REFINITIV

DELTA REPORT

10-Q

INDAPTUS THERAPEUTICS, IN

10-Q - MARCH 31, 2024 COMPARED TO 10-Q - SEPTEMBER 30, 2023

The following comparison report has been automatically generated

TOTAL DELTAS	685
CHANGES	106
DELETIONS	308
ADDITIONS	271

REFINITIV

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, March 31, 2023 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 001-40652

INDAPTUS THERAPEUTICS, INC.
(Exact name of Registrant as specified in its Charter)

Delaware	**86-3158720**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
3 Columbus Circle 15th Floor New York, New York	**10019**
(Address of principal executive offices)	**(Zip Code)**

(Registrant's telephone number, including area code) +(646) 427-2727

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 $0.01 per share	INDP	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, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☐

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

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

The number of shares of the Registrant's common stock outstanding as of November 3, 2023 May 7, 2024 was 8,401,047 8,538,883.

TABLE OF CONTENTS

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q, or Quarterly Report, contains, and management may make, certain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements other than statements of historical facts contained in this Quarterly Report are forward-looking statements. In some cases, forward-looking statements can be identified by the use of terms such as "believe," "expect," "intend," "plan," "may," "should," "anticipate," "could," "might," "seek," "target," "will," "project," "forecast," "continue" or their negatives or variations of these words or other comparable words. These statements include, without limitation, our statements about: our product candidates candidates' development, including the timing and design of the Phase 1 clinical trial of Decoy20; our expectations regarding the recommended Phase 2 dose for subsequent multi-dosing and combination studies and related timing; the anticipated effects of our product candidates; our plans to develop and commercialize our product candidates; the market potential and treatment potential of our product candidates, including Decoy20; our commercialization, marketing and manufacturing capabilities and strategy; our expectations about the willingness of healthcare professionals to use our product candidates; our general business strategy and the plans and objectives of management for future operations; our research and development activities and costs; our future results of operations and condition; the sufficiency of our cash and cash equivalents to fund our ongoing activities; activities and our ability to continue as a going concern; the impact of current macroeconomic conditions on our operations, ability to access capital, and liquidity; and any impact of a pandemic, epidemic or other future health crisis, such as the COVID-19 pandemic on our business. liquidity.

The forward-looking statements in this Quarterly Report are only predictions and are based largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements speak only as of the date of this Quarterly Report and are subject to a number of known and unknown risks, uncertainties and assumptions, including those described under the sections in this Quarterly Report entitled "Summary Risk Factors," Part II. Item 1A. "Risk Factors" and Part I. Item 2. "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere in this Quarterly Report.

Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties.

Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise. We intend the forward-looking statements contained in this Quarterly Report to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act.

SUMMARY RISK FACTORS

The principal factors and uncertainties that make investing in our common stock risky, include, among others:

- We are a clinical-stage company with a limited operating history. We are not currently profitable, do not expect to become profitable in the near future and may never become profitable.
- We have identified conditions and events that raise substantial doubt regarding our ability to continue as going concern.
- Given our lack of current cash flow, we will need to raise additional capital. If we are unable to raise a sufficient amount of capital when needed on acceptable terms or at all, we may be forced to delay, limit or eliminate some or all of our research programs, product development activities and commercialization efforts.

- Raising additional capital would cause dilution to our existing shareholders and may restrict our operations or require us to relinquish rights to our technologies or product candidates.
- Clinical and preclinical development involves lengthy and expensive processes with uncertain outcomes. Any difficulties or delays in the commencement or completion, or the termination or suspension, of our current or planned clinical trials could result in increased costs to us, delay or limit our ability to generate revenue or adversely affect our commercial prospects.

- We expect to continue to incur significant research and development expenses and other operating expenses, which may make it difficult for us to attain profitability.
- We may expend our limited resources to pursue a limited number of research programs, product candidates and specific indications and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.
- Our product candidates may cause undesirable side effects that could delay or prevent their regulatory approval or commercialization or have other significant adverse implications on our business, financial condition and results of operations.
- The commercial success of our product candidates depends upon their market acceptance among physicians, patients, healthcare payors and the medical community.
- We rely on third parties to conduct our preclinical studies and clinical trials and perform other tasks. If these third parties do not successfully carry out their contractual duties, meet expected deadlines, or comply with regulatory requirements, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business, financial condition and results of operations could be substantially harmed.
- We currently rely on third parties for the manufacture of our product candidates during clinical development, and expect to continue to rely on third parties for the foreseeable future. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates, or such quantities at an acceptable cost, which could delay, prevent or impair our development or potential commercialization efforts.
- The successful commercialization of Decoy20 or any future product candidates, if approved, will depend in part on the extent to which governmental authorities and health insurers establish coverage, adequate reimbursement levels and favorable pricing policies. Failure to obtain or maintain coverage and adequate reimbursement for our products could limit our ability to market those products and decrease our ability to generate revenue.
- Recently enacted legislation, future legislation and healthcare reform measures may increase the difficulty and cost for us to obtain marketing approval for and commercialize Decoy20 and any future product candidates and may affect the prices we may set.
- If our competitors have product candidates that are approved faster, marketed more effectively, are better tolerated, have a more favorable safety profile or are demonstrated to be more effective than our product candidates, our commercial opportunity may be adversely affected.
- Any product candidates for which we intend to seek approval as biologic products may face competition sooner than anticipated.
- We may not be able to adequately protect our proprietary or licensed technology in the marketplace.
- We may not be successful in obtaining or maintaining necessary rights to our product candidates through acquisitions and in-licenses.
- We are subject to various U.S. federal, state and foreign healthcare laws and regulations, which could increase compliance costs, and our failure to comply with these laws and regulations could harm our results of operations and financial condition.
- Actual or perceived failures to comply with applicable data protection, privacy and security laws, regulations, standards and other requirements could adversely affect our business, results of operations, and financial condition.
- A pandemic, epidemic or outbreak of an infectious disease, such as COVID-19, may materially and adversely affect our business and operations.
- Our business and operations may suffer in the event of information technology system failures, cyberattacks or deficiencies in our cybersecurity.
- Maintaining and improving our financial controls and the requirements of being a public company may strain our resources, divert management's attention and affect our ability to attract and retain qualified board members.
- Unfavorable global economic conditions could adversely affect our business, financial condition or results of operations.
- The market price of our common stock is volatile and you may sustain a complete loss of your investment.

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

INDAPTUS THERAPEUTICS, INC.

Unaudited Condensed Consolidated Balance Sheets

	September 30, 2023	December 31, 2022	March 31, 2024	December 31, 2023
Assets				
Current assets:				
Cash and cash equivalents	$ 15,963,998	$ 9,626,800	$ 9,741,638	$ 13,362,053
Marketable securities	-	16,806,009		
Prepaid expenses and other current assets	879,524	811,433	551,031	633,156
Total current assets	16,843,522	27,244,242	10,292,669	13,995,209
Non-current assets:				
Property and equipment, net	1,055	2,019	-	735
Right-of-use asset	194,751	79,294	151,118	173,206
Other assets	754,728	738,251	504,728	754,728
Total non-current assets	950,534	819,564	655,846	928,669
Total assets	$ 17,794,056	$ 28,063,806	$ 10,948,515	$ 14,923,878
Liabilities and stockholders' equity				
Current liabilities:				
Accounts payable and other current liabilities	$ 2,264,062	$ 3,352,847	$ 1,434,828	$ 2,672,327
Operating lease liability, current portion	101,004	80,494	102,464	101,705
Total current liabilities	2,365,066	3,433,341	1,537,292	2,774,032
Non-current liabilities:				
Operating lease liability, net of current portion	95,237	-	50,664	73,348
Total non-current liabilities	95,237	-	50,664	73,348
Total liabilities	2,460,303	3,433,341	1,587,956	2,847,380
Commitments and contingent liabilities (Note 7)				
Commitments and contingencies (Note 7)				
Stockholders' equity:				
Common stock: $0.01 par value, 200,000,000 shares authorized as of September 30, 2023 and December 31, 2022; 8,401,047 shares issued and outstanding as of September 30, 2023 and December 31, 2022	84,011	84,011		
Common stock: $0.01 par value, 200,000,000 shares authorized as of March 31, 2024 and December 31, 2023; 8,538,883 shares issued and outstanding as of March 31, 2024 and 8,401,047 shares issued and outstanding as of December 31, 2023			85,389	84,011
Additional paid in capital	56,664,118	54,443,705	58,499,003	57,409,643
Accumulated deficit	(41,414,376)	(29,993,685)	(49,223,833)	(45,417,156)
Accumulated other comprehensive income	-	96,434		

Total stockholders' equity	15,333,753	24,630,465	9,360,559	12,076,498
Total liabilities and stockholders' equity	$ 17,794,056	$ 28,063,806	$ 10,948,515	$ 14,923,878

See accompanying notes to the unaudited condensed consolidated financial statements

Unaudited Condensed Consolidated Statements of Operations and Comprehensive Loss

	2023	2022	2023	2022	Three Months Ended March 31,	
	Three Months Ended September 30,		Nine Months Ended September 30,			
	2023	2022	2023	2022	2024	2023
Operating expenses:						
Research and development	$ 2,226,688	$ 1,609,554	$ 5,587,073	$ 4,412,817	$ 1,591,142	$ 1,879,900
General and administrative	2,021,724	1,942,995	6,611,767	6,411,066	2,352,097	2,575,266
Total operating expenses	4,248,412	3,552,549	12,198,840	10,823,883	3,943,239	4,455,166
Loss from operations	(4,248,412)	(3,552,549)	(12,198,840)	(10,823,883)	(3,943,239)	(4,455,166)
Other income, net	326,024	86,184	778,149	156,862	136,562	201,928
Net loss	$ (3,922,388)	$ (3,466,365)	$ (11,420,691)	$ (10,667,021)	$ (3,806,677)	$ (4,253,238)
Net loss available to common stockholders per share of common stock, basic and diluted	$ (0.47)	$ (0.42)	$ (1.36)	$ (1.29)	$ (0.45)	$ (0.51)
Weighted average number of shares used in calculating net loss per share, basic and diluted	8,401,047	8,258,597	8,401,047	8,258,597	8,442,364	8,401,047
Net loss	$ (3,922,388)	$ (3,466,365)	$ (11,420,691)	$ (10,667,021)	$ (3,806,677)	$ (4,253,238)
Other comprehensive income:						
Reclassification adjustment for interest earned on marketable securities included in net loss	(140,567)	(7,836)	(430,993)	(7,836)	-	(129,229)
Change in unrealized gain on marketable securities	6,412	49,904	334,559	22,967	-	210,252

Comprehensive loss	$ (4,056,543)	$ (3,424,297)	$ (11,517,125)	$ (10,651,890)	$ (3,806,677)	$ (4,172,215)

See accompanying notes to the unaudited condensed consolidated financial statements

INDAPTUS THERAPEUTICS, INC.

Unaudited Condensed Consolidated Statements of Stockholders' Equity

	Shares	Amount	capital	deficit	Income (Loss)	Total				
	Common stock		Additional paid in	Accumulated	Other Comprehensive		Common stock		Additional paid in	Accumulated
	Shares	Amount	capital	deficit	Income (Loss)	Total	Shares	Amount	capital	deficit
Balance, January 1, 2022	8,258,597	$ 82,586	$ 51,487,881	$ (15,670,887)	$ -	$ 35,899,580				
Stock-based compensation	-	-	831,183	-	-	831,183				
Other comprehensive loss	-	-	-	-	(9,221)	(9,221)				
Net loss	-	-	-	(3,365,154)	-	(3,365,154)				
Balance, March 31, 2022	8,258,597	82,586	52,319,064	(19,036,041)	(9,221)	33,356,388				
Stock-based compensation	-	-	904,395	-	-	904,395				
Other comprehensive loss	-	-	-	-	(17,716)	(17,716)				
Net loss	-	-	-	(3,835,502)	-	(3,835,502)				
Balance, June 30, 2022	8,258,597	82,586	53,223,459	(22,871,543)	(26,937)	30,407,565				
Stock-based compensation	-	-	584,041	-	-	584,041				
Reclassification adjustment for interest earned on marketable securities included in net loss	-	-	-	-	(7,836)	(7,836)				
Change in unrealized gain on marketable securities	-	-	-	-	49,904	49,904				
Net loss	-	-	-	(3,466,365)	-	(3,466,365)				
Balance, September 30, 2022	8,258,597	$ 82,586	$ 53,807,500	$ (26,337,908)	$ 15,131	$ 27,567,309				
Balance, January 1, 2023	8,401,047	$ 84,011	$ 54,443,705	$ (29,993,685)	$ 96,434	$ 24,630,465	8,401,047	$ 84,011	$ 54,443,705	$ (29,993,685
Stock-based compensation	-	-	727,144	-	-	727,144	-	-	727,144	-

Reclassification adjustment for interest earned on marketable securities included in net loss	-	-	-	-	(129,229)	(129,229)	-	-	-	-
Change in unrealized gain on marketable securities	-	-	-	-	210,252	210,252	-	-	-	-
Net loss	-	-	-	(4,253,238)	-	(4,253,238)	-	-	-	(4,253,238
Balance, March 31, 2023	8,401,047	84,011	55,170,849	(34,246,923)	177,457	21,185,394	8,401,047	$ 84,011	$ 55,170,849	$ (34,246,923
Balance, January 1, 2024							8,401,047	$ 84,011	$ 57,409,643	$ (45,417,156
Balance							8,401,047	$ 84,011	$ 57,409,643	$ (45,417,156
Stock-based compensation	-	-	728,466	-	-	728,466	-	-	774,691	-
Reclassification adjustment for interest earned on marketable securities included in net loss	-	-	-	-	(161,197)	(161,197)				
Change in unrealized gain on marketable securities	-	-	-	-	117,895	117,895				
Issuance of shares of common stock, net of issuance costs (Note 6)							137,836	1,378	314,669	-
Net loss	-	-	-	(3,245,065)	-	(3,245,065)	-	-	-	(3,806,677
Balance, June 30, 2023	8,401,047	84,011	55,899,315	(37,491,988)	134,155	18,625,493				
Balance, March 31, 2024							8,538,883	$ 85,389	$ 58,499,003	$ (49,223,833
Balance	8,401,047	$ 84,011	$ 55,899,315	$ (37,491,988)	$ 134,155	$ 18,625,493	8,538,883	$ 85,389	$ 58,499,003	$ (49,223,833
Stock-based compensation	-	-	764,803	-	-	764,803				
Reclassification adjustment for interest earned on marketable securities included in net loss	-	-	-	-	(140,567)	(140,567)				
Change in unrealized gain on marketable securities	-	-	-	-	6,412	6,412				
Net loss	-	-	-	(3,922,388)	-	(3,922,388)				

Balance, September 30, 2023	8,401,047	$ 84,011	$ 56,664,118	$ (41,414,376)	$ -	$ 15,333,753
Balance	8,401,047	$ 84,011	56,664,118	(41,414,376)	-	15,333,753

See accompanying notes to the unaudited condensed consolidated financial statements

INDAPTUS THERAPEUTICS, INC.

Unaudited Condensed Consolidated Statements of Cash Flows

	2023	2022		
	For the Nine Months Ended September 30,		For the three months ended March 31,	
	2023	2022	2024	2023
Cash flows from operating activities:				
Net loss	$ (11,420,691)	$ (10,667,021)	$ (3,806,677)	$ (4,253,238)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation	964	1,460	735	321
Stock-based compensation	2,220,413	2,319,619	774,691	727,144
Interest earned on marketable securities	(430,993)	(7,836)	-	(129,229)
Realized gain on assets held for sale	-	(24,155)		
Changes in operating assets and liabilities:				
Prepaid expenses and other current assets	(84,568)	(26,739)		
Prepaid expenses and other assets			332,125	324,205
Accounts payable and other current liabilities	(1,088,785)	(1,725,592)	(1,237,499)	(1,630,225)
Other assets	-	(738,251)		
Operating lease right-of-use asset and liability, net	290	1,081	163	(1,200)
Net cash used in operating activities	(10,803,370)	(10,867,434)	(3,936,462)	(4,962,222)
Cash flows from investing activities:				
Proceeds received for assets held for sale	-	172,555		
Maturity of marketable securities including interest earned	24,000,000	2,000,000		
Maturity of marketable securities			-	9,000,000
Purchase of marketable securities	(6,859,432)	(23,719,073)	-	(6,859,432)
Net cash provided by (used in) investing activities	17,140,568	(21,546,518)		
Net cash provided by investing activities			-	2,140,568
Net increase (decrease) in cash and cash equivalents	6,337,198	(32,413,952)		
Cash flows from financing activities:				-
Issuance of shares of common stock			336,044	
Issuance costs			(19,997)	-

Net cash provided by financing activities			316,047	-
Net decrease in cash and cash equivalents			(3,620,415)	(2,821,654)
Cash and cash equivalents at beginning of period	9,626,800	39,132,165	13,362,053	9,626,800
Cash and cash equivalents at end of period	$ 15,963,998	$ 6,718,213	$ 9,741,638	$ 6,805,146
Noncash investing and financing activities				
Change in unrealized gain/loss on marketable securities	$ (96,434)	$ -		
Change in accumulated other comprehensive income			$ -	$ 81,023
ASC 842 lease renewal option exercise	$ 236,506	$ -	$ -	$ 236,506
Reclassification of security deposit	$ 16,477	$ -	$ -	$ 16,477
Supplemental disclosures				
Cash paid for income taxes	$ 1,600	$ 2,400		
Cash received for interest earned on deposits	$ 317,261	$ 70,353		

See accompanying notes to the unaudited condensed consolidated financial statements

NOTE 1: GENERAL

Indaptus Therapeutics, Inc. and its wholly-owned subsidiaries, Decoy Biosystems, Inc. and Intec Pharma Ltd., collectively (the "Company"), is a biotechnology company dedicated to enhancing and expanding curative cancer immunotherapy for patients with unresectable or metastatic solid tumors and lymphomas, which are responsible for more than 90% of all cancer deaths. The Company is developing a novel, multi-targeted product that activates both innate and adaptive anti-tumor and anti-viral immune responses.

Risks and uncertainties

The Company is subject to a number of risks similar to those of other companies of similar size in its industry, including, but not limited to, the need for successful development of products, the need for additional capital (or financing) to fund operating losses operations (see below), competition from substitute products and services from larger companies, protection of proprietary technology, patent litigation, and dependence on key individuals.
The Company is subject to general conditions and macroeconomic factors in the global economy including increasing concerns over banking failures and bailouts and their potential broader effect on the banking sector generally and on the biotechnology industry. Additionally, inflation, rising interest rates, overall economic conditions and uncertainties, and the risk of a severe or prolonged economic downturn could result in a variety of risks, including the Company's ability to raise additional funding on a timely basis or on acceptable terms and may additionally impact third parties upon which the Company relies to carry out its operations.

Going concern and management's plans

The Company has incurred net losses and utilized cash in operations since inception. For the nine months three-month period ended September 30, 2023 March 31, 2024, the Company incurred a net loss of approximately $11.4 3.8 million, and as of September 30, 2023 March 31, 2024, the Company had an accumulated deficit of approximately $41.4 49.2 million. In addition, during the nine months three-month period ended September 30, 2023 March 31, 2024, the Company used approximately $10.8 3.9 million of cash in operations and expects to continue to incur significant cash outflows and incur future additional losses as clinical trials and commercialization of the Company's product candidates will require significant additional financing. The Company believes that, as of the date of the issuance of these unaudited condensed consolidated financial statements, it will not have adequate cash to fund its ongoing activities beyond the second third quarter of 2024 based on its current operating plan. The Company plans to execute its operating plan by obtaining additional capital, principally through entering into collaborations, strategic alliances, or license agreements with third parties and/or additional public or private debt and equity financing. However, there is no assurance that additional capital and/or financing will be available to the Company, and even if available, whether it will be on terms acceptable to the Company or in the amounts required. If the Company is unsuccessful in securing sufficient financing, it may need to delay, reduce, or eliminate its research and development programs, which could adversely affect its business prospects, or cease operations.

As a result of these uncertainties, there is substantial doubt about the Company's ability to continue as a going concern. The unaudited condensed consolidated financial statements do not include any adjustments to the carrying amounts and classifications of assets and liabilities that would result if the Company was unable to continue as a going concern.

NOTE 2: SIGNIFICANT ACCOUNTING POLICIES

Basis of presentation

The unaudited interim condensed consolidated financial statements of the Company have been prepared in accordance with accounting principles generally accepted in the United States of America ("US GAAP") and SEC Regulation S-X Article 10 for interim financial statements. Accordingly, they do not contain all the information and notes required by US GAAP for annual financial statements. In the opinion of management, these unaudited condensed consolidated interim financial statements reflect all adjustments, which include normal recurring adjustments, necessary for a fair statement of the Company's consolidated financial position as of September 30, 2023 March 31, 2024, and the consolidated results of operations and comprehensive loss and changes in stockholders' equity for the three- and nine-month three-month periods ended September 30, 2023 March 31, 2024 and 2022 2023 and cash flows for the nine-month three-month periods ended September 30, 2023 March 31, 2024 and 2022.

2023.

These unaudited interim condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2022 December 31, 2023, as filed with the SEC on March 17, 2023 March 13, 2024. The condensed consolidated balance sheet data as of December 31, 2022 December 31, 2023, included in these unaudited condensed consolidated financial statements was derived from the audited financial statements for the year ended December 31, 2022 December 31, 2023, but does not include all disclosures required by US GAAP for annual financial statements.

The results for the nine-month three-month period ended September 30, 2023 March 31, 2024, are not necessarily indicative of the results expected for the year ending December 31, 2023 December 31, 2024.

Principles of consolidation

The unaudited condensed consolidated financial statements include the accounts of Indaptus Therapeutics, Inc. and its subsidiaries. Intercompany balances and transactions have been eliminated upon consolidation.

Use of estimates

The preparation of the unaudited condensed consolidated financial statements in accordance with US GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent liabilities at the date of the financial statements, and the reported amounts of expenses during the reporting periods. The most significant estimates relate to the determination of the fair value of stock-based compensation and the determination of period-end obligations to certain contract research organizations. Management evaluates its estimates and assumptions on an ongoing basis using historical experience and other factors, including the current economic environment, and adjusts when facts and circumstances dictate. These estimates are based on information available as of the date of the condensed consolidated financial statements; therefore, actual results could differ from those estimates.

Loss per share

Loss per share, basic and diluted, is computed on the basis of the net loss for the period divided by the weighted average number of shares of common stock outstanding during the period. Diluted loss per share is based upon the weighted average number of shares of common stock and of common stock equivalents outstanding when dilutive. Common stock equivalents include outstanding stock options and warrants which are included under the treasury stock method when dilutive.

The following number of stock options and warrants were excluded from the calculation of diluted loss per share because their effect would have been anti-dilutive for the periods presented (share data):

	Weighted average					
	Three months ended September 30,		Nine months ended September 30,		For the three months ended March 31,	
	2023	2022	2023	2022	**2024**	**2023**
Outstanding stock options	2,034,562	1,608,837	1,955,182	1,543,931	2,315,272	1,873,929
Warrants	3,090,787	3,090,787	3,090,787	3,090,787	3,090,787	3,090,787

Research and development expenses

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

The Company accrues for expenses resulting from obligations under agreements with contract research organizations (“CROs”), contract manufacturing organizations (“CMOs”), and other outside service providers for which payment flows do not match the periods over which services or materials are provided to the Company. Accruals are recorded based on estimates of services received and efforts expended pursuant to agreements with CROs, CMOs, and other outside service providers. These estimates are typically based on contracted amounts applied to the proportion of work performed and determined through analysis with internal personnel and external service providers as to the progress or stage of completion of the services. In the event advance payments are made to a CRO, CMO, or outside service provider, the payments will be recorded as a prepaid expense, which will be amortized or expensed as the contracted services are performed.

Recently adopted issued accounting standard standards

In November 2023, the FASB issued ASU 2023-07, "Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures", which sets forth improvements to the current segment disclosure requirements in accordance with Topic 280 "Segment Reporting," including clarifying that entities with a single reportable segment are subject to both new and existing segment reporting requirements. ASU 2023-07 will be effective retrospectively for fiscal years beginning after December 15, 2023, and interim periods beginning after December 15, 2024. Adoption of this ASU is currently being evaluated by the Company.

On January 1, 2023, In December 2023, the Company adopted FASB issued ASU No. 2016-13, *Measurement 2023-09, "Income Taxes (Topic 740): Improvements to Income Tax Disclosures." ASU 2023-09 requires disaggregated information about a reporting entity's effective tax rate reconciliation as well as information on income taxes paid. ASU 2023-09 is effective for public entities with annual periods beginning after December 15, 2024, with early adoption permitted. The Company is currently evaluating the impact of Credit Losses on Financial Instruments*. This standard amended this guidance on the recognition of impairment losses of certain financial instruments. The ASU established the current expected credit loss model, which is based on expected losses rather than incurred losses. Adoption of this standard had no impact on the Company's condensed its consolidated financial statements.

NOTE 3: PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets are comprised of the following:

	September 30, 2023	December 31, 2022	March 31, 2024	December 31, 2023
Prepaid insurance	$ 737,881	$ 610,208	$ 323,572	$ 554,097
Prepaid research and development	19,457	80,910	114,749	17,309
Other prepaid expenses	122,186	120,315	112,710	61,750
Total prepaid expenses and other current assets	$ 879,524	$ 811,433	$ 551,031	$ 633,156
Prepaid expenses and other current assets			$ 551,031	$ 633,156

NOTE 4: ACCOUNTS PAYABLE AND OTHER CURRENT LIABILITIES

Accounts payable and other current liabilities are comprised of the following:

	September 30, 2023	December 31, 2022	March 31, 2024	December 31, 2023
Accounts payable	$ 617,270	$ 1,378,316	$ 405,457	$ 806,004
Accrued employee costs	795,183	1,216,242	374,446	1,213,054
Accrued professional fees	124,852	172,356	107,358	39,165
Accrued research and development	559,044	311,036	353,707	439,024
Accrued board fees	117,750	116,000	117,750	117,750
Delaware franchise taxes payable	30,000	128,929	50,000	40,000
Other accrued expenses	19,963	29,968	26,110	17,330
Total accounts payable and other current liabilities	$ 2,264,062	$ 3,352,847	$ 1,434,828	$ 2,672,327

NOTE 5: STOCK-BASED COMPENSATION

The Company has an equity incentive plan for grants to employees, officers, consultants, directors, and other service providers that was approved in 2021 (the "2021 Plan"). The maximum aggregate number of shares that may be issued pursuant to this 2021 Plan is 1,864,963shares (the "Pool"); provided, however that the Pool will increase on January 1 of each calendar year beginning on January 1, 2022 and ending on and including January 1, 2024 (each, an "Evergreen Date"), in an amount equal to the lesser of (i) 3% of the total number of shares of common stock outstanding on the December 31st immediately preceding the applicable Evergreen Date and (ii) such lesser number of shares of common stock as determined to be appropriate by the Committee (as defined in the 2021 Plan) in its sole discretion. . On January 1, 2022, January 1, 2023 and January 1, 2023, January 1, 2024 the Pool was increased by 247,758shares, 252,031 shares and 252,031shares, respectively. In no event shall more than 1,864,963 shares be available for issuance for Incentive Stock Options (as defined in the 2021 Plan) under the 2021 Plan.

The 2021 Plan provides for the grant of non-qualified stock options, incentive stock options, restricted stock awards, restricted stock units, unrestricted stock awards, stock appreciation rights and other forms of stock-based compensation. The 2021 Plan permits the Company's board to change the type, terms and conditions of awards as circumstances may change. This flexibility to adjust the type of compensation to be granted is particularly important given current economic and world events.

A summary of the stock option activity during the nine three months ended September 30, 2023 March 31, 2024, is presented in the table below:

	Number of options	Weighted average Exercise price	Weighted average Remaining contractual life (in years)	Intrinsic value
Outstanding as of January 1, 2023	1,672,873	$ 13.01	8.5	$ -
Granted	425,750	$ 1.70	-	$ -
Forfeited and cancelled	(48,426)	$ 4.34	-	$ -
Outstanding as of September 30, 2023	2,050,197	$ 10.86	8.1	$ 556,523
Exercisable as of September 30, 2023	1,080,701	$ 16.37	7.6	$ 62,993
Vested and expected to vest September 30, 2023	2,050,197	$ 10.86	8.1	$ 556,523

	Number of options	Weighted average Exercise price	Weighted average Remaining contractual life (in years)	Intrinsic value
Outstanding as of January 1, 2024	2,050,197	$ 10.90	7.9	$ 36,363
Granted	345,750	$ 1.74	-	$ -
Outstanding as of March 31, 2024	2,395,947	$ 9.50	7.9	$ 417,178
Exercisable as of March 31, 2024	1,386,339	$ 14.01	7.3	$ 69,060
Vested and expected to vest as of March 31, 2024	2,395,947	$ 9.50	7.9	$ 417,178

The following table summarizes the total stock-based compensation expense included in the condensed consolidated statements of operations for the periods presented:

	For the three months ended September 30,		For the nine months ended September 30,		2024 2023 For the three months ended March 31,	
	2023	2022	2023	2022	2024	2023
Research and development	$ 200,624	$ 217,379	$ 586,854	$ 602,069	$ 217,819	$ 192,544
General and administrative	564,179	366,662	1,633,559	1,717,550	556,872	534,600
Total stock-based compensation expense	$ 764,803	$ 584,041	$ 2,220,413	$ 2,319,619	$ 774,691	$ 727,144

As of September 30, 2023 March 31, 2024, total compensation cost not yet recognized related to unvested stock options was approximately $3.0 2.0 million which is expected to be recognized over a weighted-average weighted average period of 0.9 1.3 years.

The Company estimates the fair value of stock options on the date of grant using the Black-Scholes option-pricing model. The Black-Scholes option-pricing model requires estimates of highly subjective assumptions, which affect the fair value of each stock option. The weighted average inputs used to measure the value of the options granted during the nine three months ended September 30, 2023 March 31, 2024 are presented in the table below. The weighted average fair value of stock options issued during the nine three months ended September 30, 2023 March 31, 2024 was $1.43 1.49 per share.

	2023
Stock price	$ 1.70
Exercise price	$ 1.70
Expected term (in years)	5.8
Volatility	110.9%
Risk free rate	3.7%
Dividend yield	0%

	2024
Exercise price	$ 1.74
Expected term (in years)	5.9
Volatility	115.5%
Risk free rate	4.0%
Dividend yield	0%

The following table presents the exercise price of outstanding stock options as of September 30, 2023 March 31, 2024:

Exercise price	Options outstanding
$0.01 - $8.00	1,023,249 1,368,999
$8.01 - $16.00	992,250
$16.00 or higher	34,698
Total	2,050,197 2,395,947

NOTE 6: CAPITALIZATION

As of September 30, 2023 and December 31, 2022, the Company had 200,000,000 shares of common stock authorized and 8,401,047 shares of common stock issued and outstanding. As of September 30, 2023 and December 31, 2022, there were warrants outstanding to purchase an aggregate of 3,090,787 shares of common stock of Indaptus. As of September 30, 2023, these warrants are exercisable at a weighted average price of $12.50 and their weighted average remaining contractual term is 3.2 years.

a. As of March 31, 2024 and December 31, 2023, the Company had 200,000,000shares of common stock authorized and 8,538,883and 8,401,047shares issued and outstanding as of March 31, 2024 and December 31, 2023, respectively. As of March 31, 2024 and December 31, 2023, there were warrants outstanding to purchase an aggregate of 3,090,787shares of common stock. As of March 31, 2024, these warrants are exercisable at a weighted average price of $12.50and their weighted average remaining contractual term is 2.7years.

b. On June 1, 2022, the Company entered into an At The Market Offering Agreement (the “ATM Agreement”) which was amended on September 1, 2022 with a sales agent, pursuant to which the Company may offer and sell, from time to time through the sales agent, shares of the Company’s common stock, par value $0.01 per share. The issuance and sale of common stock by the Company under the ATM Agreement is being made pursuant to the Company’s effective “shelf” registration statement on Form S-3 filed with the SEC on September 1, 2022 and declared effective on September 9, 2022. In March 2024, the Company sold 137,836 shares of the Company’s common stock for aggregate gross proceeds of $0.3 million. The Company’s ability to issue shares under the shelf registration statement on Form S-3 is limited by General Instruction I.B.6 to Form S-3.

NOTE 7: COMMITMENTS AND CONTINGENCIES

Litigation

On July 13, 2022, LTS Lohmann Therapie Systeme AG ("LTS") filed a Request for Arbitration with the International Chamber of Commerce ("Request"), naming as respondent the Company's subsidiary, Intec Israel. The Request alleges that LTS is entitled to payment of Euro 2 million under a process development agreement ("PDA") following discontinuation of the former Accordion Pill business. Intec Israel had previously accrued this amount along with other related costs. In 2022, Intec Israel paid approximately Euro 1 million (approximately $1 million USD) towards the alleged obligation.

On February 7, 2023, Intec Israel settled the dispute with LTS by paying Euro 800,000 (approximately $860,000). As the settlement amount was less than the amount accrued, the Company also recognized other income of approximately Euro 345,000 (approximately $365,000) during the year ended December 31, 2022.

From time to time, the Company could become involved in additional disputes and various litigation matters that arise in the normal course of business. These may include disputes and lawsuits related to intellectual property, licensing, contract law and employee relations matters. Periodically, the Company reviews the status of significant matters, if any exist, and assesses its potential financial exposure. If the potential loss from any claim or legal claim is considered probable and the amount of such potential loss can be estimated, the Company accrues liability for the estimated loss. Legal proceedings are subject to uncertainties, and the outcomes are difficult to predict. Because of such uncertainties, accruals are based on the best information available at the time. As additional information becomes available, the Company reassesses the potential liability related to pending claims and litigation.

Leases

On October 1, 2021, Future minimum annual lease payments and a reconciliation to the Company entered into a noncancelable two-year Company's operating lease agreement for approximately 2,000 square feet of office space in San Diego, California. The base rent is $7,999 per month with an increase of 3% after the first anniversary of the lease term commencement, which was November 1, 2021.

On April 19, 2023, the Company executed an amendment to the lease agreement to extend the lease through October 31, 2025. Accordingly, the Company remeasured its operating lease liability under the agreement and recognized an incremental lease liability and right-of-use asset of $236,506. The remeasurement was based on a 9% incremental borrowing rate.

Future minimum lease payments for the years ending December 31, under the Company's noncancelable operating lease as of September 30, 2023 March 31, 2024 are as follows:

2023 (remaining)	$ 25,105	
2024	101,705	
2025	86,862	
2024 (remaining)		$ 76,406
2025 (lease ends October 31, 2025)		86,862
Total minimum lease payments	213,672	163,268
Less: amount representing interest	(17,431)	(10,140)
Present value of operating lease liability	196,241	153,128
Less: current portion	(101,004)	(102,464)
Operating lease liability, net of current portion	$ 95,237	$ 50,664

The Company recognized rent expense of $75,280 and $73,069 during the nine months ended September 30, 2023 and 2022, respectively. The Company recognized rent expense of $25,462 and $24,356 during the three months ended September 30, 2023 March 31, 2024 and 2022, 2023, respectively. Total cash payments for the operating lease totaled $74,148 25,300 and $71,989 24,716 during the nine three months ended September 30, 2023 March 31, 2024 and 2022, 2023, respectively.

NOTE 8: SUBSEQUENT EVENTS

The Company evaluated subsequent events from September 30, 2023 March 31, 2024, the date of these unaudited condensed consolidated financial statements, through November 6, 2023 May 8, 2024, which represents the date the condensed consolidated financial statements were issued, for events requiring recognition or disclosure in the condensed consolidated financial statements for the nine three months ended September 30, 2023 March 31, 2024. The Company concluded that no events have occurred that would require recognition or disclosure in the condensed consolidated financial statements.

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

Unless the context indicates otherwise, in this Quarterly Report, the terms "Indaptus," "the Company," "we," "us" and "our" refer to Indaptus Therapeutics, Inc. (formerly Intec Parent, Inc., the successor of Intec Pharma Ltd. following the domestication merger) and, where appropriate, its consolidated subsidiaries following the domestication merger and the reverse merger described in our previous periodic reports. References to "Intec Israel" refer to Intec Pharma Ltd., the predecessor of Indaptus prior to the domestication merger, and references to "Decoy" refer to Decoy Biosystems, Inc., the entity acquired by Indaptus in connection with the reverse merger.

You should read the following discussion and analysis of our financial condition and results of operations along with our consolidated financial statements and the related notes and other financial information included elsewhere in this Quarterly Report and our Annual Report on Form 10-K for the year ended December 31, 2022 December 31, 2023 filed with the Securities and Exchange Commission ("SEC") on March 17, 2023 March 13, 2024 (the "2022 "2023 Annual Report on Form 10-K"). The following discussion contains forward-looking statements that are subject to risks, uncertainties and assumptions. You should review the sections titled "Summary Risk Factors" and Part II. Item 1A. Risk Factors" Factors in this Quarterly Report for a discussion of important factors that could cause actual results to differ materially from the results described below. Please also see the "Cautionary Note Regarding Forward-Looking Statements" section in the forepart of this Quarterly Report.

Overview

We are a clinical biotechnology company developing a novel and patented systemically-administered anti-cancer and anti-viral immunotherapy. We have evolved from more than a century of immunotherapy advances. Our approach is based on the hypothesis that efficient activation of both innate and adaptive immune cells and associated anti-tumor and anti-viral immune responses will require a multi-targeted package of immune system activating signals that can be administered safely intravenously. Our patented technology is composed of single strains of attenuated and killed, non-pathogenic, Gram-negative bacteria, designed to have reduced i.v. toxicity, but largely uncompromised ability to prime or activate many of the cellular components of innate and adaptive immunity. This approach has led to broad anti-tumor and anti-viral activity in preclinical models, including durable anti-tumor response synergy observed with each of five four different classes of existing agents, including NSAIDs, checkpoint therapy, targeted antibody therapy and low-dose chemotherapy. Tumor eradication by our technology has demonstrated activation was associated with induction of both innate and adaptive immunological memory and, importantly, did not require provision of or targeting a tumor antigen in pre-clinical preclinical models. We have carried out successful current cGMP Good Manufacturing Practice (cGMP) manufacturing of our lead clinical candidate, Decoy20, and completed other IND-enabling studies. Decoy20.

In May 2022, the U.S. Food and Drug Administration, or the FDA, cleared allowed us to proceed under our Investigational New Drug, or IND application for a Phase 1 clinical trial in patients with advanced solid tumors where currently approved therapies have failed, and in December 2022, we initiated this Phase 1 clinical trial which is an open label, multi-center, dose escalation and expansion, single arm (monotherapy) study conducted in 2 parts. The Phase 1 study has begun with a single dose escalation, which is planned to be followed by an expansion part with continuous weekly administration of Decoy20. The study is enrolling patients with advanced/metastatic solid tumors, who have exhausted approved treatment options. The study's objectives are to assess the safety and tolerability of Decoy20, to determine the maximum tolerated dose and recommended Phase 2 dose, as well as to assess Decoy20 pharmacokinetics ("PK") (PK), pharmacodynamics and clinical activity. The primary endpoint endpoints of the study is are incidence, relatedness and severity of adverse events and treatment-emergent adverse events and determining the number of subjects per cohort with dose limiting toxicity-based adverse events. Secondary endpoints include the incidence of anti-drug antibodies and neutralizing antibodies pre- and post-treatment, change in Decoy20 PK parameters over time, objective response rate in subjects with measurable disease and duration of response.

In August 2023, we completed the first cohort of patients who received a single dose in Part 1 of the Phase 1 clinical trial. Four patients were enrolled and evaluable in the first cohort. Overall, These patients experienced symptoms or generally anticipated transient adverse events (AEs) including hemodynamic changes such as changes in pulse or blood pressure that were short-lived resolved within 30 minutes and consistent laboratory abnormalities such as grade 1-3 elevations in transaminases (liver function tests) and grade 4 reductions in lymphocytes that generally resolved within three days. One patient had a dose-limiting toxicity of grade 3 bradycardia (slow heart rate) and grade 2 hypotension (low blood pressure) which resolved within approximately 90 minutes with i.v. fluids. Patients also experienced transient induction of over 50 different biomarkers associated with innate and adaptive anti-tumor immune responses. After the mechanism end of action of Decoy20. infusion, Decoy20 was cleared from the blood within 30 to 120 minutes. Peak cytokine and chemokine induction occurred within ~4 to 24 hours and most subjects returned to baseline by 24-72 hours. This rapid clearance and associated transient cytokine/chemokine induction are desired to avoid prolonged toxicity, often associated with longer term cytokine exposure.

In September 2023, we advanced into the second cohort of the Phase 1 clinical trial after receiving authorization from the Safety Review Committee. In early March 2024, we completed the second cohort of patients who received a single dose in Part 1 of the Phase 1 clinical trial and, following authorization from the Safety Review Committee, advanced into the multi-dosing part of the Phase 1 clinical trial. The second cohort dose is a reduction from the dosing in the first cohort based on the significant pharmacodynamic effect seen with the first cohort and anticipated optimal Decoy20 safety profile for both weekly dosing multi-dosing and combination approaches. As we continue to analyze the data generated, we anticipate that the data from the dose finding studies will guide the selection for the recommended Phase 2 dose for subsequent multi-dosing and combination studies, which are planned for 2024.

Impact of Macroeconomic Conditions on our Operations

Economic developments such as supply chain constraints and rising inflation and interest rates have negatively affected the global financial markets and may reduce our ability to access capital, which could negatively impact our short-term and long-term liquidity. The ultimate impact of the current economic downturn conditions is highly uncertain and subject to change. While it is unknown how long these conditions will last and what the complete financial effect will be to us, capital raise efforts and additional development of our technologies may be negatively affected. In addition, our business operations expose us to risks associated with public health crises and epidemics/pandemics, such as COVID-19. A resurgence of the COVID-19 pandemic or any new public health crisis could again affect our operations and those of third parties on which we rely, including by causing disruptions in the supply of our product candidates and the conduct of current and future clinical trials.

Components of Operating Results

Operating Expenses

Research and Development

Research and development expenses account for a significant portion of our operating expenses. Research and development expenses consist primarily of fees paid to contract research organizations, or CROs, and contract manufacturing organizations, or CMOs, as well as compensation expenses for certain employees involved in the planning, managing, and analyzing the work of the CROs and CMOs and materials used for research and development activities. We expense research and development costs as incurred.

We accrue expenses for manufacturing, preclinical studies and clinical trial activities performed by third parties based on estimates of services received and efforts expensed expended pursuant to agreements with CROs, CMOs, and other outside service providers. We determine these estimates based on contracted amounts applied to the proportion of work performed and determined through analysis with internal personnel and external service providers as to the progress or stage of completion of the services. In the event advance payments are made to a CRO, CMO, or outside service provider, we record the payments as a prepaid asset, which will be amortized or expensed as the contracted services are performed. However, actual costs and timing of these activities are highly uncertain, subject to risks and may change depending upon a number of factors, including our clinical development plan.

We expect our research and development expenses to increase substantially for the foreseeable future as we continue to ramp up our clinical development activities and incur expenses associated with hiring additional personnel to support our research and development efforts. Our expenditures on future nonclinical and clinical development programs are subject to numerous uncertainties in timing and cost to completion. The duration, costs and timing of pre-clinical preclinical studies and clinical trials and development of product candidates will depend on a variety of factors, including:

- the timing and receipt of regulatory approvals; approvals;
- the scope, rate of progress and expenses of pre-clinical preclinical studies and clinical trials and other research and development activities; activities;
- potential safety monitoring and other studies requested by regulatory agencies; agencies; and
- significant and changing government regulation.

The process of conducting the necessary clinical research to obtain FDA and other regulatory approval is costly and time consuming and the successful development of product candidates is highly uncertain. These risks and uncertainties associated with our research and development projects are discussed more fully in "Part II. Part I. Item 1A. Risk "Risk Factors - *We expect to continue to incur significant research and development expenses and other operating expenses, which may make it difficult for us to attain profitability.*" As a result of these risks and uncertainties, we are unable to determine with any degree of certainty the duration and completion costs of our research and development projects, or if, when, or to what extent we will generate revenues from the commercialization and sale of any of our product candidates that obtain regulatory approval. We may never succeed in achieving regulatory approval for any of our product candidates.

General and Administrative Expenses

General and administrative expenses include compensation, employee benefits, and stock-based compensation for executive management, finance administration and human resources, facility costs (including rent), professional service fees, and other general overhead costs, including depreciation, to support our operations.

We expect our general and administrative expenses to increase substantially for the foreseeable future as we continue to increase our headcount to support our research and development activities and operations generally, the growth of our business and, if any of our product candidates receive marketing approval, commercialization activities. We also expect to continue to incur additional expenses as a result of operating as a public company, including expenses related to compliance with the rules and regulations of the SEC, additional director and officer insurance expenses, investor relations activities, and other administrative and professional services.

Other Income, Net

Other income, net includes interest earned on deposits and investments and other items of income, expense, gain and loss that are incidental to the core operations of the Company.

Results of Operations

Three months ended September 30, 2023 March 31, 2024 compared to three months ended September 30, 2022 March 31, 2023

The following tables sets forth our results of operations for the three months ended September 30, 2023 March 31, 2024 and 2022 2023 and the relative dollar change between the two periods.

	Three months ended September 30,		Change		Three months ended March 31,		Change	
	2023	2022	$	%	2024	2023	$	%
Operating expenses:								
Research and development	$ 2,226,688	$ 1,609,554	$ 617,134	38%	$ 1,591,142	$ 1,879,900	$ (288,758)	(15)%
General and administrative	2,021,724	1,942,995	78,729	4%	2,352,097	2,575,266	(223,169)	(9)%
Total operating expenses	4,248,412	3,552,549	695,863	20%	3,943,239	4,455,166	(511,927)	(11)%
Loss from operations	(4,248,412)	(3,552,549)	(695,863)	20%	(3,943,239)	(4,455,166)	511,927	(11)%
Other income, net	326,024	86,184	239,840	278%	136,562	201,928	(65,366)	(32)%
Net loss	$ (3,922,388)	$ (3,466,365)	$ (456,023)	13%	$ (3,806,677)	$ (4,253,238)	$ 446,561	(10)%
Net loss attributable to common stockholders per share, basic and diluted	$ (0.47)	$ (0.42)	$ (0.05)	12%	$ (0.45)	$ (0.51)	$ 0.06	(12)%
Weighted average number of shares used in calculating net loss per share, basic and diluted	8,401,047	8,258,597			8,442,364	8,401,047		

Research and Development Expenses

Our research and development expenses for the three months ended September 30, 2023 March 31, 2024 amounted to approximately $2.2 million $1.6 million, an increase a decrease of approximately $600,000, $0.3 million, or approximately 38% 15%, compared to approximately $1.6 million $1.9 million for the three months ended September 30, 2022 March 31, 2023. This increase decrease was attributable primarily to our Phase 1 clinical trial and manufacturing processes of Decoy20 that were conducted in the activities related to the expansion of our pipelinethree months ended March 31, 2023. We expect our research and development expenses to increase for the remainder of the year as our Phase 1 clinical trial progresses.

General and Administrative Expenses

During Our general and administrative expenses for the three months ended September 30, 2023 March 31, 2024 amounted to approximately $2.4 million, our general a decrease of approximately $0.2 million, or approximately 9%, compared to approximately $2.6 million for the three months ended March 31, 2023. This decrease was attributable primarily to a decrease of approximately $0.5 million in legal fees, recruitment costs and administrative for directors' and officers' insurance expenses, were approximately $2.0 million, which represented and was offset by an increase of approximately $80,000 as compared to the three months ended September 30, 2022. $0.3 million in payroll and related expenses and investor relations expenses. We expect our general and administrative expenses to increase for the remainder of the year as we continue to support our research and development activities.

Other Income, Net

Other income, net increased in During the three months ended September 30, 2023 compared to the same period in 2022 primarily as a result of increased interest rates in the current period that increased interest earned on deposits and interest earned on marketable securities.

Nine months ended September 30, 2023 compared to nine months ended September 30, 2022

The following tables sets forth March 31, 2024, our results of operations for the nine months ended September 30, 2023 and 2022 and the relative dollar change between the two periods.

	Nine months ended September 30,		Change	
	2023	2022	$	%
Operating expenses:				
Research and development	$ 5,587,073	$ 4,412,817	$ 1,174,256	27%
General and administrative	6,611,767	6,411,066	200,701	3%
Total operating expenses	12,198,840	10,823,883	1,374,957	13%
Loss from operations	(12,198,840)	(10,823,883)	(1,374,957)	13%
Other income, net	778,149	156,862	621,287	396%
Net loss	$ (11,420,691)	$ (10,667,021)	$ (754,670)	7%
Net loss attributable to common stockholders per share, basic and diluted	$ (1.36)	$ (1.29)	$ (0.07)	5%
Weighted average number of shares used in calculating net loss per share, basic and diluted	8,401,047	8,258,597		

Research and Development Expenses

Our research and development expenses for the nine months ended September 30, 2023 amounted to other income, net was approximately $5.6 million $0.1 million, an increase of approximately $1.2 million, or approximately 27%, compared to approximately $4.4 million for the nine months ended September 30, 2022. This increase was attributable primarily to our Phase 1 clinical trial and activities related to the expansion of our pipeline. We expect our research and development expenses to increase for the remainder of the year as our Phase 1 clinical trial progresses.

General and Administrative Expenses

Our general and administrative expenses for the nine months ended September 30, 2023 amounted to approximately $6.6 million, an increase of approximately $200,000, or approximately 3%, compared to approximately $6.4 million for the nine months ended September 30, 2022. This increase was attributable primarily to an increase of approximately $540,000 for legal fees, payroll and related expenses, recruitment costs and other professional fees, which were partially offset by represented a decrease of approximately $340,000 in directors' and officers' insurance expenses. $0.1 millionWe expect our general and administrative expenses to increase for the remainder of the year as we continue to support our research and development activities.

Other Income, Net

Other income, net increased in the nine months ended September 30, 2023 compared to the same period in 2022 primarily as a result of increased interest rates three months ended March 31, 2023. The other income generated in the current period that increased interest consists primarily of income earned on deposits the Company's cash and interest earned on marketable securities. cash equivalent accounts.

Liquidity and Resources

We do not currently have any approved products and have never generated any revenue from product sales. Since our inception, we have funded our operations primarily through public and private offerings of our equity securities.

In August 2021, we sold a pre-funded warrant to purchase 2,727,273 shares of our common stock and a warrant to purchase 2,727,273 shares of our common stock in a private placement. The warrant was exercisable at an exercise price of $11.00 per share. In September 2021, the pre-funded warrant was fully exercised at an exercise price of $0.01 per share. The pre-funded warrant and the warrant were sold together at a combined price of $11.00, including the pre-funded exercise price. The total net proceeds to us were approximately $27.3 million, after deducting placement agent fees and offering expenses in the amount of approximately $2.7 million.

In June 2022, we entered into an At The Market Offering Agreement (the "ATM Agreement") which was amended on September 1, 2022 with H.C. Wainwright & Co., LLC, as sales agent ("Wainwright"), pursuant to which based on the prospectus supplement that was filed with the SEC on March 13, 2024, we may offer and sell, from time to time through Wainwright, shares of our common stock, par value $0.01 per share, for aggregate gross proceeds of up to $6.3 million $5.2 million. The issuance and sale of common stock by us under the ATM Agreement is being made pursuant to our effective "shelf" registration statement on Form S-3 filed with the SEC on September 1, 2022 and declared effective on September 9, 2022. No In March 2024, we sold 137,836 shares of our common stock have been sold to date under the ATM Agreement. for aggregate gross proceeds of $0.3 million.

On December 22, 2022, In December 2022, we entered into a purchase agreement and a registration rights agreement with Lincoln Park Capital Fund, LLC ("Lincoln Park"), pursuant to which we have the right, but not the obligation, to sell to Lincoln Park, and Lincoln Park is obligated to purchase from us up to an aggregate of $20.0 million of our common stock (subject to certain limitations) from time to time over the term of the purchase agreement. We also filed a registration statement on Form S-1 to cover the resale of shares of our common stock issuable under the purchase agreement.

Upon execution of the purchase agreement, we issued to Lincoln Park 142,450 initial commitment shares and are obligated to issue additional shares of common stock to Lincoln Park with a value of $125,000, calculated in accordance with the purchase agreement, on the date we have sold over $10.0 million in shares of common stock under the purchase agreement, up to a maximum of 76,220 shares of common stock (to be appropriately adjusted for any reorganization, recapitalization, non-cash dividend, stock split, reverse stock split or other similar transaction), in each case as consideration for Lincoln Park's irrevocable commitment to purchase shares of our common stock at our direction under the purchase agreement. Additionally, we have reserved up to 3,781,330 shares of our common stock for issuance and sale to Lincoln Park under the purchase agreement from time to time, if and when we determine to sell additional shares to Lincoln Park. No shares of common stock have been sold to Lincoln Park to date. under the program.

As of September 30, 2023 March 31, 2024, we had approximately $16.0 million in cash and cash equivalents of approximately $9.7 million, which we believe will enable us to fund our operating expenses and capital expenditure requirements into through the second third quarter of 2024. While we intend to finance our cash needs principally through collaborations, strategic alliances, or license agreements with third parties and/or debt or equity financings, we cannot provide any assurance that new financing will be available to us on commercially acceptable terms or in the amounts required, if at all. These conditions raise substantial doubt regarding our ability to continue as a going concern within one year after the date of the filing of this Quarterly Report. For additional information, see Note 1 to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report. Report. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect.

We have no ongoing material financing commitments, such as lines of credit or guarantees, that are expected to affect our liquidity over the next five years.

Cash Flows

Operating Activities

Net cash used in operating activities was approximately $10.8 million $3.9 million for the nine three months ended September 30, 2023 March 31, 2024, compared with net cash used in operating activities of approximately $10.9 million $4.9 million for the nine three months ended September 30, 2022 March 31, 2023.

Investing Activities

Net The decrease in net cash provided by investing used was primarily attributable to a decrease in our research and development activities, was approximately $17.1 million for the nine months ended September 30, 2023, which was mostly related to the maturity our manufacturing processes of $24.0 million Decoy20, and a decrease in marketable securities, offset by our general and administrative expenses. The decrease in net investment of approximately $6.9 million in marketable securities. Net cash used was also attributable to the settlement fee that was paid in investing activities was approximately $21.5 million for the nine months ended September 30, 2022, which was primarily related to net investment in marketable securities in the amount of approximately $23.7 million, offset by approximately $0.2 million from the proceeds received for assets held for sale and by $2.0 million from the maturity of marketable securities. February 2023.

Financing Investing Activities

There was no net cash provided by or used in investing activities in the three months ended March 31, 2024. Net cash provided by investing activities was approximately $2.1 million for the three months ended March 31, 2023, which was related to the maturity of $9.0 million in marketable securities, offset by net investment of approximately $6.9 million in marketable securities.

Financing Activities

Net cash provided by financing activities for the three months ended March 31, 2024 was approximately $0.3 million, which was provided by issuance and sale of our common stock under the ATM Agreement. There was no net cash provided by or used in financing activities in the nine three months ended September 30, 2023 and 2022. March 31, 2023.

Funding Requirements

Our operating expenses have increased substantially since 2022 and are expected to continue to increase in the future in connection with our ongoing activities, particularly as we expect our research and development expenses to increase substantially as we continue to ramp up our clinical development activities and incur expenses associated with our Phase 1 clinical trial and with hiring additional personnel to support our research and development efforts. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. Furthermore, we expect to continue to incur significant costs associated with operating as a public company.

We believe that our existing cash and cash equivalents as of March 31, 2024 are adequate to fund our ongoing activities through the third quarter of 2024.

Our future capital requirements will depend on many factors, including, but not limited to:

- the scope, progress, results and costs of preclinical studies and clinical trials;
- the scope, prioritization and number of our clinical trials and other research and development programs;
- the amount of revenues we receive under future licensing, collaboration, development and commercialization arrangements with respect to our product candidates;
- the impact of any pandemic, such as the COVID-19 pandemic, epidemic or other future health crisis on our business and operations;
- the costs of the development and expansion of our operational infrastructure;
- the costs, timing and outcome of regulatory review of our product candidates;
- the ability of us, or our collaborators, to achieve development milestones, marketing approval and other events or developments under our potential future licensing agreements;

- the costs of filing, prosecuting, enforcing and defending patent claims and other intellectual property rights; rights;
- the costs and timing of securing manufacturing arrangements for clinical or commercial production; production;
    - the costs of contracting with third parties to provide sales and marketing capabilities for us or establishing such capabilities ourselves; ourselves;
    - the costs of acquiring or undertaking development and commercialization efforts for any future products, product candidates or technology; technology;
    - the magnitude of our general and administrative expenses; expenses; and
    - any cost that we may incur under future in- and out-licensing arrangements relating to one or more of our product candidates.

Identifying potential product candidates and conducting preclinical studies and clinical trials is a time-consuming, expensive and uncertain process that takes many years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of product candidates that we do not expect to be commercially available for the next couple of years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all. For example, the trading prices for our and other biopharmaceutical companies' stock have been highly volatile as a result of current macroeconomic conditions and market volatility. As a result, we may face difficulties raising capital through sales of our common stock on acceptable terms, if at all. If we are unsuccessful in securing sufficient financing, we may need to delay, reduce, or eliminate our research and development programs, which could adversely affect our business prospects, or cease operations. For additional information, see Note 1 to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report and "Risk Factors" in Part II. Item 1A of this Quarterly Report.

Contractual Obligations

Operating lease liabilities represent our commitment for future rent made under a non-cancelable lease for our offices in San Diego, CA. The total future payments for our operating lease obligation on September 30, 2023 March 31, 2024 were approximately $214,000, $0.15 million, of which approximately $101,000 $0.1 million is due in the next twelve months and the remaining payments are due over the following years. through October 2025. For additional details regarding our lease, see Note 7 to our unaudited condensed consolidated financial statements included in this Quarterly Report.

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

Critical Accounting Policies

This discussion and analysis of our financial condition and results of operations is based on our unaudited condensed consolidated financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these unaudited condensed consolidated financial statements requires us to make estimates that affect the reported amounts of our assets, liabilities and expenses. Significant accounting policies employed, including the use of estimates, are presented in the notes to our annual financial statements included in our 2022 2023 Annual Report on Form 10-K. We periodically evaluate our estimates, which are based on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. Critical accounting policies are those that are most important to the portrayal of our financial condition and results of operations and require our subjective or complex judgments, resulting in the need to make estimates about the effect of matters that are inherently uncertain. If actual performance should differ from historical experience or if the underlying assumptions were to change, our financial condition and results of operations may be materially impacted.

Our critical accounting policies are described under the heading “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Policies” in our 2022 2023 Annual Report on Form 10-K. During the nine three months ended September 30, 2023 March 31, 2024, there were no material changes to our critical accounting policies from those discussed in our 2022 2023 Annual Report on Form 10-K.

Recently Adopted Issued Accounting Standard

On January 1, 2023 In November 2023, the FASB issued ASU 2023-07, "Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures", we adopted ASU No. 2016-13, Measurement of Credit Losses on Financial Instruments. This standard amended guidance on the recognition of impairment losses of certain financial instruments. The ASU established which sets forth improvements to the current expected credit loss model, which is based on expected losses rather than incurred losses. segment disclosure requirements in accordance with Topic 280 "Segment Reporting," including clarifying that entities with a single reportable segment are subject to both new and existing segment reporting requirements. ASU 2023-07 will be effective retrospectively for fiscal years beginning after December 15, 2023, and interim periods beginning after December 15, 2024. Adoption of this standard had no ASU is currently being evaluated.

In December 2023, the FASB issued ASU No. 2023-09, "Income Taxes (Topic 740): Improvements to Income Tax Disclosures." ASU 2023-09 requires disaggregated information about a reporting entity's effective tax rate reconciliation as well as information on income taxes paid. ASU 2023-09 is effective for public entities with annual periods beginning after December 15, 2024, with early adoption permitted. We are currently evaluating the impact of this guidance on our unaudited condensed consolidated financial statements.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

We are a smaller reporting company as defined in Rule 12b-2 of the Securities Exchange Act of 1934, as amended (the "Exchange Act") and are not required to provide the information otherwise required under this Item 3.

Item 4. Controls and Procedures

Limitations on Effectiveness of Controls and Procedures

In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints, and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and principal financial officer, evaluated, as of September 30, 2023 March 31, 2024, the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). Based on that evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of September 30, 2023 March 31, 2024.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended September 30, 2023 March 31, 2024 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we may become involved in various lawsuits and legal proceedings, which arise in the ordinary course of business. Litigation is subject to inherent uncertainties, and an adverse result in these or other matters may arise from time to time that may harm our business.

There are currently no pending material legal proceedings, and we are currently not aware of any legal proceedings or claims against us or our property that we believe will have any significant effect on our business, financial position or operating results. None of our officers or directors is a party against us in any legal proceeding.

Item 1A. Risk Factors

You should carefully consider the factors described below, together with all of the other information contained in this Quarterly Report, including the unaudited condensed consolidated financial statements and the related notes included in this Quarterly Report beginning on page F-1, before deciding whether to invest in our common stock. If any of the risks discussed below actually occur, our business, financial condition, operating results and cash flows could be materially adversely affected. This could cause the trading price of our common stock to decline, and you may lose all or part of your investment.

Risks Related to Our Financial Position and Capital Requirements

We are a clinical-stage company with a limited operating history. We are not currently profitable, do not expect to become profitable in the near future and may never become profitable.

We are a clinical-stage biotechnology company focused primarily on developing a novel and patented systemically-administered anti-cancer and anti-viral immunotherapy. All of our product candidates are in the pre-clinical preclinical or early clinical development stage, and none of our product candidates have been approved for marketing or are being marketed or commercialized.

As a result, we have no meaningful historical operations upon which to evaluate our business and prospects and have not yet demonstrated an ability to obtain marketing approval for any of our product candidates or successfully overcome the risks and uncertainties frequently encountered by companies in the biopharmaceutical industry. As a result, we have not been profitable and have incurred significant operating losses in every reporting period since our inception. For the nine months three-month period ended September 30, 2023 March 31, 2024, we reported a net loss of approximately $11.4 million $3.8 million and as of September 30, 2023 March 31, 2024, we had an accumulated deficit of approximately $41.4 million $49.2 million.

For the foreseeable future, we expect to continue to incur losses, which will increase significantly from historical levels as we expand our development activities, seek regulatory approvals for our product candidates, and begin to commercialize them if they are approved by the FDA, the European Medicines Agency, or the EMA, or comparable foreign authorities. Further, the net losses we incur may fluctuate significantly from quarter-to-quarter and year-to-year, such that a period-to-period comparison of our results of operations may not be a good indication of our future performance. Even if we succeed in developing and commercializing one or more product candidates, we may never become profitable, or even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' equity and working capital.

We have identified conditions and events that raise substantial doubt regarding our ability to continue as a going concern.

We have incurred net losses and utilized cash in operations since inception as described above. In addition, as of September 30, 2023 March 31, 2024, we had approximately $16.0 million $9.7 million in cash and cash equivalents, and during the nine months three-month period ended September 30, 2023 March 31, 2024, we used $10.8 million $3.9 million of cash in operations and expect to continue to incur significant cash outflows and incur future additional losses to execute our operating plan. While we intend to finance our cash needs principally through collaborations, strategic alliances, or license agreements with third parties and/or debt or equity financings, we cannot provide any assurance that new financing will be available to us on commercially acceptable terms or in the amounts required, if at all. Due to the uncertainty in securing additional funding, and as existing cash resources are not sufficient to fund planned operations for at least 12 months from the insufficient amount filing of cash and cash equivalents as of September 30, 2023, this Quarterly Report, we have concluded that substantial doubt exists about our ability to continue as a going concern within one year after the date of the filing of this Quarterly Report. concern. If we are unsuccessful in securing sufficient financing, we may need to delay, reduce, or eliminate our research and development programs, which could adversely affect our business prospects, or cease operations.

Our unaudited condensed consolidated financial statements included in this Quarterly Report have been prepared on a going concern basis under which an entity is able to realize its assets and satisfy its liabilities in the ordinary course of business. The unaudited condensed consolidated financial statements do not give effect to any adjustments relating to the carrying values and classification of assets and liabilities that would be necessary should we be unable to continue as a going concern within one year after the date that the financial statements are issued.

Our future operations are dependent upon the successful entry into collaborations, strategic alliances, or license agreements with third parties and/or on the identification and successful completion of equity or debt financing and the achievement of profitable operations at an indeterminate time in the future. There can be no assurances that we will be successful in completing these collaborations or alliances, equity or debt financing or in achieving profitability. As such, there can be no assurance that we will be able to continue as a going concern.

Substantial doubt about our ability to continue as a going concern may materially and adversely affect the price per share of our common stock, and it may be more difficult for us to obtain financing. If potential collaborators decline to do business with us or potential investors decline to participate in any future financings financing due to such concerns, our ability to increase our cash position may be limited. The perception that we may not be able to continue as a going concern may cause others to choose not to deal with us due to concerns about our ability to meet our contractual obligations. If we are unable to continue as a going concern, you could lose all or part of your investment in our Company.

Given our lack of current cash flow, we will need to raise additional capital. If we are unable to raise a sufficient amount of capital when needed in required amounts and on acceptable terms or at all, we may be forced to delay, limit or eliminate some or all of our research programs, product development activities and commercialization efforts.

Since we will be unable to generate sufficient, if any, cash flow to fund our operations for the foreseeable future, we will need to seek additional equity or debt financing to provide the capital required to maintain or expand our operations.

There can be no assurance that we will be able to raise sufficient additional capital on acceptable terms or at all. If such additional financing is not available on satisfactory terms, or is not available in sufficient amounts, we may be required to delay, limit or eliminate some or all of our research programs, product development activities and commercialization efforts, and our ability to achieve our business objectives, our competitiveness, and our business, financial condition and results of operations may be materially adversely affected. In addition, we may be required to grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. Our inability to fund our business could lead to the loss of your investment.

Our future capital requirements will depend on many factors, including, but not limited to:

- the scope, rate of progress, results and cost of our clinical trials, preclinical studies and other related activities;
- the timing of, and the costs involved in, obtaining regulatory approvals for any of our current or future product candidates;
- the number and characteristics of the product candidates we seek to develop or commercialize;
- the cost of manufacturing clinical supplies, and establishing commercial supplies, of our product candidates;
- the cost of commercialization activities, if any, of our current or future product candidates that are approved for sale, including marketing, sales and distribution costs;
- the expenses needed to attract and retain skilled personnel;
- the costs associated with being a public company;
- the amount of revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive marketing approval; and
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing possible patent claims, including litigation costs and the outcome of any such litigation.

Even if we believe we have sufficient funds for our current or future operating plans, we may continue to seek additional capital if market conditions are favorable or in light of specific strategic considerations. Adequate additional financing may not be available to us on acceptable terms, or at all. If we are unable to obtain sufficient funding on a timely basis, in required amounts or on favorable terms, we may be required to significantly delay, reduce or eliminate one or more of our research or product development programs and/or commercialization efforts. We may also be unable to expand our operations or otherwise capitalize on business opportunities as desired. Any of these events could materially adversely affect our financial condition and business prospects.

Raising additional capital would cause dilution to our shareholders and may restrict our operations or require us to relinquish rights to our technologies or product candidates.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity and/or debt financings and collaborations, licensing agreements or other strategic arrangements. We may seek additional capital through a combination of private and public equity offerings, "at-the-market" issuances, equity-linked and structured transactions, debt (straight, convertible, or otherwise) financings, collaborations and licensing arrangements. 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 may include liquidation or other preferences that adversely affect your rights as a shareholder. For example, in June 2022, we entered into an at the market offering agreement, which was amended on September 1, 2022, with a sales agent pursuant to which, based on the prospectus supplement that was filed with the SEC on March 13, 2024, we may offer and sell from time to time shares of our common stock for aggregate gross proceeds of up to $3.7 million $5.2 million. Additionally, in December 2022, we entered into a purchase agreement and a registration rights agreement with Lincoln Park Capital Fund, LLC (Lincoln Park) pursuant to which Lincoln Park has committed to purchase up to $20.0 million of our common stock from time to time over a 36-month period (unless extended to a 48-month period pursuant to the terms thereof). We may also issue in the future equity securities that provide for rights, preferences and privileges senior to those of our common stock. Given our need for cash and that equity issuances are the most common type of fundraising for similarly situated companies, the risk of dilution is particularly significant for our stockholders. Depending upon market liquidity at the time, additional sales of shares registered at any given time could cause the trading price of our common stock to decline. Debt financing, if available, would result in increased fixed payment obligations and may involve agreements that include covenants limiting or restricting our ability to take specific actions such as incurring debt, making capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams or product candidates, or grant licenses on terms that are not favorable to us.

Risks Related to the Discovery and Development of Our Product Candidates

We are dependent on the success of one or more of our current product candidates, and we cannot be certain that any of them will receive regulatory approval or be commercialized.

We have spent significant time, money and effort on the development of our lead product candidate, Decoy20. As a result, our business is largely dependent on the commencement of and success of clinical trials evaluating Decoy20 and our ability to complete the development of, obtain regulatory approval for, and successfully commercialize Decoy20 in a timely manner. The process to develop, obtain regulatory approval and commercialize Decoy20 is long, complex, costly and uncertain as to the outcome.

To date, no clinical trials designed to provide substantial evidence of safety, purity, potency or efficacy have been completed with any of our product candidates. All of our product candidates will require additional development, including clinical trials as well as further preclinical studies to evaluate their toxicology and optimize their formulation and regulatory approvals before they can be commercialized. Positive results obtained during early development do not necessarily mean later development will succeed or that regulatory approvals will be obtained. Our development efforts may not lead to commercial products, either because our product candidates fail to be safe and effective, or in the case of our product candidates regulated as biologics, safe, pure and potent, or because we have inadequate financial or other resources to advance our product candidates through the clinical development and approval processes. If any of our product candidates fail to demonstrate safety, purity, potency or efficacy at any time or during any phase of development, we would experience potentially significant delays in, or be required to abandon, development of the product candidate.

We do not anticipate that any of our current product candidates will be eligible to receive regulatory approval from the FDA, the EMA or comparable foreign authorities and begin commercialization for a number of years, if ever. Even if we ultimately receive regulatory approval for any of these product candidates, we or our potential future partners, if any, may be unable to commercialize them successfully for a variety of reasons. These include, for example, the availability of alternative treatments, lack of cost-effectiveness, the cost of manufacturing the product on a commercial scale and competition with other products. The success of our product candidates may also be limited by the prevalence and severity of any adverse side effects. If we fail to commercialize one or more of our current product candidates, we may be unable to generate sufficient revenues to attain or maintain profitability, and our financial condition may decline.

Clinical and preclinical development involves a lengthy and expensive process with an uncertain outcome. Any difficulties or delays in the commencement or completion, or the termination or suspension, of our current or planned clinical trials could result in increased costs to us, delay or limit our ability to generate revenue or adversely affect our commercial prospects.

Before obtaining approval from regulatory authorities for the commercialization of any of our product candidates, we must conduct extensive clinical trials to demonstrate the safety, purity, and potency, or efficacy of the product candidate in humans. Preclinical and clinical drug development is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the preclinical study or clinical trial process. Despite promising preclinical or clinical results, any product candidate can unexpectedly fail at any stage of preclinical or clinical development. The historical failure rate for product candidates in our industry is high.

The results from preclinical studies or early clinical trials of a product candidate may not predict the results of later clinical trials of the product candidate, and interim results of a clinical trial are not necessarily indicative of final results. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy characteristics despite having progressed through preclinical studies and initial clinical trials. It is not uncommon to observe results in clinical trials that are unexpected based on preclinical studies and early clinical trials, and many product candidates fail in clinical trials despite very promising early results. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in clinical development even after achieving promising results in earlier studies.

Before we can initiate clinical trials for any product candidates, we must submit the results of preclinical studies to the FDA, the EMA or comparable foreign regulatory authorities along with other information, including information about product candidate chemistry, manufacturing and controls and our proposed clinical trial protocol, as part of an IND or similar regulatory submission. The FDA, the EMA or comparable foreign regulatory authorities may require us to conduct additional preclinical studies for any product candidate before it allows us to initiate clinical trials under any IND or similar regulatory submission, which may lead to delays and increase the costs of our preclinical development programs. Moreover, even if we commence clinical trials, issues may arise that could cause regulatory authorities to suspend or terminate such clinical trials. Any such delays in the commencement or completion of our ongoing and planned clinical trials for our product candidates could significantly affect our product development timelines and product development costs and harm our financial position.

We do not know whether our planned clinical trials will begin on time or be completed on schedule, if at all. The commencement, data readouts and completion of clinical trials can be delayed for a number of reasons, including delays related to:

- inability to generate sufficient preclinical, toxicology, or other in vivo or in vitro data to support the initiation or continuation of clinical trials;
- failure in obtaining allowance or approval from regulatory authorities to commence a trial or reaching a consensus with regulatory authorities on trial design;
- the FDA, the EMA or comparable foreign regulatory authorities disagreeing as to the design or implementation of our clinical trials;

- any failure or delay in reaching an agreement with 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;
- delays in identifying, recruiting and training suitable clinical investigators;
- failure in obtaining approval from one or more institutional review boards ("IRBs") (IRBs) or ethics committees at clinical trial sites;
- IRBs refusing to approve, suspending or terminating the trial at an investigational site, precluding enrollment of additional subjects, or withdrawing their approval of the trial;
- changes or amendments to the clinical trial protocol;
- clinical sites deviating from the trial protocol or dropping out of a trial;
- failure by our CROs to perform in accordance with Good Clinical Practice ("GCP") (GCP) requirements or applicable regulatory rules and guidelines in other countries;
- failure in manufacturing sufficient quantities of our product candidates, or obtaining sufficient quantities of combination therapies, for use in clinical trials;

- subjects failing to enroll or remain in our trials at the rate we expect, or failing to return for post-treatment follow-up, including subjects failing to remain in our trials;
- patients choosing an alternative product for the indications for which we are developing our product candidates, or participating in competing clinical trials;
- lack of adequate funding to continue a clinical trial, or costs being greater than we anticipate;
- subjects experiencing severe or serious unexpected drug-related adverse effects;
- occurrence of serious adverse events in trials of the same class of agents conducted by other companies that could be considered similar to our product candidates;
- selection of clinical endpoints that require prolonged periods of clinical observation or extended analysis of the resulting data;
- transfer of manufacturing processes to larger-scale facilities operated by a contract manufacturing organization ("CMO") (CMO), delays or failure by our CMOs or us to make any necessary changes to such manufacturing process, or failure of our CMOs to produce clinical trial materials in accordance with current Good Manufacturing Practice ("cGMP") (cGMP), regulations or other applicable requirements; and
- third parties being unwilling or unable to satisfy their contractual obligations to us in a timely manner.

In addition, disruptions caused by the COVID-19 pandemic (including any variants thereof) or any future pandemic may increase the likelihood that we encounter such difficulties or delays in initiating, enrolling, conducting or completing our planned and ongoing clinical trials.

Clinical trials must be conducted in accordance with the FDA and other applicable regulatory authorities' legal requirements, regulations and guidelines, and remain subject to oversight by these governmental agencies and ethics committees or IRBs at the medical institutions where such clinical trials are conducted. We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by a Data Safety Monitoring Board for such trial or by the FDA, the EMA or comparable foreign regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or applicable clinical trial protocols, adverse findings from inspections of clinical trial sites by the FDA, the EMA or comparable foreign regulatory authorities, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. In addition, changes in regulatory requirements and policies may occur, and we may need to amend clinical trial protocols to comply with these changes. Amendments may require us to resubmit our clinical trial protocols to regulators or to IRBs for reexamination, which may impact the costs, timing or successful completion of a clinical trial.

Moreover, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA, the EMA or comparable foreign regulatory authorities. The FDA, the EMA or comparable foreign regulatory authority may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA, the EMA or comparable foreign regulatory authority may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA, the EMA or comparable foreign regulatory authority, as the case may be, and may ultimately lead to the denial of marketing approval of one or more of our product candidates.

In addition, the FDA's, the EMA's and other regulatory authorities' policies with respect to clinical trials may change and additional government regulations may be enacted. For instance, the regulatory landscape related to clinical trials in the EU recently evolved. The EU Clinical Trials Regulation ("CTR") (CTR) which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. While the Clinical Trials Directive required a separate clinical trial application ("CTA") (CTA) to be submitted in each member state, to both the competent national health authority and an independent ethics committee, the CTR introduces a centralized process and only requires the submission of a single application to all member states concerned. The CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each member state, leading to a single decision per member state. The assessment procedure of the CTA has been harmonized as well, including a joint assessment by all member states concerned, and a separate assessment by each member state with respect to specific requirements related to its own territory, including ethics rules. Each member state's decision is communicated to the sponsor via the centralized EU portal. Once the CTA is approved, clinical study development may proceed. The CTR foresees a three-year transition period. The extent to which ongoing and new clinical trials will be governed by the CTR varies. Clinical trials for which an application was submitted (i) prior to January 31, 2022 under the Clinical Trials Directive, or (ii) between January 31, 2022 and January 31, 2023 and for which the sponsor has opted for the application of the Clinical Trials Directive remain governed by said Directive until January 31, 2025. After this date, all clinical trials (including those which are ongoing) will become subject to the provisions of the CTR. Compliance with the CTR requirements by us and our third-party service providers, such as CROs, may impact our developments plans. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies governing clinical trials, our development plans may be impacted.

In addition, many of the factors that cause, or lead to, the termination or suspension of, or a delay in the commencement or completion of, clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate. Any resulting delays to our clinical trials could shorten any period during which we may have the exclusive right to commercialize our product candidates. In such cases, our competitors may be able to bring products to market before we do, and the commercial viability of our product candidates could be significantly reduced. Any of these occurrences may harm our business, financial condition and prospects.

We expect to continue to incur significant research and development expenses and other operating expenses, which may make it difficult for us to attain profitability.

We expect to expend substantial funds in research and development, including preclinical studies and clinical trials of our product candidates, and to manufacture and market any product candidates in the event they are approved for commercial sale. We also may need additional funding to develop or acquire complementary companies, technologies and assets, as well as for working capital requirements and other operating and general corporate purposes. Moreover, our planned increases in staffing will dramatically increase our costs in the near and long-term.

Because the successful development of our product candidates is uncertain, we are unable to precisely estimate the actual funds we will require to develop and potentially commercialize them. In addition, we may not be able to generate sufficient revenue, even if we are able to commercialize any of our product candidates, to become profitable.

We may expend our limited resources to pursue a limited number of research programs, product candidates and specific indications and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Due to our limited financial and managerial resources, we must focus on a limited number of research programs and product candidates and on specific indications. As such, we are currently focused on the development of Decoy20. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications for anti-cancer and anti-viral immunotherapy that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products.

Our product candidates may cause undesirable side effects that could delay or prevent their regulatory approval or commercialization, cause us to suspend or discontinue clinical trials, abandon a product candidate, limit the commercial profile of an approved product, or result in other significant adverse implications on our business, financial condition and results of operations.

As is the case with pharmaceuticals generally, it is likely that there may be side effects and adverse events associated with our product candidates' use. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. For example, because the mechanism of action of our product candidates depends on stimulation of the immune system, there is the potential for over-stimulation or undesirable immune reactions. Undesirable side effects caused by our product candidates, whether used alone or in combination with other therapies, could cause us or regulatory authorities to interrupt, delay or halt clinical trials or the delay or denial of regulatory approval by the FDA, the EMA or comparable foreign regulatory authorities, or, if such product candidates are approved, result in a more restrictive label and other post-approval requirements. Any treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial or could result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

If our product candidates are associated with undesirable side effects or have unexpected characteristics in preclinical studies or clinical trial, when used alone or in combination with other approved products or product candidates, we may need to interrupt, delay or abandon their development or limit development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective.

Patients in our ongoing and planned clinical trials may, in the future, suffer significant adverse events or other side effects not observed in our preclinical studies or previous clinical trials. Patients treated with our product candidates may also be undergoing surgical, radiation or chemotherapy treatments, which can cause side effects or adverse events that are unrelated to our product candidate, but may still impact the success of our clinical trials. The inclusion of critically ill patients in our clinical trials may result in deaths or other adverse medical events due to other therapies or medications that such patients may be using or due to the gravity of such patients' illnesses. If such significant adverse events or other side effects are observed in any of our current or future clinical trials, we may have difficulty recruiting patients to the clinical trials, or we may be required to abandon the trials or our development efforts of that product candidate altogether. We, the FDA, other comparable regulatory authorities or an IRB may suspend clinical trials of a product candidate at any time for various reasons, including a belief that subjects in such trials are being exposed to unacceptable health risks or adverse side effects. Even if the side effects do not preclude the product candidate from obtaining or maintaining regulatory approval, undesirable side effects may inhibit market acceptance due to tolerability concerns as compared to other available therapies. Any of these developments could materially harm our business, financial condition and prospects.

Additionally, if any of our product candidates receives regulatory approval, and we or others later identify undesirable side effects caused by such product, a number of potentially significant negative consequences could result. For example, the FDA could require us to adopt a Risk Evaluation and Mitigation Strategy (REMS), to ensure that the benefits of treatment with such product candidate outweigh the risks for each potential patient, which may include, among other things, a communication plan to health care practitioners, patient education, extensive patient monitoring or distribution systems and processes that are highly controlled, restrictive and more costly than what is typical for the industry. We or our collaborators may also be required to adopt a REMS or engage in similar actions, such as patient education, certification of health care professionals or specific monitoring, if we or others later identify undesirable side effects caused by any product that we develop alone or with collaborators. Other potentially significant negative consequences associated with adverse events include:

- we may be required to suspend marketing of a product, or we may decide to remove such product from the marketplace;
- regulatory authorities may withdraw or change their approvals of a product;
- regulatory authorities may require additional warnings on the label or limit access of a product to selective specialized centers with additional safety reporting and with requirements that patients be geographically close to these centers for all or part of their treatment;
- we may be required to create a medication guide outlining the risks of a product for patients, or to conduct post-marketing studies;
- we may be required to change the way a product is administered;
- we could be subject to fines, injunctions, or the imposition of criminal or civil penalties, or be sued and held liable for harm caused to subjects or patients; and
- a product may become less competitive, and our reputation may suffer.

Any of these events could diminish the usage or otherwise limit the commercial success of our product candidates and prevent us from achieving or maintaining market acceptance of our product candidates, if approved by the FDA or other regulatory authorities.

We may find it difficult to enroll patients in our clinical trials. If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

Patient enrollment is a significant factor in the timing of clinical trials, and the timing of our clinical trials depends, in part, on the speed at which we can recruit patients to participate in our trials, as well as completion of required follow-up periods. We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials to such trial's conclusion as required by the FDA or other comparable regulatory authorities. The conditions for which we currently plan to evaluate our product candidates are diseases with limited patient pools from which to draw for clinical trials. The eligibility criteria of our clinical trials, once established, may further limit the pool of available trial participants.

Patient enrollment for any of our clinical trials may be affected by other factors, including:

- size and nature of the targeted patient population;
- severity of the disease or condition under investigation;
- availability and efficacy of approved therapies for the disease or condition under investigation;
- patient eligibility criteria for the trial in question as defined in the protocol;
- perceived risks and benefits of the product candidate under study;
- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any products that may be approved for, or any product candidates under investigation for, the indications we are investigating;
- efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment;
- proximity and availability of clinical trial sites for prospective patients;
- continued enrollment of prospective patients by clinical trial sites; and
- the risk that patients enrolled in clinical trials will drop out of such trials before completion; and
- delays or difficulties in enrollment and completion of studies due to the COVID-19 pandemic or any future pandemics. completion.

Additionally, other pharmaceutical companies targeting these same diseases are recruiting clinical trial patients from these patient populations, which may make it more difficult to fully enroll our clinical trials. We also rely on, and will continue to rely on, CROs and clinical trial sites to ensure proper and timely conduct of our clinical trials and preclinical studies. Though we have entered into agreements governing their services, we will have limited influence over their actual performance. Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our product candidates and jeopardize our ability to obtain regulatory approval for the sale of our product candidates. Furthermore, even if we are able to enroll a sufficient number of patients for our clinical trials, we may have difficulty maintaining enrollment of such patients in our clinical trials.

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

From time to time, we may publicly disclose interim, topline, or preliminary data from our clinical trials and preclinical studies, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the interim, topline, or preliminary results that we report may differ from future results of the same studies or trials, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline and preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the topline or preliminary data we previously published. As a result, topline and preliminary data should be viewed with caution until the final data is available.

Interim data from clinical trials that we may complete are further subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data becomes available. Adverse differences between interim, topline, or preliminary data and final data could significantly harm our business prospects. Further, disclosure of such data by us or by our competitors could result in volatility in the price of our common stock.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or our business. If the interim, topline, or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

Our efforts to discover product candidates beyond our current product candidates may not succeed, and any product candidates we recommend for clinical development may not actually begin clinical trials.

We intend to expand our existing pipeline of core assets. However, the process of researching and developing new product candidates is expensive, time-consuming and unpredictable. Data from our current preclinical programs may not support the clinical development of our product candidates, and we may not identify any additional products suitable for recommendation for clinical development. Moreover, any product candidate we recommend for clinical development may not demonstrate, through preclinical studies, indications of safety and potential efficacy that would support advancement into clinical trials. Such findings would potentially impede our ability to maintain or expand our clinical development pipeline. Our ability to develop new product candidates and advance them into clinical development also depends upon our ability to fund our research and development operations, and we cannot be certain that additional funding will be available on acceptable terms, or at all.

The regulatory approval processes of the FDA, the EMA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.

The clinical development, manufacturing, labeling, storage, record-keeping, advertising, promotion, import, export, marketing and distribution of our product candidates are subject to extensive regulation by the FDA in the U.S. and by comparable foreign regulatory authorities in foreign markets, such as the EMA in Europe. In the U.S., we are not permitted to market our product candidates in the U.S. until we receive regulatory approval of a BLA Biologics License Application (BLA) or NDA New Drug Application (NDA) from the FDA. The process of obtaining such regulatory approval is expensive, often takes many years following the commencement of clinical trials and can vary substantially based upon the type, complexity and novelty of the product candidates involved, as well as the target indications and patient population. Approval policies or regulations may change, and the FDA, EMA and comparable regulatory authorities have substantial discretion in the approval process, including the ability to delay, limit or deny approval of a product candidate for many reasons. Despite the time and expense invested in clinical development of product candidates, regulatory approval of a product candidate is never guaranteed. Of the large number of drugs in development, only a small percentage successfully complete the FDA, EMA or comparable regulatory approval processes and are commercialized.

Prior to obtaining approval to commercialize a product candidate in the U.S. or abroad, we must demonstrate with substantial evidence from adequate and well-controlled clinical trials, and to the satisfaction of the FDA, EMA or comparable foreign regulatory authorities, that such product candidates are safe and effective for their intended uses, and in the case of biological products, that such product candidates are safe, pure and potent. Results from nonclinical studies and clinical trials can be interpreted in different ways. Even if we believe available nonclinical or clinical data support the safety purity, potency or efficacy of our product candidates, such data may not be sufficient to obtain approval from the FDA and comparable foreign regulatory authorities. The FDA, EMA or comparable foreign regulatory authorities, as the case may be, may also require us to conduct additional preclinical studies or clinical trials for our product candidates either prior to or post-approval, or may object to elements of our clinical development program.

The FDA, EMA or comparable foreign regulatory authorities can delay, limit or deny approval of a product candidate for many reasons, including:

- such authorities may disagree with the design or execution of our clinical trials;
- negative or ambiguous results from our clinical trials or results may not meet the level of statistical significance required by the FDA, EMA or comparable foreign regulatory agencies for approval;
- serious and unexpected drug-related side effects may be experienced by participants in our clinical trials or by individuals using drugs similar to our product candidates;
- the population studied in the clinical trial may not be sufficiently broad or representative to assure safety in the full population for which we seek approval;
- such authorities may not accept clinical data from trials that are conducted at clinical facilities or in countries where the standard of care is potentially different from that of their own country;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- such authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- such authorities may not agree that the data collected from clinical trials of our product candidates are acceptable or sufficient to support the submission of a Biologics License Application ("BLA"), New Drug Approval ("NDA") BLA, NDA or other submission or to obtain regulatory approval in the U.S. or elsewhere, and such authorities may impose requirements for additional preclinical studies or clinical trials;
- such authorities may disagree with us regarding the formulation, labeling and/or the product specifications of our product candidates;
- approval may be granted only for indications that are significantly more limited than those sought by us, and/or may include significant restrictions on distribution and use;
- such authorities may find deficiencies in the manufacturing processes or facilities of the third-party manufacturers with which we contract for clinical and commercial supplies; or
- such authorities may not accept a submission due to, among other reasons, the content or formatting of the submission.

With respect to foreign markets, approval procedures vary among countries and, in addition to the foregoing risks, may involve additional product testing, administrative review periods and agreements with pricing authorities. Even if we eventually complete clinical trials and receive approval of a BLA, NDA or comparable foreign marketing application for our product candidates, the FDA or comparable foreign regulatory authority may grant approval contingent on the performance of costly additional clinical trials and/or the implementation of a REMS, which may be required because the FDA believes it is necessary to ensure safe use of the product after approval. Any delay in obtaining, or inability to obtain, applicable regulatory approval would delay or prevent commercialization of that product candidate and would materially adversely impact our business and prospects.

Even if we obtain FDA approval for any of our product candidates in the United States, we may never obtain approval for or commercialize such candidates in any other jurisdiction, which would limit our ability to realize their full market potential.

In order to market any products in any particular jurisdiction, we must establish and comply with numerous and varying regulatory requirements on a country-by-country basis regarding safety and efficacy. Approval by the FDA in the United States does not ensure approval by regulatory authorities in other countries or jurisdictions. However, the failure to obtain approval in one jurisdiction may negatively impact our ability to obtain approval elsewhere. In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country.

Approval processes vary among countries and can involve additional product testing and validation, as well as additional administrative review periods. Seeking foreign regulatory approval could result in difficulties and increased costs for us and require additional preclinical studies or clinical trials which could be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. We do not have any product candidates approved for sale in any jurisdiction, including in international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of any product we develop will be unrealized.

Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, prevent new or modified products from being developed, reviewed, approved or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the FDA and foreign regulatory authorities to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA's or foreign regulatory authorities' ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's or foreign regulatory authorities' ability to perform routine functions. Average review times at the FDA and foreign regulatory authorities have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies, such as the EMA following its relocation to Amsterdam and resulting staff changes, may also slow the time necessary for new drugs, and biologics or modifications to approved drugs and biologics to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities.

Separately, in response to the global COVID-19 pandemic, the FDA postponed most inspections of domestic and foreign manufacturing facilities at various points. Even though the FDA has since resumed standard inspection operations, of domestic facilities where feasible, the FDA has continued to monitor and implement changes to its inspectional activities to ensure the safety of its employees and those of the firms it regulates as it adapts to the evolving COVID-19 pandemic, and any resurgence of the virus or emergence of new variants may lead to further inspectional or administrative delays. Regulatory authorities outside the United States may adopt similar policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Even if we receive regulatory approval for any product candidate, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expenses.

Any regulatory approvals that we may receive for our product candidates will require the submission of reports to regulatory authorities and surveillance to monitor the safety and efficacy of the product candidate, may contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, and may include burdensome post-approval study or risk management requirements. For example, the FDA may require a REMS in order to approve our product candidates, which could entail requirements for a medication guide, physician training and communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or foreign regulatory authorities approve our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our product candidates 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 on-going compliance with cGMPs and GCP for any clinical trials that we may conduct. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic, unannounced inspections by the FDA and other regulatory authorities for compliance with cGMP regulations and standards. If we or a regulatory agency discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facilities where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. In addition, failure to comply with FDA and other comparable foreign regulatory requirements may subject our company to administrative or judicially imposed sanctions, including:

- restrictions on the marketing or manufacturing of our products, withdrawal of the product from the market or voluntary or mandatory product recalls;
- restrictions on product distribution or use, or requirements to conduct post-marketing studies or clinical trials;

- fines, restitutions, disgorgement of profits or revenues, warning letters, untitled letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications submitted by us or suspension or revocation of approvals;
- product seizure or detention, or refusal to permit the import or export of our products; and
- injunctions or the imposition of civil or criminal penalties.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and generate revenue and could require us to expend significant time and resources in response and could generate negative publicity.

The FDA's and other regulatory authorities' policies may change and additional government regulations may be promulgated that could prevent, limit or delay marketing authorization of any product candidates we develop. We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. 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, we may be subject to enforcement action and we may not achieve or sustain profitability.

The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses.

The FDA strictly regulates marketing, labeling, advertising and promotion of prescription drugs. These regulations include standards and restrictions for direct-to-consumer advertising, industry-sponsored scientific and educational activities, promotional activities involving the internet and off-label promotion. Any regulatory approval that the FDA grants is limited to those specific diseases and indications for which a product is deemed to be safe and effective by FDA. While physicians in the United States may choose, and are generally permitted, to prescribe drugs for uses that are not described in the product's labeling and for uses that differ from those tested in clinical trials and approved by the regulatory authorities, our ability to promote any products will be narrowly limited to those indications that are specifically approved by the FDA.

If we are found to have promoted such off-label uses, we may become subject to significant liability. The U.S. federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion of any product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

Risks Related to Our Dependence on Third Parties

The commercial success of our product candidates depends upon their market acceptance among physicians, patients, healthcare payors and the medical community.

Even if our product candidates obtain regulatory approval, our products, if any, may not gain market acceptance among physicians, patients, healthcare payors and the medical community. The degree of market acceptance of any of our approved product candidates will depend on a number of factors, including:

- the effectiveness of our approved product candidates as compared to currently available products;
- patient willingness to adopt our approved product candidates in place of current therapies;
- our ability to provide acceptable evidence of safety and efficacy;
- relative convenience and ease of administration;
- the prevalence and severity of any adverse side effects;
- restrictions on use in combination with other products;
- availability of alternative treatments;
- pricing and cost-effectiveness assuming either competitive or potential premium pricing requirements, based on the profile of our product candidates and target markets;
- effectiveness of our or our partners' sales and marketing strategy;
- our ability to obtain sufficient third-party coverage or reimbursement; and
- potential product liability claims.

In addition, the potential market opportunity for our product candidates is difficult to precisely estimate. Our estimates of the potential market opportunity for our product candidates include several key assumptions based on our industry knowledge, industry publications, third-party research reports and other surveys. Independent sources have not verified all of our assumptions. If any of these assumptions prove to be inaccurate, then the actual market for our product candidates could be smaller than our estimates of our potential market opportunity. If the actual market for our product candidates is smaller than we expect, our product revenues may be limited, it may be harder than expected to raise funds, and it may be more difficult for us to achieve or maintain profitability. If we fail to achieve market acceptance of our product candidates in the U.S. and abroad, our revenue will be limited and it will be more difficult to achieve profitability.

We rely on third parties to conduct our preclinical studies and clinical trials and perform other tasks. If these third parties do not successfully carry out their contractual duties, meet expected deadlines, or comply with regulatory requirements, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business, financial condition and results of operations could be substantially harmed.

We rely upon third-party CROs, medical institutions, clinical investigators and contract laboratories to monitor and manage data for our ongoing preclinical and clinical programs. These CROs, investigators and other third parties play a significant role in the conduct and timing of these trials and subsequent collection and analysis of data. Though we expect to carefully manage our relationships with such CROs, investigators and other third parties, there can be no assurance that we will not encounter challenges or delays in the future, or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects. Further, while we have and will have agreements governing the activities of our third-party contractors, we have limited influence over their actual performance. Nevertheless, we maintain responsibility for ensuring that each of our clinical trials and preclinical studies is conducted in accordance with the applicable protocol, legal, regulatory, and scientific standards and our reliance on these third parties does not relieve us of our regulatory responsibilities. We and our CROs and other vendors are required to comply with requirements for cGMP, or similar foreign requirements, GCP, and good laboratory practice or GLP (GLP), which are a collection of laws and regulations enforced by the FDA, the EMA and comparable foreign authorities for all of our product candidates in clinical development. Regulatory authorities enforce these regulations through periodic inspections of preclinical study and clinical trial sponsors, principal investigators, preclinical study and clinical trial sites, and other contractors. If we or any of our CROs or vendors fail to comply with applicable regulations, the data generated in our preclinical studies and clinical trials may be deemed unreliable, and the FDA, the EMA or comparable foreign authorities may require us to perform additional preclinical studies and clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with products produced consistent with cGMP regulations, or similar foreign requirements. Our failure to comply with these regulations may require it to repeat clinical trials, which would delay the development and regulatory approval processes.

We may not be able to enter into arrangements with CROs on commercially reasonable terms, or at all. In addition, our CROs will not be our employees, and except for remedies available to us under our agreements with such CROs, we will not be able to control whether or not they devote sufficient time and resources to our ongoing preclinical and clinical programs. If CROs 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 data they obtain is compromised due to the failure to adhere to our protocols, regulatory requirements, or for other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. CROs may also generate higher costs than anticipated. As a result, our business, financial condition and results of operations and the commercial prospects for our product candidates could be materially and adversely affected, our costs could increase, and our ability to generate revenue could be delayed.

In addition, principal investigators for our clinical trials may be asked to serve as scientific advisors or consultants to us from time to time and may receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or the FDA concludes that the financial relationship may have affected the interpretation of the study, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection by the FDA of any BLA or NDA we submit. Any such delay or rejection could prevent us from commercializing our product candidates.

In addition, our CROs have the right to terminate their agreements with us in the event of an uncured material breach and under other specified circumstances. If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative third parties on commercially reasonable terms or at all. Switching or adding additional CROs, medical institutions, clinical investigators or contract laboratories involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work replacing a previous CRO. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. There can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse effect on our business, financial condition or results of operations.

We currently rely on third parties for the manufacture of our product candidates during clinical development, and expect to continue to rely on third parties for the foreseeable future. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates, or such quantities at an acceptable cost, which could delay, prevent or impair our development or potential commercialization efforts.

We do not own or operate manufacturing facilities and have no current plans to develop our own clinical or commercial-scale manufacturing capabilities. We rely, and expect to continue to rely, on third parties for the manufacture of our product candidates, and related raw materials for clinical development, as well as for commercial manufacture if any of our product candidates receives regulatory approval. The facilities used by our third-party manufacturers must be approved for the manufacture of our product candidates by the FDA, EMA, or any comparable foreign regulatory authority, pursuant to inspections that will be conducted after we submit an NDA or BLA to the FDA, or submit a comparable marketing application to a foreign regulatory authority. We do not control the manufacturing process of, and are completely dependent on, third-party manufacturers for compliance with cGMP requirements for manufacture of our product candidates. If these third-party manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or any comparable foreign regulatory authority, they will not be able to secure and/or maintain regulatory approval for the use of their manufacturing facilities.

In addition, we have no control over the ability of third-party manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA, EMA or any comparable foreign regulatory authority does not approve these facilities for the manufacture our product candidates, or if such authorities withdraw any such approval in the future, we may be required to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, seizures or recalls, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our financial position.

Our or a third party's failure to execute on our manufacturing requirements on commercially reasonable terms and in compliance with cGMP or other regulatory requirements could adversely affect our business in a number of ways, including:

- an inability to initiate or complete clinical trials of our product candidates in a timely manner;
- delay in submitting regulatory applications, or receiving regulatory approvals, for our product candidates;
- subjecting third-party manufacturing facilities to additional inspections by regulatory authorities;
- requirements to cease development or to recall batches of our product candidates; and
- in the event of approval to market and commercialize any product candidate, an inability to meet commercial demands.

In addition, we do not have any long-term commitments or supply agreements with any third-party manufacturers. We may be unable to establish any long-term supply agreements with third-party manufacturers or to do so on acceptable terms, which increases the risk of failing to timely obtain sufficient quantities of our product candidates or such quantities at an acceptable cost. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- failure of third-party manufacturers to comply with regulatory requirements and maintain quality assurance;
- breach of the manufacturing agreement by the third party;
- failure to manufacture our product candidates according to our specifications;
- failure to manufacture our product according to our schedule or at all;
- misappropriation of our proprietary information, including our trade secrets and know-how; and
- termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval, and any related remedial measures may be costly or time consuming to implement. We do not currently have arrangements in place for redundant supply or a second source for all required raw materials used in the manufacture of our product candidates. If our existing or future third-party manufacturers cannot perform as agreed, we may be required to replace such manufacturers and we may be unable to replace them on a timely basis or at all, which would have a material adverse impact on our financial position.

Any collaboration arrangement that we may enter into in the future may not be successful, which could adversely affect our ability to develop and commercialize our current and potential future product candidates.

We may seek collaboration arrangements with biopharmaceutical companies for the development or commercialization of our current and potential future product candidates. To the extent that we decide to enter into collaboration agreements, we will face significant competition in seeking appropriate collaborators. Moreover, collaboration arrangements are complex and time consuming to negotiate, execute and implement. We may not be successful in our efforts to establish and implement collaborations or other alternative arrangements should we choose to enter into such arrangements, and the terms of the arrangements may not be favorable to us. If and when we collaborate with a third party for development and commercialization of a product candidate, we can expect to relinquish some or all of the control over the future success of that product candidate to the third party. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborators generally have significant discretion in determining the efforts and resources that they will apply to these collaborations.

Disagreements between parties to a collaboration arrangement can lead to delays in developing or commercializing the applicable product candidate and can be difficult to resolve in a mutually beneficial manner. In some cases, collaborations with biopharmaceutical companies and other third parties are terminated or allowed to expire by the other party. Any such termination or expiration would adversely affect our business, financial condition and results of operations.

If we are unable to develop our own commercial organization or enter into agreements with third parties to sell and market our product candidates, we may be unable to generate significant revenues.

We do not have a sales and marketing organization, and we have no experience as a company in the sales, marketing and distribution of pharmaceutical products. If any of our product candidates are ever approved for commercialization, we may be required to develop our sales, marketing and distribution capabilities, or make arrangements with a third party to perform sales and marketing services. Developing a sales force for any product resulting from any of our product candidates is expensive and time consuming and could delay any product launch. We may be unable to establish and manage an effective sales force in a timely or cost-effective manner, if at all, and any sales force we do establish may not be capable of generating sufficient demand for our product candidates. To the extent that we enter into arrangements with collaborators or other third parties to perform sales and marketing services, our product revenues are likely to be lower than if we marketed and sold our product candidates independently. If we are unable to establish adequate sales and marketing capabilities, independently or with others, we may not be able to generate significant revenues and may not become profitable.

Risks Related to Commercialization

The successful commercialization of Decoy20 or any future product candidates, if approved, will depend in part on the extent to which governmental authorities and health insurers establish coverage, adequate reimbursement levels and favorable pricing policies. Failure to obtain or maintain coverage and adequate reimbursement for our products could limit our ability to market those products and decrease our ability to generate revenue.

The availability of coverage and the adequacy of reimbursement by governmental healthcare programs such as Medicare and Medicaid, private health insurers and other third-party payors are essential for most patients to be able to afford prescription medications such as Decoy20 and any future product candidates, if approved. Our ability to achieve coverage and acceptable levels of reimbursement for our products by third-party payors will have an effect on our ability to successfully commercialize those products. Accordingly, we will need to successfully implement a coverage and reimbursement strategy for any approved product candidate. Even if we obtain coverage for a given product by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high.

If we participate in the Medicaid Drug Rebate Program or other governmental pricing programs, in certain circumstances, our products would be subject to ceiling prices set by such programs, which could reduce the revenue we may generate from any such products. Participation in such programs would also expose us to the risk of significant civil monetary penalties, sanctions and fines should we be found to be in violation of any applicable obligations thereunder.

For products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs. Additionally, separate reimbursement for the product itself or the treatment or procedure in which the product is used may not be available, which may impact physician utilization. We cannot be sure that coverage and reimbursement in the United States, the European Union or elsewhere will be available, or at an acceptable level, for any product that we may develop, and any reimbursement that may become available may be decreased or eliminated in the future.

Third-party payors increasingly are challenging prices charged for biopharmaceutical products and services, and many third-party payors may refuse to provide coverage and reimbursement for particular drugs when an equivalent generic drug or a less expensive therapy is available. It is possible that a third-party payor may consider our products as substitutable and only offer to reimburse patients for the less expensive product. Even if we are successful in demonstrating improved efficacy or improved convenience of administration with our products, pricing of existing drugs may limit the amount we will be able to charge for our products. These payors may deny or revoke the reimbursement status of a given product or establish prices for new or existing marketed products at levels that are too low to enable us to realize an appropriate return on our investment in product development. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our products and may not be able to obtain a satisfactory financial return on products that we may develop.

There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved products. In the United States, third-party payors, including private and governmental payors, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs will be covered. Some third-party payors may require pre-approval of coverage for new or innovative devices or drug therapies before they will reimburse healthcare providers who use such therapies. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for Decoy20 and any future product candidates.

Obtaining and maintaining reimbursement status is time-consuming, costly and uncertain. The Medicare and Medicaid programs increasingly are used as models for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs. However, no uniform policy for coverage and reimbursement for products exists among third-party payors in the United States. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently and, in some cases, at short notice, and we believe that changes in these rules and regulations are likely.

Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe and other countries has and will continue to put pressure on the pricing and usage of our products candidates, if approved in these jurisdictions. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medical products but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our products. Accordingly, in markets outside the United States, if any, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our products. We expect to experience pricing pressures in connection with the sale of any of our products due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, and prescription drugs, surgical procedures and other treatments in particular, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products.

Recently enacted legislation, future legislation and healthcare reform measures may increase the difficulty and cost for us to obtain marketing approval for and commercialize Decoy20 and any future product candidates and may affect the prices we may set.

In the United States and some foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system, including cost-containment measures that may reduce or limit coverage and reimbursement for newly approved drugs and affect our ability to profitably sell any product candidates for which we obtain marketing approval. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare.

By way of example, in March 2010, the ACA was enacted in the United States. The ACA established an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents; extended manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations; expanded eligibility criteria for Medicaid programs; expanded the entities eligible for discounts under the 340B drug pricing program; increased the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program; established a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research; and establishes a Center for Medicare & Medicaid Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending.

Since its enactment, there have been executive, judicial and Congressional challenges to certain aspects of the ACA, and on June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court's decision, President Biden had issued an executive order to initiate a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is unclear how the healthcare reform measures will impact our business.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. On March 11, 2021, the American Rescue Plan Act of 2021 was signed into law, which eliminates eliminate the statutory cap on the Medicaid drug rebate, currently set beginning January 1, 2024 at 100% of a drug's AMP, beginning January 1, 2024. AMP. Further, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs. Such scrutiny has resulted in several recent congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient assistance programs, and reform government program reimbursement methodologies for products. Most recently, the Inflation Reduction Act of 2022, or IRA, included a number of significant drug pricing reforms, which include the establishment of a drug price negotiation program within the U.S. Department of Health and Human Services, or HHS (beginning in 2026) that requires manufacturers to charge a negotiated "maximum fair price" for certain selected drugs or pay an excise tax for noncompliance, the establishment of rebate payment requirements on manufacturers under Medicare Parts B and D to penalize price increases that outpace inflation (first due in 2023), and a redesign of the Part D benefit, as part of which manufacturers are required to provide discounts on Part D drugs (beginning in 2025). The IRA permits the HHS Secretary to implement many of these provisions through guidance, as opposed to regulation, for the initial years. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, although the drug price negotiation program is currently subject to legal challenges. For that and other reasons, it is currently unclear how the IRA will be effectuated. Additional drug pricing proposals could appear in future legislation. Further, it is possible that additional governmental action is taken in response to the COVID-19 pandemic.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for Decoy20 and any future product candidates, if approved, or put pressure on our product pricing, which could negatively affect our business, results of operations, financial condition and prospects.

We expect that these new laws and other healthcare reform measures that may be adopted in the future may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize Decoy20 and any future product candidates, if approved.

Product liability lawsuits against us could cause us to incur substantial liabilities and could limit commercialization of any product candidates that we may develop.

We will face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk if we commercially sell any product candidates that we may develop. If we cannot successfully defend ourselves against claims that our product candidates caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates that we may develop;
- injury to our reputation and significant negative media attention;
- regulatory investigations that could require costly recalls or product modifications;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;
- loss of potential revenue;
- the diversion of management's attention away from managing our business; and
- the inability to commercialize any product candidates that we may develop.

Although we maintain product liability insurance coverage, it may not be adequate to cover all liabilities that we may incur and is subject to deductibles and coverage limitations. We anticipate that we will need to increase our insurance coverage when and if we successfully commercialize any product candidate. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. If we are unable to obtain insurance at acceptable cost or otherwise protect against potential product liability claims, we will be exposed to significant liabilities, which may materially and adversely affect our business and financial position. These liabilities could prevent or interfere with our commercialization efforts.

We are subject to a multitude of manufacturing risks, any of which could substantially increase our costs and limit the supply of our product candidates.

The process of manufacturing our product candidates is complex, highly regulated, and subject to several risks. For example, the process of manufacturing our product candidates is extremely susceptible to product loss due to contamination, equipment failure or improper installation or operation of equipment, or vendor or operator error. Even minor deviations from normal manufacturing processes for any of our product candidates could result in reduced production yields, product defects, and other supply disruptions. If microbial, viral, or other contaminations are discovered in our product candidates or in the manufacturing facilities in which our product candidates are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. In addition, the manufacturing facilities in which our product candidates are made could be adversely affected by equipment failures, labor shortages, natural disasters, power failures and numerous other factors.

In addition, any adverse developments affecting manufacturing operations for our product candidates may result in shipment delays, inventory shortages, lot failures, withdrawals or recalls, or other interruptions in the supply of our product candidates. We also may need to take inventory write-offs and incur other charges and expenses for product candidates that fail to meet specifications, undertake costly remediation efforts, or seek costlier manufacturing alternatives.

Risks Related to Competition, Retaining Key Employees and Managing Growth

If our competitors have product candidates that are approved faster, marketed more effectively, are better tolerated, have a more favorable safety profile or are demonstrated to be more effective than our product candidates, our commercial opportunity may be adversely affected.

The industry in which we operate is characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. While we believe that our technology, knowledge, experience and scientific resources provide it with competitive advantages, we face potential competition from many different sources, including commercial biotechnology enterprises, academic institutions, government agencies and private and public research institutions. Any product candidates that we successfully develop and commercialize will compete with existing immunotherapies and new immunotherapies that may become available in the future.

Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical studies, clinical trials, regulatory approvals and marketing approved products than we do. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Our competitors may succeed in developing technologies and therapies that are more effective, better tolerated or less costly than any which we are developing, or that would render our product candidates obsolete and noncompetitive. Even if we obtain regulatory approval for any of our product candidates, our competitors may succeed in obtaining regulatory approvals for their products earlier than we do. We will also face competition from these third parties in recruiting and retaining qualified scientific and management personnel, in establishing clinical trial sites and patient registration for clinical trials, and in acquiring and in-licensing technologies and products complementary to our programs or advantageous to our business.

The key competitive factors affecting the success of each of our product candidates, if approved, are likely to be its efficacy, safety, tolerability, frequency and route of administration, convenience and price, the level of branded and generic competition, market acceptance by physicians and patients, and the availability of coverage and reimbursement from government and other third-party payors.

Any product candidates for which we intend to seek approval as biologic products may face competition sooner than anticipated.

The Patient Protection and Affordable Care Act, signed into law on March 23, 2010, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of its product.

We believe that any of our future product candidates approved as a biological product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to Congressional action or otherwise, or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Moreover, the extent to which a biosimilar, once approved, could be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products will depend on a number of marketplace and regulatory factors that are still developing.

Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.

We are highly dependent on our current senior management. If we fail to retain current members of our senior management and scientific personnel, or to attract and keep additional key personnel, we may be unable to successfully develop or commercialize our product candidates. We are highly dependent on our chief executive officer, Jeffrey A. Meckler, and our chief scientific officer, Michael J. Newman, Ph.D. Our success depends on our continued ability to attract, retain and motivate highly qualified management and scientific personnel. However, competition for qualified personnel is intense. We may not be successful in attracting qualified personnel to fulfill our current or future needs on a full-time employment basis, or at all. In the event we are unable to fill critical open employment positions, we may need to delay our operational activities and goals, including the development of the company's product candidates, and may have difficulty in meeting our obligations as a public company. We do not currently maintain "key person" insurance on any of our employees.

In addition, competitors and others are likely in the future to attempt to recruit our employees. The loss of the services of any of our key personnel, the inability to attract or retain highly qualified personnel in the future or delays in hiring such personnel, particularly senior management and other technical personnel, could materially and adversely affect our business, financial condition and results of operations. In addition, the replacement of key personnel likely would involve significant time and costs and may significantly delay or prevent the achievement of our business objectives. From time to time, our management seeks the advice and guidance of certain scientific advisors and consultants regarding clinical and regulatory development programs and other customary matters. These scientific advisors and consultants are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us. In addition, our scientific advisors may have arrangements with other companies to assist those companies in developing products or technologies that may compete with us.

We will need to increase the size of our organization and may not successfully manage our growth.

We are an early clinical-stage biotechnology company with a small number of employees, and our management systems currently in place are not likely to be adequate to support our future growth plans. Our ability to grow and to manage our growth effectively will require us to hire, train, retain, manage and motivate additional employees and to implement and improve our operational, financial and management systems. These demands also may require the hiring of additional senior management personnel or the development of additional expertise by our senior management personnel. Hiring a significant number of additional employees, particularly those at the management level, would increase our expenses significantly. Moreover, if we fail to expand and enhance our operational, financial and management systems in conjunction with our potential future growth, it could have a material adverse effect on our business, financial condition and results of operations.

Risks Related to Our Intellectual Property

We may not be able to adequately protect our proprietary or licensed technology in the marketplace.

We depend on our ability to protect our proprietary technology and products, or those that we may license. We intend to rely on trade secret, patent, copyright and trademark laws, confidentiality, license, and other agreements with employees and third parties to protect our intellectual property. Our success depends in large part on our ability and any licensor's or licensee's ability to obtain and maintain patent protection in the U.S. and other countries with respect to our proprietary or licensed technology and products. We cannot be certain that patent enforcement activities by future licensors will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents or other intellectual property rights. We also cannot be certain that future licensors will allocate sufficient resources or prioritize their or our enforcement of such patents. Even if we are not a party to these legal actions, an adverse outcome could prevent us from licensing intellectual property that we may need to operate our business, which would have a material adverse effect on our business, financial condition and results of operations.

We believe we will be able to obtain, through prosecution of patent applications covering our owned technology, adequate patent protection for our proprietary technology. If we are compelled to spend significant time and money protecting or enforcing our patents and future patents that we may own, designing around patents held by others or licensing or acquiring, potentially for large fees, patents or other proprietary rights held by others, our business, financial condition and results of operations may be materially and adversely affected. If we are unable to effectively protect the intellectual property that we own or in-license, other companies may be able to offer the same or similar products for sale, which could materially adversely affect our business, financial condition and results of operations. The patents of others from whom we may license technology, and any future patents we may own, may be challenged, narrowed, invalidated or circumvented, which could limit our ability to stop competitors from marketing the same or similar products or limit the length of term of patent protection that we may have for our products.

We may not be successful in obtaining or maintaining necessary rights to our product candidates through acquisitions and in-licenses.

We may be unable to acquire or in-license any compositions, methods of use, processes or other intellectual property rights from third parties that we identify as necessary for our current or future product candidates. We may face competition with regard to acquiring and in-licensing third-party intellectual property rights, including from a number of more established companies. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license intellectual property rights to us. We also may be unable to acquire or in- license third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment.

We may enter into collaboration agreements with U.S. and foreign academic institutions to accelerate development of our current or future preclinical product candidates. Typically, these agreements include an option for the company to negotiate a license to the institution's intellectual property rights resulting from the collaboration. Even with such an option, we may be unable to negotiate a license within the specified timeframe or under terms that are acceptable to us. If we are unable to license rights from a collaborating institution, the institution may offer the intellectual property rights to other parties, potentially blocking our ability to pursue our desired program.

If we are unable to successfully obtain required third-party intellectual property rights or maintain our existing intellectual property rights, we may need to abandon development of the related program and our business, financial condition and results of operations could be materially and adversely affected.

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

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or patent applications will be due to be paid to the United States Patent and Trademark Office ("USPTO") "USPTO" and various governmental patent agencies outside of the U.S. in several stages over the lifetime of the applicable patent and/or patent application. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If this occurs with respect to our in-licensed patents or patent applications we may file in the future, our competitors might be able to use our technologies, which would have a material adverse effect on our business, financial condition and results of operations.

The patent positions of products are often complex and uncertain. The breadth of claims allowed in patents in the U.S. and many jurisdictions outside of the U.S. may not be consistent. Changes in either the patent laws or interpretations of patent laws in the U.S. and other countries may diminish the value of our licensed or owned intellectual property or create uncertainty. In addition, publication of information related to our current product candidates and potential products may prevent us from obtaining or enforcing patents relating to these product candidates and potential products, including without limitation composition-of-matter patents, which are generally believed to offer the strongest patent protection.

Patents that we may own now or may own or license in the future do not necessarily ensure the protection of our licensed or owned intellectual property for a number of reasons, including, without limitation, the following:

- the patents may not be broad or strong enough to prevent competition from other products that are identical or similar to our product candidates;
- there can be no assurance that the term of a patent can be extended under the provisions of patent term extensions afforded by U.S. law or similar provisions in foreign countries, where available;
- the issued patents and patents that we may own now or may obtain or license in the future may not prevent generic or biosimilar entry into the market for our product candidates;
- we, or third parties from whom we in-license or may license patents, may be required to disclaim part of the term of one or more patents;
- there may be prior art of which we are not aware that may affect the validity or enforceability of a patent claim;
- there may be prior art of which we are aware, which we do not believe affects the validity or enforceability of a patent claim, but which, nonetheless, ultimately may be found to affect the validity or enforceability of a patent claim;
- there may be other patents issued to others that will affect our freedom to operate;
- if the patents are challenged, a court could determine that they are invalid or unenforceable;
- there might be a significant change in the law that governs patentability, validity and infringement of our licensed patents or any future patents we may own that adversely affects the scope of our patent rights;
- a court could determine that a competitor’s technology or product does not infringe our patents or any future patents we may own; and
- the patents could irretrievably lapse due to failure to pay fees or otherwise comply with regulations or could be subject to compulsory licensing. If we encounter delays in our development or clinical trials, the period of time during which we could market our potential products under patent protection would be reduced.

Our competitors may be able to circumvent patents or future patents that we may own by developing similar or alternative technologies or products in a non-infringing manner. Our competitors may seek to market generic or biosimilar versions of any approved products by submitting abbreviated new applications or biosimilar biological product applications to the FDA in which our competitors claim that our licensed patents or any future patents we may own are invalid, unenforceable or not infringed. Alternatively, our competitors may seek approval to market their own products similar to or otherwise competitive with our products. In these circumstances, we may need to defend or assert our patents or any future patents we may own, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or other agency with jurisdiction may find our licensed patents or any future patents we may own invalid or unenforceable. We may also fail to identify patentable aspects of our research and development before it is too late to obtain patent protection. Even if we own or in-license valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives.

The issuance of a patent is not conclusive as to its inventorship, scope, ownership, priority, validity or enforceability. In this regard, third parties may challenge our patents or any future patents we may own in the courts or patent offices in the U.S. and abroad. 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, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and potential products. In addition, 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.

Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.

Patents have a limited lifespan, and the protection patents afford is limited. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Even if patents covering our product candidates are obtained, once the patent life has expired for patents covering a product or product candidate, we may be open to competition from competitive products and services. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. We may infringe the intellectual property rights of others, which may prevent or delay our product development efforts and prevent us from commercializing, or increase the costs of commercializing, our products.

Our commercial success depends significantly on our ability to operate without infringing the patents and other intellectual property rights of third parties. For example, there could be issued patents of which we are not aware that our current or potential future product candidates infringe. There also could be patents that we believe we do not infringe upon, but that we may ultimately be found to infringe upon.

Moreover, patent applications are in some cases maintained in secrecy until patents are issued. The publication of discoveries in the scientific or patent literature frequently occurs substantially later than the date on which the underlying discoveries were made and patent applications were filed. Because patents can take many years to issue, there may be currently pending applications of which we are unaware that may later result in issued patents that our product candidates or potential products infringe. For example, pending applications may exist that claim or can be amended to claim subject matter that our product candidates or potential products infringe. Competitors may file continuing patent applications claiming priority to already issued patents in the form of continuation, divisional, or continuation-in-part applications, in order to maintain the pendency of a patent family and attempt to cover our product candidates.

Third parties may assert that we are employing their proprietary technology without authorization and may sue us for patent or other intellectual property infringement. These lawsuits are costly and could adversely affect our business, financial condition and results of operations and divert the attention of managerial and scientific personnel. If we are sued for patent infringement, we would need to demonstrate that our product candidates, potential products or methods either do not infringe the claims of the relevant patent or that the patent claims are invalid, and we may not be able to do this. Proving invalidity is difficult. For example, in the U.S., proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could have a material adverse effect on us. In addition, we may not have sufficient resources to bring these actions to a successful conclusion. If a court holds that any third-party patents are valid, enforceable and cover our products or their use, the holders of any of these patents may be able to block our ability to commercialize our products unless it acquires or obtains a license under the applicable patents or until the patents expire.

We may not be able to enter into licensing arrangements or make other arrangements at a reasonable cost or on reasonable terms. Any inability to secure licenses or alternative technology could result in delays in the introduction of our products or lead to prohibition of the manufacture or sale of products by us. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, in any such proceeding or litigation, we could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially and adversely affect our business, financial condition and results of operations. Any claims by third parties that we have misappropriated their confidential information or trade secrets could have a similar material and adverse effect on our business, financial condition and results of operations. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations.

Any claims or lawsuits relating to infringement of intellectual property rights brought by or against us will be costly and time consuming and may adversely affect our business, financial condition and results of operations.

We may be required to initiate litigation to enforce or defend our licensed and owned intellectual property. Lawsuits to protect our intellectual property rights can be very time consuming and costly. There is a substantial amount of litigation involving patent and other intellectual property rights in the biopharmaceutical industry generally. Such litigation or proceedings could substantially increase our operating expenses and reduce the resources available for development activities or any future sales, marketing or distribution activities.

In any infringement litigation, any award of monetary damages we receive may not be commercially valuable. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are resolved. Further, any claims we assert against a perceived infringer could provoke these parties to assert counterclaims against us alleging that we have infringed their patents. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

In addition, our patents and patent applications, and patents and patent applications that we may apply for, own or license in the future, could face other challenges, such as interference proceedings, opposition proceedings, re-examination proceedings and other forms of post-grant review. Any of these challenges, if successful, could result in the invalidation of, or in a narrowing of the scope of, any of our patents and patent applications and patents and patent applications that we may apply for, own or license in the future subject to challenge. Any of these challenges, regardless of their success, would likely be time consuming and expensive to defend and resolve and would divert our management and scientific personnel's time and attention.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.

As is the case with other biotechnology companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biotechnology industry involves both technological and legal complexity and is costly, time-consuming and inherently uncertain. For example, the U.S. previously enacted and is currently implementing wide-ranging patent reform legislation. Specifically, on September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law and included a number of significant changes to U.S. patent law, and many of the provisions became effective in March 2013. However, it may take the courts years to interpret the provisions of the Leahy-Smith Act, and the implementation of the statute could increase the uncertainties and costs surrounding the prosecution of our licensed and future patent applications and the enforcement or defense of our licensed and future patents, all of which could have a material adverse effect on our business, financial condition and results of operations.

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

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on product candidates throughout the world could be prohibitively expensive. Competitors may use our licensed and owned technologies in jurisdictions where we have not licensed or obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we may obtain or license patent protection, but where patent enforcement is not as strong as that in the U.S. These products may compete with our products in jurisdictions where we do not have any issued or licensed patents and any future patent claims or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, which could make it difficult for us to stop the infringement of our licensed patents and future patents we may own, or marketing of competing products in violation of our proprietary rights generally. Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the U.S. As a result, we may encounter significant problems in protecting and defending our licensed and owned intellectual property both in the U.S. and abroad. Proceedings to enforce our future patent rights, if any, in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business.

We may be unable to adequately prevent disclosure of trade secrets and other proprietary information.

In order to protect our proprietary technology and processes, we rely in part on confidentiality agreements with our corporate partners, employees, consultants, manufacturers, outside scientific collaborators and sponsored researchers and other advisors. These agreements may not effectively prevent disclosure of our confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover our trade secrets and proprietary information. Failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

We may be subject to claims challenging the inventorship of our patents, any future patents we may own, and other intellectual property.

Although we are not currently experiencing any claims challenging the inventorship of our patents or our owned intellectual property, we may in the future be subject to claims that former employees, collaborators or other third parties have an interest in our patents or other owned intellectual property as an inventor or co-inventor. For example, we may have inventorship disputes arise from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business, financial condition and results of operations. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Risks Related to Healthcare Laws and Other Legal Compliance Matters

We are subject to various U.S. federal, state and foreign healthcare laws and regulations, which could increase compliance costs, and our failure to comply with these laws and regulations could harm our results of operations and financial condition.

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers expose us to broadly applicable foreign, federal and state fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute any products for which we obtain marketing approval. Such laws include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or providing any remuneration (including any kickback, bribe or certain rebates), directly or indirectly, overtly or covertly, in cash or in kind, in return for, either the referral of an individual or the purchase, lease, or order, or arranging for or recommending the purchase, lease, or order of any good, facility, item or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation;

- the federal false claims laws, including the civil False Claims Act, and civil monetary penalties laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, to the federal government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making or causing to be made a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;

- the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the federal Anti- Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the Centers for Medicare & Medicaid Services (CMS), information related to payments and other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician practitioners (physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiology assistants and certified nurse-midwives), and teaching hospitals and other healthcare providers, as well as ownership and investment interests held by such healthcare professionals and their immediate family members; 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; some state laws require biotechnology companies to comply with the biotechnology industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; some state laws that require biotechnology companies to report information on the pricing of certain drug products; and some state and local laws that require the registration or pharmaceutical sales representatives.

Efforts to ensure that our current and future business arrangements with third parties will comply with applicable healthcare and privacy laws and regulations will involve ongoing 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 penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government-funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings and the curtailment or restructuring of our operations. Defending against any such actions can be costly and time-consuming and may require significant financial and personnel resources.

Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. Further, if any of the physicians or other healthcare providers or entities with whom we expect to do business are found not to be in compliance with applicable laws or regulations, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government-funded healthcare programs.

Actual or perceived failures to comply with applicable data protection, privacy and security laws, regulations, standards and other requirements could adversely affect our business, results of operations, and financial condition.

The global data protection landscape is rapidly evolving, and we are or may become subject to numerous state, federal and foreign laws, requirements and regulations governing the collection, use, disclosure, retention, and security of personal information. Implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, and we cannot yet determine the impact future laws, regulations, standards, or perception of their requirements may have on our business. This evolution may create uncertainty in our business, affect our ability to operate in certain jurisdictions or to collect, store, transfer use and share personal information, necessitate the acceptance of more onerous obligations in our contracts, result in liability or impose additional costs on us. Each of these laws is subject to varying interpretations by courts and government agencies, creating complex compliance issues. If we fail to comply with applicable laws and regulations, we may face government investigations and/or enforcement actions, fines, civil or criminal penalties, private litigation or adverse publicity that could adversely affect our business, financial condition and results of operation. For example, we may be subject to criminal penalties if we knowingly obtain or disclose individually identifiable health information from a covered entity in a manner that is not authorized or permitted by the Health Insurance Portability and Accountability Act, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and regulations implemented thereunder or applicable state laws.

Violations of or liabilities under environmental, health and safety laws and regulations could subject us to fines, penalties or other 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, the handling, use, storage, treatment and disposal of hazardous materials and wastes and the cleanup of contaminated sites. Our operations involve the use of potentially hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We could incur substantial costs as a result of violations of or liabilities under environmental requirements in connection with our operations or property, including fines, penalties and other sanctions, investigation and cleanup costs and third-party claims. Although we generally contract with third parties for the disposal of hazardous materials and wastes from our operations, we cannot eliminate the 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.

Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of changes to applicable laws and regulations and cannot be certain of our future compliance. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts.

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.

Other Risks Related to Our Business

A pandemic, epidemic or outbreak of an infectious disease, such as COVID-19, may materially and adversely affect our business and operations.

Pandemics, epidemics or other infectious disease outbreaks have in the past and could in the future negatively affect our business. The COVID-19 pandemic has affected the United States and global economies and has affected our operations and those of third parties on which we rely, including by causing disruptions in the supply of our product candidates and the conduct of current and future clinical trials. For example, the pandemic has caused our GMP process to take longer than expected. In addition, the COVID-19 pandemic has affected, and may continue to affect, the operations of the FDA and other health authorities, which could result in delays of reviews and approvals, including with respect to our product candidates. Additionally, while the potential economic impact brought by, and the duration of the COVID-19 pandemic (including any variants thereof) is difficult has contributed to assess or predict, the current economic downturn and volatility in the global financial markets related to the COVID-19 pandemic may reduce making our ability to access capital which could more challenging and thereby negatively impact impacting our short-term and long-term liquidity. The ultimate impact of the COVID-19 pandemic (including any variants thereof) or any future pandemic, epidemic or outbreak of an infectious disease is highly uncertain and cannot be predicted.

Our business and operations may suffer in the event of information technology system failures, cyberattacks or deficiencies in our cybersecurity.

We collect and maintain information in digital form that is necessary to conduct our business, and we are increasingly dependent on information technology systems and infrastructure to operate our business. In the ordinary course of our business, we collect, store and transmit large amounts of confidential information, including intellectual property, proprietary business information and personal information of customers and our employees and contractors. It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information.

Our information technology systems and those of our third-party service providers, strategic partners and other contractors or consultants are vulnerable to attack and damage or interruption from computer viruses and malware (e.g. ransomware), malicious code, natural disasters, terrorism, war, telecommunication and electrical failures, hacking, cyberattacks, phishing attacks and other social engineering schemes, employee theft or misuse, human error, fraud, denial or degradation of service attacks, sophisticated nation-state and nation-state-supported actors or unauthorized access or use by persons inside our organization, or persons with access to systems inside our organization. We have also outsourced elements of our information technology infrastructure, and as a result a number of third-party vendors may or could have access to our confidential information.

Further, attacks upon information technology systems are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives and expertise. As a result of the changes brought about by the COVID-19 pandemic, we We may also face increased cybersecurity risks due to our reliance on internet technology and the number of our employees who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience security breaches that may remain undetected for an extended period. Even if identified, we may be unable to adequately investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence.

We and certain of our service providers are from time to time subject to cyberattacks and security incidents. While we do not believe that we have experienced any significant system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations, whether due to a loss, corruption or unauthorized disclosure of our trade secrets, personal information or other proprietary or sensitive information or other similar disruptions. If a security breach or other incident were to result in the unauthorized access to or unauthorized use, disclosure, release or other processing of personal information, it may be necessary to notify individuals, governmental authorities, supervisory bodies, the media and other parties pursuant to privacy and security laws. We could also incur liability, including litigation exposure, penalties and fines, and we could become the subject of regulatory action or investigation. Our competitive position could be harmed and the further development and commercialization of our products and services could be delayed. We maintain cyber liability insurance; however, this insurance may not be sufficient to cover the financial, legal, business or reputational losses that may result from an interruption or breach of our systems. While we have implemented a cybersecurity risk management program, there can be no assurance that our cybersecurity risk management program and processes, including our policies, controls or procedures, will be fully implemented, complied with or effective in protecting our systems and information.

We may engage in strategic transactions that could impact our liquidity, increase our expenses and present significant distractions to our management.

From time to time, we may consider strategic transactions, such as acquisitions of companies, asset purchases and out-licensing or in-licensing of products, product candidates or technologies. Additional potential transactions that we may consider include a variety of different business arrangements, including spin-offs, strategic partnerships, joint ventures, restructurings, divestitures, business combinations and investments. Any such transaction may require us to incur non-recurring or other charges, may increase our near- and long-term expenditures and may pose significant integration challenges or disrupt our management or business, which could adversely affect our business, financial condition and results of operations. For example, these transactions may entail numerous operational and financial risks, including:

- exposure to unknown liabilities;
- disruption of our business and diversion of our management's time and attention in order to develop acquired products, product candidates or technologies;
- incurrence of substantial debt or dilutive issuances of equity securities to pay for any of these transactions;
- higher-than-expected transaction and integration costs;

- write-downs of assets or goodwill or impairment charges;
- increased amortization expenses;
- difficulty and cost in combining the operations and personnel of any acquired businesses or product lines with our operations and personnel;
- impairment of relationships with key suppliers or customers of any acquired businesses or product lines due to changes in management and ownership; and
- inability to retain key employees of any acquired businesses.

Accordingly, although there can be no assurance that we will undertake or successfully complete any transactions of the nature described above, any transactions that we do complete may be subject to the foregoing or other risks and could have a material adverse effect on our business, financial condition and results of operations.

Risks Related to Our Common Stock

The market price of our common stock is volatile and you may sustain a complete loss of your investment.

Our common stock currently trades on the Nasdaq Capital Market. The market price of our common stock has been, and is likely to continue to be, volatile. The market price of our common stock may fluctuate significantly in response to numerous factors, some of which are beyond our control, such as:

- inability to obtain the approvals necessary to commence clinical trials;
- results of clinical and preclinical studies;

- announcements of regulatory approval or the failure to obtain it, or specific label indications or patient populations for its use, or changes or delays in the regulatory review process;
- announcements of technological innovations, new products or product enhancements by us or others;
- adverse actions taken by regulatory agencies with respect to our clinical trials, manufacturing supply chain or sales and marketing activities;
- changes or developments in laws, regulations or decisions applicable to our product candidates or patents;
- any adverse changes to our relationship with manufacturers, suppliers or partners;
- announcements concerning our competitors or the pharmaceutical or biotechnology industries in general;
- achievement of expected product sales and profitability or our failure to meet expectations;
- our commencement of or results of, or involvement in, litigation, including, but not limited to, any product liability actions or intellectual property infringement actions;
- any major changes in our board of directors, management or other key personnel;
- legislation in the United States, Europe and other foreign countries relating to the sale or pricing of pharmaceuticals;
- announcements by us of significant strategic partnerships, out-licensing, in-licensing, joint ventures, acquisitions or capital commitments;

- expiration or terminations of licenses, research contracts or other collaboration agreements;
- public concern as to the safety of therapeutics we, any licensees or others develop;
- success of research and development projects;
- developments concerning intellectual property rights or regulatory approvals;
- variations in us and our competitors' results of operations;
- changes in earnings estimates or recommendations by securities analysts, if our common stock is covered by analysts;
- future issuances of common stock or other securities;
- general market conditions, including the volatility of market prices for shares of biotechnology companies generally, and other factors, including factors unrelated to our operating performance;
- political and economic instability, war or acts of terrorism (such as Russia's invasion of Ukraine and the armed conflict in Israel) the Middle East) or natural disasters, emergence of a pandemic, or other widespread health emergencies (or concerns over the possibility of such an emergency, similar to the unprecedented COVID-19 pandemic); and
- the other factors described in this "Risk Factors" section.

These factors and any corresponding price fluctuations may materially and adversely affect the market price of our common stock, which would result in substantial losses by our investors.

Further, the stock market in general, the Nasdaq Capital Market and the market for biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of companies like theirs. See also "-General "General Risk Factors - "*Unfavorable global economic conditions could adversely affect our business, financial condition or results of operations*." Broad market and industry factors may negatively affect the market price of our common stock regardless of our actual operating performance. In addition, a systemic decline in the financial markets and related factors beyond our control may cause our share price to decline rapidly and unexpectedly. Price volatility of our common stock might be worse if the trading volume of our common stock is low. In the past, following periods of market volatility, stockholders have often instituted securities class action litigation. This risk is especially relevant for us because biopharmaceutical companies have experienced significant stock price volatility in recent years. If we face such securities litigation, it could result insubstantial in substantial costs and a diversion of management's resources and attention, which could harm our business. Future sales of our common stock could also reduce the market price of our stock.

Moreover, the liquidity of our common stock will be limited, not only in terms of the number of shares of common stock that can be bought and sold at a given price, but by potential delays in the timing of executing transactions in our common stock and a reduction in security analyst and media's coverage of us, if any. These factors may result in lower prices for our common stock than might otherwise be obtained and could also result in a larger spread between the bid and ask prices for our common stock. In addition, without a large float, our common stock will be less liquid than the stock of companies with broader public ownership and, as a result, the trading prices of our common stock may be more volatile. In the absence of an active public trading market, an investor may be unable to liquidate their investment in our common stock. Trading of a relatively small volume of our common stock may have a greater impact on the trading price of our common stock than would be the case if our public float were larger. We cannot predict the prices at which our common stock will trade in the future.

An active trading market for our common stock may not be sustained.

An active public trading market for our common stock may not be sustained. The lack of an active market may impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. The lack of an active market may also reduce the fair value of your shares. An inactive market may also impair our ability to raise capital to continue to fund operations by selling shares and may impair our ability to acquire other companies or technologies by using our shares as consideration.

If securities or industry analysts do not publish or cease publishing research or reports, or publish unfavorable reports about us, our business or our market, our share price and trading volume could be negatively impacted.

The trading market for our common stock could be influenced by the research and reports that industry or securities analysts may publish about us, our business, our market or our competitors. We do not have any control over these analysts and cannot provide any assurance that analysts will cover us or provide favorable coverage. If any of the analysts who may cover us adversely change their recommendation regarding our common stock, or provide more favorable relative recommendations about our competitors, our share price would likely decline. If any analyst who may cover us were to cease coverage of us or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could negatively impact our share price or trading volume.

Sales of a substantial number of our shares in the public market by our existing shareholders could cause our share price to decline.

Sales of a substantial number of our shares in the public market or the perception that these sales might occur, could depress the market price of our securities and could impair our ability to raise capital through the sale of additional equity securities. We are not able to predict the effect that sales may have on the prevailing market price of our securities.

We are a "smaller reporting company" and the reduced disclosure requirements applicable to smaller reporting companies may make our common stock less attractive to investors.

We are considered a "smaller reporting company." We are therefore entitled to rely on certain reduced disclosure requirements, such as an exemption from providing selected financial data and executive compensation information. These exemptions and reduced disclosures in our SEC filings due to our status as a smaller reporting company may make it harder for investors to analyze our results of operations and financial prospects. We cannot predict whether investors will find our common stock less attractive because we may 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 prices may be more volatile.

Maintaining and improving our financial controls and the requirements of being a public company may strain our resources, divert management's attention and affect our ability to attract and retain qualified board members.

As a public company, we are subject to the reporting requirements of the Securities Exchange Act of 1934, or the Exchange Act, the Sarbanes-Oxley Act and The Nasdaq Stock Market LLC ("Nasdaq") (Nasdaq) rules. The requirements of these rules and regulations will increase our legal and financial compliance costs, make some activities more difficult, time-consuming or costly and place strain on our personnel, systems and resources. The Exchange Act requires, among other things, that we file annual, quarterly and current reports with respect to our business and financial condition.

The Sarbanes-Oxley Act requires, among other things, that we disclose whether we maintain effective disclosure controls and procedures and internal control over financial reporting. Ensuring that we have adequate internal financial and accounting controls and procedures in place is a costly and time-consuming effort that needs to be re-evaluated frequently.

We may need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge. Implementing any appropriate changes to our internal controls may require specific compliance training for our directors, officers and employees, entail substantial costs, and take a significant period of time to complete. Such changes may not, however, be effective in maintaining the adequacy of our internal controls, and any failure to maintain that adequacy, or consequent inability to produce accurate financial statements on a timely basis, could increase our operating costs and could materially impair our ability to operate our business. Moreover, effective internal controls are necessary for us to produce reliable financial reports and are important to help prevent fraud.

In accordance with Nasdaq rules, we will be required to maintain a majority independent board of directors. The various rules and regulations applicable to public companies make it more difficult and more expensive for us to maintain directors' and officers' liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to maintain coverage. If we are unable to maintain adequate directors' and officers' insurance, our ability to recruit and retain qualified officers and directors will be significantly curtailed.

It is expected that the rules and regulations applicable to public companies will result in us incurring substantial legal and financial compliance costs. These costs will decrease our net income or increase our net loss and may require us to reduce costs in other areas of our business.

Failure to maintain effective internal control over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act of 2002 could have a material adverse effect on our share price.

As a public company in the U.S., we incur significant accounting, legal and other expenses in order to comply with requirements of the SEC, and the Nasdaq Capital Market, including requirements under Section 404 and other provisions of the Sarbanes-Oxley Act. Pursuant to Section 404, we are required to furnish a report by our management on our internal control over financial reporting. However, so long as we remain a smaller reporting company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. The process to document and evaluate our internal control over financial reporting to achieve compliance with Section 404 within the prescribed period is both costly and challenging. If we fail to maintain the adequacy of our internal control over financial reporting as such standards are modified, supplemented or amended from time to time, we may not be able to ensure that we can conclude on an ongoing basis that we have effective internal control over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act of 2002 and the related rules and regulations of the SEC. If we cannot in the future favorably assess the effectiveness of our internal control over financial reporting, investor confidence in the reliability of our financial reports may be adversely affected, which could have a material adverse effect on our share price.

If the Domestication Merger (defined below), taken together with the Merger (defined below), fails to qualify as a Section 351(a) Exchange, former U.S. holders of Intec Israel Pharma (Intec Israel) ordinary shares may recognize taxable gain as a result of the Domestication Merger.

On July 27, 2021, Intec Israel, Indaptus Therapeutics, Inc. and Domestication Merger Sub Ltd., an Israeli company and a wholly owned subsidiary of Indaptus, completed a domestication merger (the "Domestication Merger"), pursuant to the terms and conditions of an Agreement and Plan of Merger and Reorganization, dated April 27, 2021, whereby Domestication Merger Sub Ltd. merged with and into Intec Israel, with Intec Israel being the surviving entity and a wholly-owned subsidiary of Indaptus Therapeutics, Inc. On August 3, 2021, Indaptus Therapeutics, Inc. completed its merger with Decoy, pursuant to an Agreement and Plan of Merger and Reorganization (the "Merger Agreement"), dated March 15, 2021, following which Decoy became the surviving entity and a wholly-owned subsidiary of Indaptus Therapeutics, Inc. and the business conducted by Decoy became the business conducted by the combined company. Intec Israel intended for the Merger to qualify as a Section 351(a) Exchange. The position of Intec Israel is not binding on the IRS or the courts, and Intec Israel does not intend to request a ruling from the IRS with respect to the Merger. Accordingly, there can be no assurance that the IRS will not challenge the qualification of the Domestication Merger and the Merger as a Section 351(a) Exchange or that a court will not sustain such a challenge. If the IRS were to be successful in any such contention, or if for any other reason the Domestication Merger was not treated as part of a Section 351(a) Exchange, the Domestication Merger could be a taxable event to the former U.S. holders of ordinary shares of Intec Israel. Former holders of Intec Israel's ordinary shares are urged to consult with their own tax advisors with respect to the tax consequences of the Domestication Merger.

Notwithstanding that the Domestication Merger and the Merger together are intended to qualify as a Section 351(a) Exchange, the Domestication Merger could be a taxable event for certain former U.S. Holders of Intec Israel ordinary shares.

Subject to the limitations and qualifications described in "*The Merger - Material U.S. Federal Income Tax Consequences of the Domestication Merger and the Merger*," described in the registration statement on Form S-4, as amended (File No. 333-255389), filed by us with the SEC, or the Form S-4, including the application of the passive foreign investment company, or PFIC rules, the Domestication Merger is intended to qualify, taken together with the Merger, as a Section 351(a) Exchange. Nonetheless, certain former U.S. Holders of Intec Israel's ordinary shares are likely to be taxed under the PFIC rules of the Code because of the likelihood that Intec Israel is classified as a PFIC.

General Risk Factors

Unfavorable global economic or geopolitical conditions could adversely affect our business, financial condition or results of operations.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. For example, the U.S. and global markets have been experiencing and are continuing to experience extreme volatility and disruptions in the capital and credit markets and commodity prices due to rising inflation and interest rates, geopolitical tensions such as the conflict between Russia and Ukraine and the armed conflict in Israel and Gaza, and other macroeconomic factors. A severe or prolonged economic downturn, such as the current macroeconomic environment, could result in a variety of risks to our business, including, our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers of raw materials used to manufacture our product candidates for our clinical trials, possibly resulting in supply disruption. Furthermore, our stock price may decline due in part to the volatility of the stock market and any general economic downturn.

Changes in tax law and regulations could adversely affect our business, financial condition and results of operations.

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could affect the tax treatment of any of our future earnings. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. Generally, future changes in applicable tax laws and regulations, or their interpretation and application, potentially with retroactive effect, could have an adverse effect on our business, financial condition and results of operations. We are unable to predict whether such changes will occur and, if so, the ultimate impact on our business. We urge investors to consult with their legal and tax advisers regarding the implications of potential changes in tax laws on an investment in our common stock.

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

None.

Item 3. Defaults Upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

During the three months ended September 30, 2023 March 31, 2024, no director or "officer" (as defined in Rule 16a-1(f) under the Exchange Act) of the Company adopted or terminated a "Rule "Rule 10b5-1 trading arrangement" arrangement" or "non-Rule "non-Rule 10b5-1 trading arrangement„" as each term is defined in Item 408(a) of Regulation S-K.

Item 6. Exhibits

Exhibit No.	Exhibit Description
3.1	Amended and Restated Certificate of Incorporation of Indaptus Therapeutics, Inc., dated as of July 23, 2021 (incorporated herein by reference to Exhibit 3.1 of the Company's Current Report on Form 8-K filed with the SEC on July 23, 2021)
3.2	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Indaptus Therapeutics, Inc. dated August 3, 2021 (incorporated herein by reference to Exhibit 3.1 of the Company's Current Report on Form 8-K filed with the SEC on August 6, 2021)
3.3	Amended and Restated Bylaws of Indaptus Therapeutics, Inc., dated as of July 23, 2021 January 22, 2024 (incorporated herein by reference to Exhibit 3.2 of the Company's Current Report on Form 8-K filed with the SEC on July 23, 2021)
3.4	Amendment No. 1 to the Amended and Restated Bylaws of Indaptus Therapeutics, Inc., dated as of July 20, 2022 (incorporated by reference to Exhibit 3.1 of the Company's Current Report on Form 8-K filed with the SEC on July 20, 2022 January 23, 2024)
31.1*	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a), promulgated under the Securities Exchange Act of 1934, as amended
31.2*	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a), promulgated under the Securities Exchange Act of 1934, as amended
32.1#	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2#	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS*	Inline XBRL Instance Document
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Labels Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as Inline XBRL document and included in Exhibit 101)

* Filed herewith

\# Furnished herewith

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

Indaptus Therapeutics, Inc.

Date: November 6, 2023 May 8, 2024

By: */s/ Jeffrey A. Meckler*
Jeffrey A. Meckler
Chief Executive Officer
(Principal Executive Officer)

Date: November 6, 2023 May 8, 2024

By: */s/ Nir Sassi*
Nir Sassi
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 31.1

CERTIFICATIONS

I, Jeffrey A. Meckler, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the quarter ended September 30, 2023 March 31, 2024 of Indaptus Therapeutics, Inc. (the "registrant");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f)and 15d-15(f)) for the registrant and have:

    a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 6, 2023 May 8, 2024

/s/ Jeffrey A. Meckler
Jeffrey A. Meckler
Chief Executive Officer and Director
(principal executive officer)

Exhibit 31.2

CERTIFICATIONS

I, Nir Sassi, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the quarter ended September 30, 2023 March 31, 2024 of Indaptus Therapeutics, Inc. (the "registrant");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f)and 15d-15(f)) for the registrant and have:

    a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 6, 2023 May 8, 2024

/s/ Nir Sassi
Nir Sassi
Chief Financial Officer
(principal financial officer)

Exhibit 32.1

Indaptus Therapeutics, Inc.

Certification Pursuant to
18 U.S.C. Section 1350,
as Adopted Pursuant to
Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the Quarterly Report of Indaptus Therapeutics, Inc. (the "Company") on Form 10-Q for the quarter ended September 30, 2023 March 31, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Jeffrey A. Meckler, Chief Executive Officer and Director of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(a) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(b) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Jeffrey A. Meckler
Jeffrey A. Meckler
Chief Executive Officer and Director
(principal executive officer)

Date: November 6, 2023 May 8, 2024

Exhibit 32.2

Indaptus Therapeutics, Inc.

Certification Pursuant to
18 U.S.C. Section 1350,
as Adopted Pursuant to
Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the Quarterly Report of Indaptus Therapeutics, Inc. (the "Company") on Form 10-Q for the quarter ended September 30, 2023 March 31, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Nir Sassi, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(a) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(b) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Nir Sassi
Nir Sassi
Chief Financial Officer
(principal financial officer)

Date: November 6, 2023 May 8, 2024

DISCLAIMER

THE INFORMATION CONTAINED IN THE REFINITIV CORPORATE DISCLOSURES DELTA REPORT™ IS A COMPARISON OF TWO FINANCIALS PERIODIC REPORTS. THERE MAY BE MATERIAL ERRORS, OMISSIONS, OR INACCURACIES IN THE REPORT INCLUDING THE TEXT AND THE COMPARISON DATA AND TABLES. IN NO WAY DOES REFINITIV OR THE APPLICABLE COMPANY ASSUME ANY RESPONSIBILITY FOR ANY INVESTMENT OR OTHER DECISIONS MADE BASED UPON THE INFORMATION PROVIDED IN THIS REPORT. USERS ARE ADVISED TO REVIEW THE APPLICABLE COMPANY'S ACTUAL SEC FILINGS BEFORE MAKING ANY INVESTMENT OR OTHER DECISIONS.

REFINITIV