report, we have not issued any unregistered securities.

Use of Proceeds from Sales of Registered Securities

On February 4, 2022, our registration statement on Form S-1 (File No. 333-260099) and our registration statement on Form S-1MEF (File No. 333-262512) (collectively, the "Registration Statements") were declared effective by the SEC. Pursuant to such Registration Statements, we sold an aggregate of 3,200,000 shares of our common stock at a price of $5.00 per share for aggregate net cash proceeds of approximately $13.1 million, which amount is net of $1.12 million in underwriter's discounts, and commissions, and $1.8 million of other expenses incurred in connection with the offering. We closed the offering on February 8, 2022.

On August 24, 2022, our registration statement on Form S-1 (File No. 333-266857), which was filed on August 15, 2022, was declared effective by the SEC. Pursuant to such registration statement, we sold an aggregate of 1,015,598 shares of our common stock at a price of $8.25, and 909,091 of pre-funded warrants to purchase one share of common stock at $8.25 per share for aggregate net cash proceeds of approximately $14.3 million, which amount is net of $1.4 million in placement agent fees, and $0.3 million of other expenses incurred in connection with the offering. We closed the private placement on July 29, 2022. In this offering, we also issued to the investors who participated in the offering preferred investment options to purchase up to an aggregate of 1,924,689 shares of common stock, at an exercise price of $9.65 per share with a term of three and one-half years from the date of issuance.

We intend to use the net proceeds of these offerings to fund the Phase 1 development of NXP800 and NXP900, to continue development and sponsored research related to our current product candidates or any future product candidate, hiring of additional personnel, capital expenditures, costs of operating as a public company and other general corporate purposes.

There has been no material change in the expected use of the net proceeds from our initial public offering as described in our final prospectuses filed with the SEC on February 8, 2022 and August 15, 2022, respectively, pursuant to Rule 424(b) under the Securities Act. We invested the funds received in an interest-bearing money market account.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits

Exhibit No.	Description
31.1*	Certification of Chief Executive Officer of Nuvectis Pharma, Inc. pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, dated November 5, 2024.
31.2*	Certification of Principal Financial Officer of Nuvectis Pharma, Inc. pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, dated November 5, 2024.
32.1**	Certification of Chief Executive Officer of Nuvectis Pharma, Inc. pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, dated November 5, 2024.
32.2**	Certification of Principal Financial Officer of Nuvectis Pharma, Inc. pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, dated November 5, 2024.
101*	The following financial information from the Company's quarterly report on Form 10-Q for the period ended September 30, 2024, formatted in Inline Extensible Business Reporting Language (XBRL): (i) the Condensed Balance Sheets, (ii) the Condensed Statements of Operations, (iii) the Condensed Statement of Stockholders' Equity, (iv) the Condensed Statements of Cash Flows, and (v) Notes to the Condensed Financial Statements.
104*	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

* Filed herewith.
** Furnished herewith.

Signatures

Pursuant to the requirements of the Securities Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Fort Lee, State of New Jersey, on this 5th day of November 2024.

Nuvectis Pharma, Inc.

By: /s/ Ron Bentsur
Name: Ron Bentsur
Title: Chairman, Chief Executive Officer and President

By: /s/ Michael J Carson
Name: Michael J Carson
Title: Vice President of Finance
(Principal Financial and Accounting Officer)