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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 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, NY	**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:

Common stock, par value $0.01	**INDP**	**Nasdaq Capital Market**
(Title of each class)	**Trading Symbol(s)**	**(Name of each exchange on which registered)**

Securities registered pursuant to Section 12(g) of the Act:
None

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES ☐ NO ☒

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. YES ☐ NO ☒

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

Indicate by check mark whether the Registrant has submitted electronically, every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit such files). YES ☒ NO ☐

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

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

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

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to § 240.10D-1(b). ☐

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

At June 30, 2024, the last business day of the Registrant's most recently completed second fiscal quarter, the aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant was $15,039,986.

The number of shares of Registrant's common stock outstanding as of March 12, 2025 was 14,429,244.

DOCUMENTS INCORPORATED BY REFERENCE

None.

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ABOUT THIS ANNUAL REPORT

All references to "we," "us," "our," "Indaptus Therapeutics", "Indaptus", "the Company" and "our company", in this Annual Report on Form 10- K, or our Annual Report, are to Indaptus Therapeutics, Inc. (formerly Intec Parent, Inc.) and, where appropriate, its consolidated subsidiaries, Intec Pharma Ltd. and Decoy Biosystems, Inc. All references to "common stock" and "share capital" refer to common stock and share capital of Indaptus. Our historical results do not necessarily indicate our expected results for any future periods. Any discrepancies in any table between totals and sums of the amounts listed are due to rounding. Unless otherwise indicated, or the context otherwise requires, references in this Annual Report to financial and operational data for a particular year refer to the fiscal year of our Company ended December 31 of that year.

EXPLANATORY NOTE

Market data and certain industry data and forecasts used throughout this Annual Report were obtained from market research databases, consultant surveys commissioned by us, publicly available information, reports of governmental agencies and industry publications and surveys. Industry surveys, publications, consultant surveys commissioned by us and forecasts generally state that the information contained therein has been obtained from sources believed to be reliable. We have relied on certain data from third-party sources, including internal surveys, industry forecasts and market research, which we believe to be reliable based on our management's knowledge of the industry. Statements as to our market position are based on the most currently available data. While we are not aware of any misstatements regarding the industry data presented in this Annual Report, our estimates involve risks and uncertainties and are subject to change based on various factors, including those discussed under Part I. Item 1A. "Risk Factors" in this Annual Report.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual 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 Annual Report on Form 10-K 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' 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; 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 on our business.

The forward-looking statements in this Annual 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 Annual Report and are subject to a number of known and unknown risks, uncertainties and assumptions, including those described under the sections in this Annual Report entitled "Summary Risk Factors," Part I. Item 1A. "Risk Factors" and Part II. Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere in this Annual 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 Annual 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.
- 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

Item 1. Business.

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 four different classes of existing agents, including NSAIDs, checkpoint therapy, targeted antibody therapy and low-dose chemotherapy. Tumor eradication by our technology was associated with induction of both innate and adaptive immunological memory and, importantly, did not require provision of or targeting a tumor antigen in preclinical models. We have carried out successful current Good Manufacturing Practice (cGMP) manufacturing of our lead clinical candidate, Decoy20.

In May 2022, the U.S. Food and Drug Administration, or the FDA, allowed us to proceed under our IND for a Phase 1 clinical trial in patients with advanced solid tumors where currently approved therapies have failed. In December 2022, we initiated an open label, multi-center, dose escalation and expansion, single arm (monotherapy) Phase 1 study conducted in 2 parts. The Phase 1 study began with single dose administration and has now been followed with continuous weekly dosing of Decoy20 in tumor-specific expansion cohorts. The study is enrolling patients with any one of six 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, the optimal biologically active and recommended Phase 2 dose, as well as to assess Decoy20 pharmacokinetics (PK), pharmacodynamics and clinical activity. The primary endpoints of the study 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 and duration of response.

In August 2023, we evaluated the first four patients who received a single dose of 7 x 10^7 Decoy20 in Part 1 of the Phase 1 clinical trial. All four patients who enrolled were evaluable in the first cohort. These patients experienced generally anticipated transient adverse events including hemodynamic changes such as changes in pulse or blood pressure that resolved within 30 minutes and 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 end of 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 cytokine/chemokines returned to the patient's respective 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 began the second cohort of the Phase 1 clinical trial after receiving authorization from the Safety Review Committee. The second cohort dose was a reduction from 7 x 10^7 Decoy20 dose to 3 x 10^7 Decoy20. In March 2024, we completed the second cohort of patients who received a single dose of 3 x 10^7 Decoy20 in Part 1 of the clinical trial Patients on the second (lower dose) cohort experienced adverse events similar in frequency and severity to the higher dose cohort with one dose-limiting toxicity of grade 3 ALT elevation that required one week to resolve. Pharmacodynamic effects included transient induction of multiple biomarkers. Clearance of Decoy20 was similarly rapid. Following authorization from the Safety Review Committee, we advanced into the weekly dosing part of the trial.

In May and June 2024, we enrolled two additional patients in the first cohort who received a single dose of 7 x 10^7 Decoy20, and in August 2024 we received the authorization from the Safety Review Committee to initiate the weekly dosing with 7 x 10^7 Decoy20.

As of October 2024, we completed one month of the weekly dosing part in the first six patients at the 3 x 10^7 Decoy20 dose and following the review of the safety data by the Safety Review Committee we received the authorization to initiate unrestricted enrollment of patients at the 3 x 10^7 Decoy20 dose. As of March 12, 2025, we have enrolled more than 20 patients in the weekly dosing among the two Decoy20 dose levels and we have observed early signs of potential benefits emerging with some patients with stable disease. We are working to increase the number of trial sites to accelerate patient enrollment and data collection.

In October 2024, we entered into a clinical supply agreement, or the Supply Agreement, with BeiGene Switzerland GmbH, or BeiGene, to advance clinical evaluation of Decoy20 in combination with BeiGene's anti-PD-1 antibody, tislelizumab, or the BeiGene Product, for the treatment of patients with advanced solid tumors, or the Combination Study. This Combination Study builds on preclinical results where Decoy20, combined with a PD-1 inhibitor, demonstrated high tumor eradication rates and established immunological memory. We intend to seek approval from the FDA to initiate the Combination Study, which is anticipated to begin in 2025.

Under the terms of the Supply Agreement, we will pay for all costs associated with the Combination Study (other than the cost of the BeiGene Product), BeiGene will supply the BeiGene Product to us for the purposes of the study, and we will supply Decoy20 for the purposes of the Combination Study. The Supply Agreement will terminate upon the earlier of (i) the one-year anniversary of the date that we provide BeiGene with the Combination Study's final clinical study report or (ii) the date of termination of the Combination Study, subject to early termination in certain circumstances.

In February 2025, we announced that we received clinical trial authorization from Health Canada to initiate a clinical trial for Decoy20 which allows us to expand our ongoing U.S. clinical trial to Canadian sites. The trial will enroll patients in Canada under the current protocol, which involves weekly dosing of Decoy20. We also plan to submit an amendment to Health Canada to initiate the Combination Study in Canada.

Unlike many competitor products, our technology does not depend on targeting with or to a specific antigen, providing broad potential across multiple indications. Our products are designed to have a much shorter half-life and produce less systemic exposure than small molecule, antibody or human cell-based therapies, potentially reducing the risk of non-specific auto-immune reactions. Our technology has produced single agent activity and/or combination therapy-based durable responses in lymphoma, hepatocellular, colorectal and pancreatic tumors and has also showed activity against hepatitis B virus (HBV) and HIV infection in standard preclinical models. Our target indications include, but are not limited to, colorectal, hepatocellular (± HBV), bladder, cervical and pancreatic carcinoma, which according to GLOBOCAN 2020, account in the aggregate for 23% of yearly cancer cases and over 28% of yearly cancer deaths world-wide.

Historically, we have operated virtually with a team of highly experienced consultants and advisors, carrying out research and development at contract research organizations (CROs). We have developed patented treatment methods (and associated patented compositions) for attenuation and killing of non-pathogenic, Gram-negative bacteria (34 issued or granted patents). Since our inception, we have funded our operations primarily through public and private offerings of our equity securities.

Recent Developments

February 2025 Equity Line

On February 12, 2025, we entered into a Standby Equity Purchase Agreement, or the SEPA with YA II PN, LTD., a Cayman Islands exempt limited company, or Yorkville. Pursuant to the SEPA, we have the right, but not the obligation, to sell to Yorkville from time to time up to $20.0 million of our common stock, during the 36 months following the execution of the Purchase Agreement, subject to the restrictions and satisfaction of the conditions in the SEPA. At our option, the shares of common stock would be purchased by Yorkville from time to time at a price equal to 97% of the lowest of the three daily VWAPs during a three consecutive trading day period commencing on the date that we, subject to certain limitations, deliver a notice to Yorkville that the Company is committing Yorkville to purchase such shares of common stock. We may also specify a certain minimum acceptable price per share in each Advance. As consideration for Yorkville's irrevocable commitment to purchase our shares, we issued to Yorkville 305,960 shares of common stock. Under the applicable rules of Nasdaq and pursuant to the SEPA, in no event may we issue or sell to Yorkville more than 2,823,244 shares of common stock, or the Exchange Cap, which is 19.99% of the shares of common stock outstanding immediately prior to the execution of the SEPA, unless (i) we obtain stockholder approval to issue shares of common stock in excess of the Exchange Cap or (ii) the average price of all applicable sales of common stock under the SEPA equals or exceeds $0.81722 per share (which represents the lower of (i) the Nasdaq Official Closing Price (as reflected on Nasdaq.com) on the trading day immediately preceding the effective date or (ii) the average Nasdaq Official Closing Price of the common stock (as reflected on Nasdaq.com) for the five trading days immediately preceding the effective date). In addition, effective February 12, 2025, we terminated the purchase agreement that we entered into with Lincoln Park Capital Fund, LLC in December 2022.

January 2025 Financing

On January 12, 2025, we entered into securities purchase agreements, or the January 2025 Purchase Agreements, with certain institutional and accredited investors, or the January 2025 Purchasers. The January 2025 Purchase Agreements provide for the sale and issuance by us of an aggregate of: (i) 2,109,383 shares of our common stock and (ii) warrants to purchase 2,109,383 shares of common stock in a private placement, or the January 2025 Warrants. The shares and January 2025 Warrants were sold on a combined basis for consideration of $1.065 for one share and a January 2025 Warrant. The exercise price of the January 2025 Warrants is $0.94 per share.

The January 2025 Warrants were immediately exercisable upon issuance and will expire five years following the date of issuance. The January 2025 Warrants contain standard adjustments to the exercise price including for stock splits, stock dividends and reorganizations. In lieu of making the cash payment otherwise contemplated to be made upon exercise in payment of the aggregate exercise price, the holder may, in the event the shares underlying the January 2025 Warrants are not registered under the Securities Act, elect instead to receive upon such exercise (either in whole or in part) the net number of shares of common stock determined according to a formula set forth in the January 2025 Warrants. Under the terms of the January 2025 Warrants, a holder (together with its affiliates) may not exercise any portion of its January 2025 Warrant to the extent that the holder would beneficially own more than 4.99% or 9.99%, depending on the individual investor, of the outstanding common stock immediately after exercise, or the Beneficial Ownership Limitation, except that upon at least 61 days' prior notice from the holder to us, the holder may increase the Beneficial Ownership Limitation, provided that the Beneficial Ownership Limitation in no event exceeds 19.99%.

Paulson Investment Company, LLC, or Paulson, served as the exclusive placement agent for the issuance and sale of the securities. As compensation for such placement agent services, we paid Paulson an aggregate cash fee equal to 7.0% of the gross proceeds received by us from the offering, and a non-accountable expense of $25,000. As additional compensation to Paulson, we issued to the Paulson (or its designees) a warrant, or the January 2025 Placement Agent Warrants, to purchase an aggregate of 147,656 shares at an exercise price per share equal to $1.175 per share. The January 2025 Placement Agent Warrants are exercisable six months from the date of issuance and expire on the fifth anniversary of the issue date.

November 2024 Financing

On November 22, 2024, we entered into securities purchase agreements, or the November 2024 Purchase Agreements, with certain institutional and accredited investors, or the November 2024 Purchasers. The November 2024 Purchase Agreements provide for the sale and issuance by us of an aggregate of: (i) 1,817,017 shares of our common stock in a registered direct offering and (ii) warrants to purchase 1,817,017 shares of common stock in a private placement, or the November 2024 Warrants. The shares and November 2024 Warrants were sold on a combined basis for consideration of $1.175 for one share and a November 2024 Warrant. The exercise price of the November 2024 Warrants is $1.05 per share. One of the November 2024 Purchasers was our Chief Executive Officer, who purchased 42,553 shares and November 2024 Warrants to purchase 42,553 shares, or the Affiliate Securities, at the same price and upon the same terms as the other November 2024 Purchasers.

The November 2024 Warrants were immediately exercisable upon issuance and will expire five years following the date of issuance. The November 2024 Warrants contain standard adjustments to the exercise price including for stock splits, stock dividends and reorganizations. In lieu of making the cash payment otherwise contemplated to be made upon exercise in payment of the aggregate exercise price, the holder may, in the event the shares underlying the November 2024 Warrants are not registered under the Securities Act, elect instead to receive upon such exercise (either in whole or in part) the net number of shares of common stock determined according to a formula set forth in the November 2024 Warrants. Under the terms of the November 2024 Warrants, a holder (together with its affiliates) may not exercise any portion of its November 2024 Warrant to the extent that the holder would beneficially own more than the Beneficial Ownership Limitation, except that upon at least 61 days' prior notice from the holder to us, the holder may increase the Beneficial Ownership Limitation, provided that the Beneficial Ownership Limitation in no event exceeds 19.99%.

Paulson served as the exclusive placement agent for the issuance and sale of the securities. As compensation for such placement agent services, we paid Paulson an aggregate cash fee equal to 7.0% of the gross proceeds received by us from the offering (excluding the Affiliate Securities), and a non-accountable expense of $25,000. As additional compensation to Paulson, we issued to the Paulson (or its designees) a warrant, or the November 2024 Placement Agent Warrants, to purchase an aggregate of 124,212 shares at an exercise price per share equal to $1.3125 per share. The November 2024 Placement Agent Warrants are exercisable six months from the date of issuance and expire on the fifth anniversary of the issue date.

Supply Agreement

On October 17, 2024, we entered into a clinical supply agreement, or the Supply Agreement, with BeiGene Switzerland GmbH, or BeiGene, to advance clinical evaluation of Decoy20, our novel product candidate designed to induce a broad immune response to fight cancer, in combination with BeiGene's anti-PD-1 antibody, tislelizumab, or the BeiGene Product, for the treatment of patients with advanced solid tumors, or the Combination Study. We intend to seek approval from the FDA to initiate the Combination Study, which is anticipated to begin in 2025. Under the terms of the Supply Agreement, we will pay for all costs associated with the Combination Study (other than the cost of the BeiGene Product), BeiGene will supply the BeiGene Product to us for the purposes of the study, and we will supply Decoy20 for the purposes of the Combination Study. The Supply Agreement will terminate upon the earlier of (i) the one-year anniversary of the date that we provide BeiGene with the Combination Study's final clinical study report or (ii) the date of termination of the Combination Study, subject to early termination in certain circumstances

August 2024 Financing

On August 8, 2024, we completed a registered direct offering, pursuant to which we sold and issued to certain investors, including one of our officers, 1,643,837 shares of common stock. In addition, in a concurrent private placement, we issued to the investors unregistered warrants to purchase 1,643,837 shares of common stock, or the August 2024 Private Placement. The warrants were immediately exercisable at an exercise price of $1.70 per share and expire five years from the date of issuance. The combined purchase price for one share of common stock and one warrant was $1.825, resulting in gross proceeds of approximately $3.0 million, before deducting placement agent and other offering expenses in the amount of approximately $0.5 million.

Background

Approved immunotherapies, such as Interluekin-2, Interferon-alpha and the more recently approved "checkpoint" and CAR-T therapies produce durable responses in a few percent to about fifty percent of patients across about a dozen out of over one hundred different types of cancer. Although checkpoint therapies are able to effectively cure many previously incurable patients, only about 15% of patients receiving this type of therapy respond. The main limitation of existing immunotherapies is that they each activate only one or a small number of key steps in either the innate or adaptive immune system, but there is general agreement that highly efficient cancer immunotherapy will require activation of both innate and adaptive immunity. The human body's innate and adaptive immune systems are each capable of cell-mediated destruction of tumors if the tumor cells are recognized as foreign or damaged. Activation of innate and adaptive responses is also dependent on immune cells sensing the presence of "danger." The most potent immune cell activating danger signals are released by bacteria and viruses in the setting of infection, and include agonists of immune cell receptors, such as Toll-Like (TLR), NOD and STING. Bacterial danger signals, including TLR agonists are called pathogen-associated molecular patterns (PAMPs) and can activate both innate and adaptive immune cells, including antigen-presenting cells, promoting innate (NK, macrophage) and adaptive (T cell-mediated) destruction of tumors.

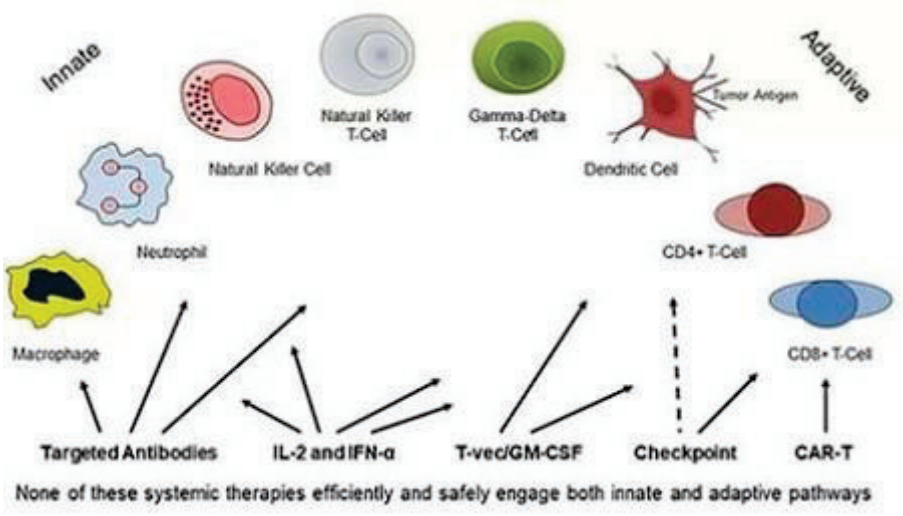
The oldest form of cancer immunotherapy involves the provision of decoy danger signals from bacteria. It was based on the long-standing observation of tumor regression in the setting of bacterial infection. Treatment of cancer patients with heat-killed bacteria ("Coley's toxins") was established in 1891 and used for 70 years with significant success. For example, ≥5-year survival was reported for 45% of 432 inoperable sarcoma, lymphoma, melanoma, and carcinoma patients. Despite this success, several limitations led to the abandonment of this approach by the pharmaceutical industry. Although there was an indication that Coley's toxins worked best when administered intravenously (i.v.), it was too toxic when given by this route, limiting the approach to local administration, which produced highly variable results. Another limitation was lack of knowledge about the mechanism of action, preventing optimization and standardization of manufacturing, leading to another source of variability in clinical response. Due to this high variability, Coley's toxins was not grandfathered-in as an approved drug by the FDA in 1963 and was supplanted by radiation and chemotherapy, despite the fact that these more modern approaches rarely produce durable responses in advanced cancer patients. Scientists now understand the mechanism of action of Coley's toxins. Gram-negative bacteria contain multiple immune-stimulating danger signals, including TLR agonists such as

lipopolysaccharide (LPS). Bacteria and purified or mono-specific TLR agonists, including LPS derivatives, have been validated and approved for prevention and treatment of early stage cancer. However, a safe and effective TLR agonist-based approach for advanced cancer has been elusive, possibly due to limitations in the ability of intratumorally administered, mono-specific TLR agonists to induce potent, systemic anti-tumor immune responses. In addition, the intratumoral approach is not feasible with all tumor types or patients. Our hypothesis is that an effective TLR agonist-based immunotherapy for advanced cancer will require invention of a packaged, multi-TLR agonist or multi-danger signal product that is modified or attenuated to allow safe i.v. administration.

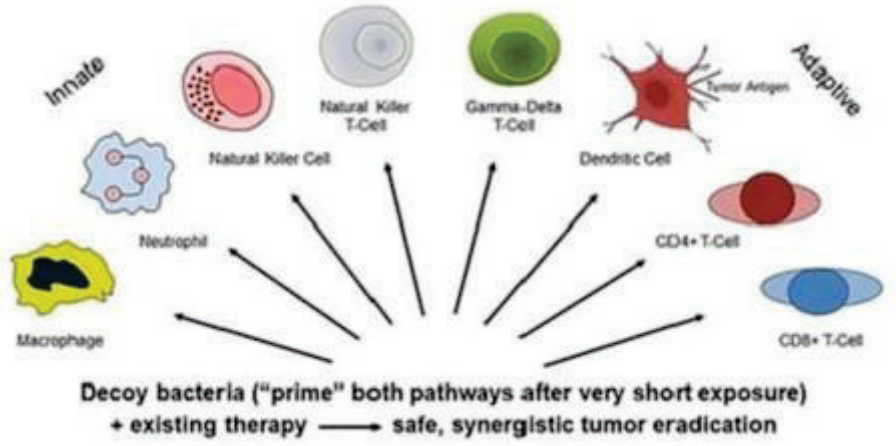
Our Approach

Our patented approach is based on the hypothesis that efficient activation of both innate and adaptive immune cells and associated anti-tumor immune responses can be achieved by using intact bacteria, containing multiple PAMPs, which have been attenuated so that they can be administered safely intravenously. Because LPS appears to be the most important contributor to both toxicity and efficacy, our patented product candidates are single strains of killed, non-pathogenic Gram-negative bacteria that have been treated in an effort to kill the bacteria and significantly reduce, but not completely eliminate, the cell surface LPS-endotoxin activity. Our product candidates are designed to have enhanced sufficient residual LPS to synergize with other PAMPs in the bacteria to efficiently prime innate and adaptive immune pathways. 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 four different classes of existing agents, including NSAIDs, checkpoint therapy, targeted antibody therapy and low-dose chemotherapy. Tumor eradication by our technology is designed to produce both innate and adaptive immunological memory and, importantly, not require provision of an exogenous tumor antigen, potentially due to the ability of LPS and other PAMPS to activate dendritic cells that have already captured a tumor antigen.

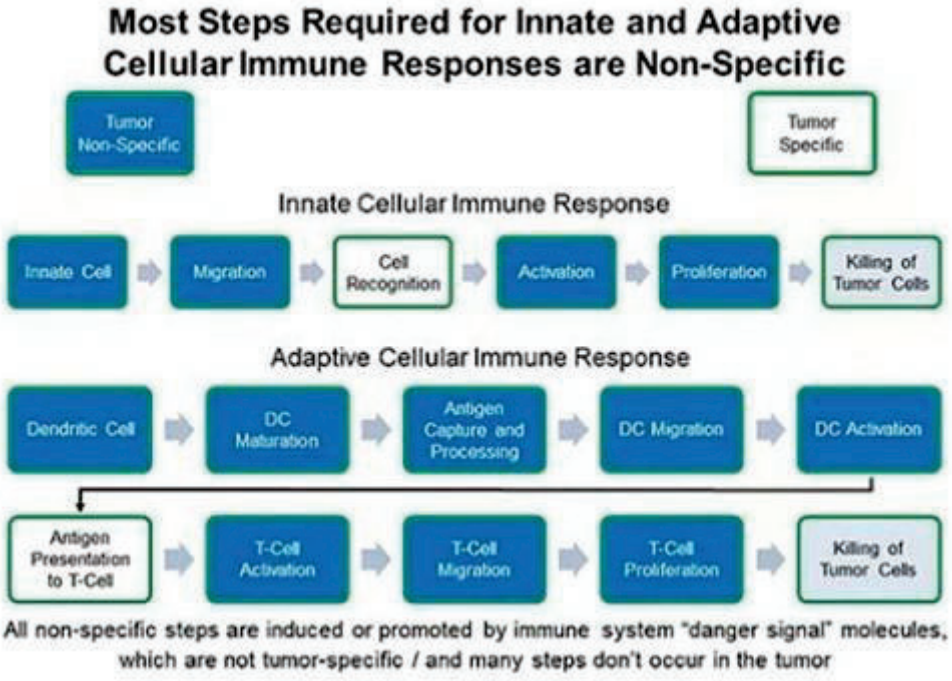
All immune cells can participate in killing of tumors and viruses. As illustrated below, current therapies activate only one or a small subset of both pathways and cure only a small percentage of patients.



Our technology, however, is designed to synergize with existing therapies to activate both innate and adaptive immune cells, inducing efficient anti- tumor immune responses with a wide safety margin. Induction of adaptive anti-tumor immune responses and immunological memory by our technology does not require an exogenous tumor antigen.



Innate and adaptive immune responses require identification of a tumor as foreign or not self. However, most steps required for migration and activation of immune cells are unrelated to the tumor or are tumor non-specific. All innate and adaptive non-specific steps are induced or promoted by immune system "danger signal" molecules, such as those found in our bacteria. Bacteria-derived danger signals are also able to enhance the processing and recognition of tumor antigens, which are frequently present, but not "seen" by the immune system.



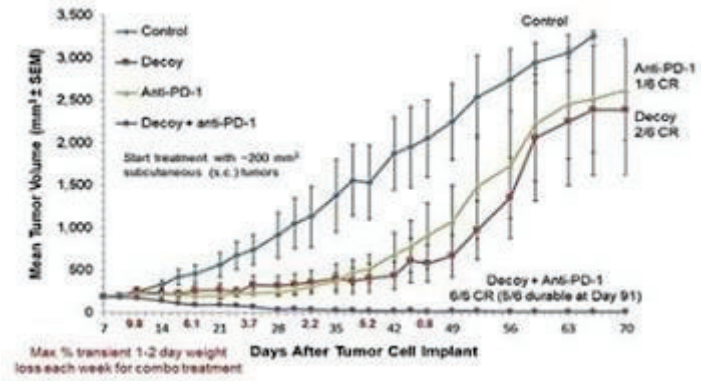
Results

Preclinical Trials

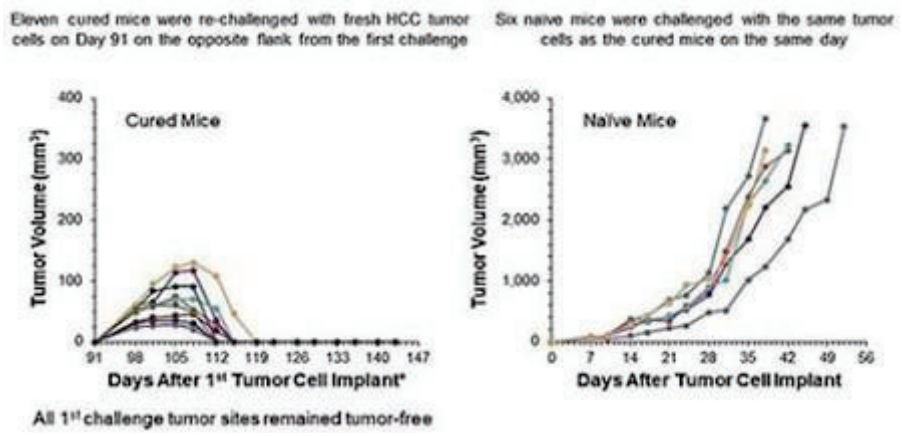
In preclinical models, Indaptus treated bacteria induced less systemic toxicity than untreated bacteria but were still able to activate innate and adaptive immune responses. Despite exhibiting reduced in vivo pyrogenicity and a higher maximally tolerated dose, our bacteria were able to induce secretion of most cytokines and chemokines from mouse and human immune cells in vitro at levels comparable to those seen with untreated bacteria. Our bacteria were also able to synergize with human immune cells to kill human tumor cells in vitro.

We have observed significant single agent anti-tumor activity and/or combination therapy-mediated regression with durable responses in established non-Hodgkin's lymphoma, as well as colorectal, hepatocellular and pancreatic carcinoma in preclinical syngeneic and human tumor xenograft models. Our bacteria synergized with each of four different classes of approved agents in preclinical models, including NSAIDs, checkpoint therapy, targeted antibody therapy and low-dose chemotherapy to induce tumor regression, providing significant flexibility for targeting of diverse types of cancer. Our technology is designed to eradicate tumors via activation of both innate (NK cell) and adaptive (CD4+ and CD8+ T cell) mechanisms, with the goal of producing both innate and adaptive immunological memory. In our preclinical studies, tumor eradication occurred at non-toxic doses of our bacteria, with a very wide (10 to ≥33-fold) therapeutic index. Notable mechanism of action information has also been obtained, via gene expression analysis with treated tumors and plasma cytokine analysis, demonstrating that our combination technology has the potential to turn "cold" tumors into "hot" tumors and induce, activate or recruit innate and adaptive genes, cells and pathways. Immune cell pre-depletion studies have demonstrated that both innate (NK) and adaptive (CD4 T and CD8 T) immune cells are involved in tumor eradication. We have also demonstrated significant single agent activity against chronic Hepatitis B virus (HBV) and human immunodeficiency virus (HIV) infection in standard preclinical models.

We have carried out successful cGMP manufacturing and stability studies with our lead product candidate, Decoy20. In addition, IND-enabling multi-dose toxicology studies have been completed and did not produce sustained induction of factors that are associated with cytokine release syndrome.



The chart above demonstrates that our bacteria synergize with Anti-PD-1 Checkpoint therapy to regress established mouse hepatocellular carcinoma (HCC) Tumors. All mice (all groups) received a low-dose, non-steroidal anti-inflammatory drug (NSAID/Indomethacin), which increases the number of regressions in the combination setting. Most regressions were durable, with 5/6 combination regressions stable through termination at Day 91 and in a repeat experiment through termination at Day 143 (see next Figure below) (CR = complete response or complete regression). The repeat experiment also produced 5/6 or 6/6 durable regressions per group over a 33-fold Indaptus concentration range and an absence of safety concerns, demonstrating a very wide therapeutic index. Similar tumor eradication results have been obtained by combining our bacteria with low-dose chemotherapy in a mouse non-Hodgkin's lymphoma model. Eradication of established non-Hodgkin's lymphoma tumors by our technology has also been observed with human tumor xenografts, via activation of the innate immune system. Development and preclinical efficacy characterization of a systemically administered multiple Toll-like receptor (TLR) agonist for antitumor immunotherapy [abstract]. In: Proceedings of the Fourth CRI-CIMT-EATI-AACR International Cancer Immunotherapy Conference: Translating Science into Survival; Sept 30-Oct 3, 2018; New York, NY. Philadelphia (PA): AACR; Cancer Immunol Res 2019;7(2 Suppl):Abstract nr B178.



The chart above illustrates that the synergistic tumor eradication by our technology and Anti-PD-1 produces immunological memory. Established tumors were regressed in 11 mice by combination treatment as in the Figure above and then the mice were re-challenged with fresh HCC tumor cells, without further treatment. All of the new tumors were rejected. Similar results have been obtained by combining our bacteria with low-dose chemotherapy in a non-Hodgkin's lymphoma model.

Clinical Trial

In May 2022, the FDA allowed us to proceed under our 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, pharmacodynamics and clinical activity. The primary endpoint of the study is 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, patients experienced symptoms or adverse events (AEs) that were short-lived and consistent with the mechanism of action of Decoy20. 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 cohort of the Phase 1 clinical trial. The second cohort dose was 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 multi-dosing and combination approaches. In May 2024, we successfully dosed the first patient in the multi-dose portion of the Phase I clinical trial with Decoy20. The primary goal of this stage of the trial was to evaluate the safety of Decoy20 when administered multiple times to the same patient. We intend to progress Decoy20 into combination studies with a checkpoint inhibitor. In August 2024, the Safety Review Committee convened to review the safety data at the higher Decoy20 dose with single dose administration and the safety data at the lower Decoy20 dose with weekly administration. The data led to the decision to continue dosing additional patients at the lower Decoy20 dose on a weekly schedule and initiate dosing patients at the higher Decoy20 dose on a weekly schedule. In October 2024, the Safety Review Committee examined weekly administration data at the lower Decoy20 dose and cleared unrestricted enrollment of patients at this dose. As of March 12, 2025, we have enrolled more than 20 patients in the weekly dosing among the two Decoy20 dose levels and we have observed early signs of potential benefits emerging with some patients with stable disease. We are working to increase the number of trial sites to accelerate patient enrollment and data collection.

In February 2025, we announced that we received clinical trial authorization from Health Canada to initiate a clinical trial for Decoy20 which allows us to expand our ongoing U.S. clinical trial to Canadian sites. The trial will enroll patients in Canada under the current protocol, which involves weekly dosing of Decoy20. We also plan to submit an amendment to Health Canada to initiate the Combination Study in Canada.

Business Strategy

Our mission is to enhance and expand curative cancer immunotherapy for patients with unresectable or metastatic solid tumors and lymphomas, which are responsible for approximately 90% of all cancer deaths.

Our business strategy includes:

- adding operational, financial and management information systems and personnel, including personnel to support our planned product development and commercialization efforts, as well as to support our reporting and other compliance obligations as a public reporting company;
- advancing to the expansion portion of the Phase 1 clinical trial for Decoy20;
- expanding our bacterial product platform to target additional types of cancer, as well as additional infectious diseases;
- maintaining, expanding and protecting our intellectual property portfolio; and
- seeking regulatory approvals for any product candidates that successfully complete clinical trials.

Competitive Advantages

Our bacteria contain multiple constituents, capable of priming or activating many of the cellular components of both innate and adaptive immunity, but have been attenuated by a patented process to reduce the potential for over-stimulation of the immune system and consequential induction of undesirable autoimmune reactions. Our bacteria are also likely to be cleared very quickly by the liver and spleen, which may further reduce the risk of non-specific autoimmune side effects, relative to other types of immunotherapy that are designed for continuous exposure. We believe a short exposure of our products is sufficient to act alone and as a "primer" to enhance other products. Additionally, our products can be manufactured by a highly cost-efficient process, potentially providing accelerated patient access in both developed and developing geographical regions.

Governmental Regulation

Among others, the FDA and comparable regulatory authorities in state and local jurisdictions and in other countries impose substantial and burdensome requirements upon companies involved in the clinical development, manufacture, marketing and distribution of drugs such as those we are developing. These agencies and other federal, state and local entities regulate, among other things, the research and development, testing, manufacture, quality control, safety, effectiveness, labeling, storage, record keeping, approval, advertising and promotion, distribution, post-approval monitoring and reporting, sampling and export and import of our product candidates.

U.S. Regulation of Drugs and Biologics

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act (FDCA) and its implementing regulations, and biologics under the FDCA and the Public Health Service Act (PHSA) and its implementing regulations. FDA approval is required before any new unapproved drug or dosage form, including a new use of a previously approved drug, can be marketed in the United States. Drugs and biologics are also subject to other federal, state, and local statutes and regulations. The process required by the FDA before product candidates may be marketed in the United States generally involves the following:

- completion of extensive preclinical laboratory tests, animal studies and formulation studies, performed in accordance with the Good Laboratory Practices (GLP) regulations and other applicable regulations;
- submission to the FDA an IND, which must become effective before human clinical studies may begin and must be updated annually;
- approval by an independent institutional review board (IRB) or ethics committee representing each clinical site before each clinical study may be initiated;

- performance of adequate and well-controlled human clinical studies in accordance with Good Clinical Practice (GCP), requirements to establish the safety and efficacy, or with respect to biologics, the safety, purity and potency of the product candidate for each proposed indication;
- preparation of and submission to the FDA of a new drug application (NDA) or biologics license application, (BLA), after completion of all pivotal clinical studies;
- a determination by the FDA within 60 days of its receipt of an NDA or BLA to file the application for review;
- potential review of the product application by an FDA advisory committee, where appropriate and if applicable;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facilities where the proposed product drug is produced to assess compliance with cGMP, to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity, and of potential inspection of selected clinical investigation sites to assess compliance with GCPs; and
- FDA review and approval of an NDA or BLA prior to any commercial marketing or sale of the drug in the United States.

Once a product candidate is identified for development, it enters the preclinical testing stage. Preclinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information and analytical data, to the FDA as part of an IND. An IND is a request for authorization from the FDA to administer an investigational drug product to humans. An IND will also include a protocol detailing, among other things, the objectives of the clinical trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated, if the trial includes an efficacy evaluation. Some preclinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, places the clinical trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Clinical holds also may be imposed by the FDA at any time before or during clinical trials due to safety concerns about on-going or proposed clinical trials or non-compliance with specific FDA requirements, and the trials may not begin or continue until the FDA notifies the sponsor that the hold has been lifted.

All clinical trials must be conducted under the supervision of one or more qualified investigators in accordance with GCPs, which include the requirement that all research subjects provide their informed consent in writing for their participation in any clinical trial. Clinical trials must be conducted under protocols detailing the objectives of the trial, dosing procedures, subject selection and exclusion criteria and the safety and effectiveness criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND, and a separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments. While the IND is active, progress reports summarizing the results of the clinical trials and nonclinical studies performed since the last progress report, among other information, must be submitted at least annually to the FDA, and written IND safety reports must be submitted to the FDA and investigators for serious and unexpected suspected adverse events, findings from other studies suggesting a significant risk to humans exposed to the same or similar drugs, findings from animal or in vitro testing suggesting a significant risk to humans, and any clinically important increased incidence of a serious suspected adverse reaction compared to that listed in the protocol or investigator brochure.

Furthermore, an independent IRB at each institution participating in the clinical trial must review and approve each protocol before a clinical trial commences at that institution and must also approve the information regarding the trial and the consent form that must be provided to each trial subject or his or her legal representative, monitor the study until completed and otherwise comply with IRB regulations. The FDA or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. In addition, some clinical trials are overseen by an independent group of qualified experts organized by the sponsor, known as a data safety monitoring board or committee. Depending on its charter, this group may determine whether a trial may move forward at designated check points based on access to certain data from the trial. There are also requirements governing the reporting of ongoing clinical studies and clinical study results to public registries, including clinicaltrials.gov.

The clinical investigation of a drug is generally divided into three phases. Although the phases are usually conducted sequentially, they may overlap or be combined.

- Phase 1. The product candidate is initially introduced into healthy human subjects or patients with the target disease or condition. These studies are designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness.
- Phase 2. The product candidate is administered to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.
- Phase 3. The product candidate is administered to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval.

Post-approval trials, sometimes referred to as Phase 4 studies, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of an NDA.

During the development of a product candidate, sponsors are given opportunities to meet with the FDA at certain points. These points may be prior to submission of an IND, at the end of Phase 2, and before an NDA or BLA is submitted. Meetings at other times may be requested. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date, for the FDA to provide advice, and for the sponsor and the FDA to reach agreement on the next phase of development. Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the product in commercial quantities in accordance with cGMPs. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final drug. In addition, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

NDA and BLA Review Process

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, nonclinical studies and clinical trials are submitted to the FDA as part of an NDA or BLA requesting approval to market the product for one or more indications. The NDA or BLA must include all relevant data available from pertinent preclinical studies and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing and controls and proposed labeling, among other things. Data can come from company-sponsored clinical studies intended to test the safety and effectiveness of the product, or from a number of alternative sources, including studies initiated and sponsored by investigators. The submission of an NDA or BLA requires payment of a substantial application user fee to the FDA, unless a waiver or exemption applies.

In addition, under the Pediatric Research Equity Act, or PREA, an NDA or BLA or supplement to an NDA or BLA must contain data to assess the safety and effectiveness of the biological product candidate for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The Food and Drug Administration Safety and Innovation Act requires that a sponsor who is planning to submit a marketing application for a drug or biological product that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration submit an initial pediatric study plan within sixty days after an end-of-Phase 2 meeting or as may be agreed between the sponsor and FDA. Unless otherwise required by regulation, PREA does not apply to any drug or biological product for an indication for which orphan designation has been granted.

Within 60 days following submission of the application, the FDA reviews the submitted BLA or NDA to determine if the application is substantially complete before the agency accepts it for filing. The FDA may refuse to file any NDA or BLA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the NDA or BLA must be resubmitted with the additional information. Once an NDA or BLA has been accepted for filing, the FDA's goal is to review standard applications within ten months after the filing date, or, if the application qualifies for priority review, six months after the FDA accepts the application for filing. In both standard and priority reviews, the review

process may also be extended by FDA requests for additional information or clarification. The FDA reviews an NDA to determine, among other things, whether a product candidate is safe and effective for its intended use and whether its manufacturing is sufficient to assure and preserve the product's identity, strength, quality and purity. The FDA reviews a BLA to determine, among other things, whether a product candidate is safe, pure and potent and the facility in which it is manufactured, processed, packed or held meets standards designed to assure the product's continued safety, purity and potency. When reviewing an NDA or BLA, the FDA may convene an advisory committee to provide clinical insight on application review questions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving an NDA or BLA, the FDA will typically inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA or BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP.

After the FDA evaluates the NDA or BLA and conducts inspections of manufacturing facilities where the investigational product and/or its drug substance will be produced, the FDA may issue an approval letter or a Complete Response Letter, or CRL. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A CRL indicates that the review cycle of the application is complete, and the application will not be approved in its present form. A CRL usually describes the specific deficiencies in the NDA or BLA identified by the FDA and may require additional clinical data, including additional clinical trials, or other significant and time-consuming requirements related to clinical trials, nonclinical studies or manufacturing. If a CRL is issued, the sponsor must resubmit the NDA or BLA, addressing all of the deficiencies identified in the letter, or withdraw the application. Even if such data and information are submitted, the FDA may decide that the NDA or BLA does not satisfy the criteria for approval.

If regulatory approval of a product is granted, such approval will be granted for particular indications and may entail limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the NDA or BLA with a Risk Evaluation and Mitigation Strategy, or REMS, to ensure the benefits of the product outweigh its risks. A REMS is a safety strategy to manage a known or potential serious risk associated with a product and to enable patients to have continued access to such medicines by managing their safe use, and could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. The FDA may also require one or more Phase 4 post-market studies and surveillance to further assess and monitor the product's safety and effectiveness after commercialization, and may limit further marketing of the product based on the results of these post-marketing studies.

Expedited Development and Review Programs

The FDA offers a number of expedited development and review programs for qualifying product candidates. For example, the fast track program is intended to expedite or facilitate the process for reviewing new products that meet certain criteria. Specifically, product candidates are eligible for fast track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast track designation applies to the combination of the product candidate and the specific indication for which it is being studied. The sponsor of a fast track product candidate has opportunities for more frequent interactions with the review team during product development and, once an NDA or BLA is submitted, the application may be eligible for priority review. A fast track product candidate may also be eligible for rolling review, where the FDA may consider for review sections of the NDA or BLA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA or BLA, the FDA agrees to accept sections of the NDA or BLA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA or BLA.

A product candidate intended to treat a serious or life-threatening disease or condition may also be eligible for breakthrough therapy designation to expedite its development and review. A product candidate can receive breakthrough therapy designation if preliminary clinical evidence indicates that the product candidate, alone or in combination with one or more other drugs or biologics, may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation includes all of the fast track program features, as well as more intensive FDA interaction and guidance beginning as early as Phase 1 and an organizational commitment to expedite the development and review of the product candidate, including involvement of senior managers.

Any marketing application for a drug or biologic submitted to the FDA for approval, including a product candidate with a fast track designation and/or breakthrough therapy designation, may be eligible for other types of FDA programs intended to expedite the FDA review and approval process, such as priority review. A product candidate is eligible for priority review if it has the potential to provide a significant improvement in the treatment, diagnosis or prevention of a serious disease or condition. For new-molecular-entity NDAs and original BLAs, priority review designation means the FDA's goal is to take action on the marketing application within six months of the 60-day filing date (as compared to ten months under standard review).

Additionally, depending on the design of the applicable clinical trials, product candidates studied for their safety and effectiveness in treating serious or life-threatening diseases or conditions may receive accelerated approval upon a determination that the product candidate has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of accelerated approval, the FDA will generally require the sponsor to perform adequate and well-controlled confirmatory clinical studies to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit, and may require that such confirmatory studies be underway before granting any accelerated approval. Products receiving accelerated approval may be subject to expedited withdrawal procedures if the sponsor fails to conduct the required confirmatory studies in a timely manner or if such studies fail to verify the predicted clinical benefit. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

Fast track designation, breakthrough therapy designation, priority review, and accelerated approval do not change the standards for approval but may expedite the development or approval process. Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. We may explore some of these opportunities for our product candidates as appropriate.

Orphan drug designation

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, which is a disease or condition that affects fewer than 200,000 individuals in the United States or, if it affects more than 200,000 individuals in the United States, there is no reasonable expectation that the cost of developing and making a drug product available in the United States for this type of disease or condition will be recovered from sales of the product. Orphan designation must be requested before submitting an NDA or BLA. After the FDA grants orphan designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications to market the same drug or biologic for the same disease or condition for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity or inability to manufacture the product in sufficient quantities. The designation of such drug or biologic also entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. However, competitors, may receive approval of different products for the disease or condition for which the orphan product has exclusivity or obtain approval for the same product but for a different disease or condition for which the orphan product has exclusivity. Orphan exclusivity also could block the approval of a competing product for seven years if a competitor obtains approval of the "same drug," as defined by the FDA, or if the active ingredient of the product candidate is determined to be contained within the competitor's product for the same disease or condition. In addition, if an orphan designated product receives marketing approval for a disease or condition broader than what is designated, it may not be entitled to orphan exclusivity.

Post-Approval Requirements

Any products manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing user fee requirements, under which the FDA assesses an annual program fee for each product identified in an approved NDA or BLA. Drug and biologic manufacturers and their subcontractors are

required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMPs, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMPs and impose reporting requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMPs and other aspects of regulatory compliance.

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of a product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of existing product approvals;
- product seizure or detention, or refusal of the FDA to permit the import or export of products;
- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs;
- mandated modification of promotional materials and labeling and the issuance of corrective information;
- the issuance of safety alerts, Dear Healthcare Provider letters, press releases and other communications containing warnings or other safety information about the product; or
- injunctions or the imposition of civil or criminal penalties.

The FDA closely regulates the marketing, labeling, advertising and promotion of drug products and biologics. A company can make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products.

Drug Product Marketing Exclusivity

Market exclusivity provisions authorized under the FDCA can delay the submission or the approval of certain marketing applications. For example, the FDCA provides a five-year period of non-patent data exclusivity within the United States to the first applicant to obtain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not approve or even accept for review an abbreviated new drug application, or ANDA, or an NDA submitted under Section 505(b)(2), or 505(b)(2) NDA, submitted by another company for another drug based on the same active moiety, regardless of whether the drug is intended for the same indication as the original innovative drug or for another indication, where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement to one of the patents listed with the FDA by the innovator NDA holder.

The FDCA alternatively provides three years of non-patent exclusivity for an NDA, or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the modification for which the drug received approval on the basis of the new

clinical investigations and does not prohibit the FDA from approving ANDAs or 505(b)(2) NDAs for drugs containing the active agent for the original indication or condition of use. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to any preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Pediatric exclusivity is another type of marketing exclusivity available in the United States. Pediatric exclusivity provides for an additional six months of marketing exclusivity attached to another period of existing exclusivity, including patent terms, if a sponsor conducts clinical trials in children in response to a written request from the FDA. The issuance of a written request does not require the sponsor to undertake the described clinical trials.

Biosimilars and Reference Product Exclusivity

The Biologics Price Competition and Innovation Act of 2009, or BPCIA, created an abbreviated approval pathway for biological products that are highly similar, or "biosimilar," to or interchangeable with an FDA-approved reference biological product. The FDA has issued several guidance documents outlining an approach to review and approval of biosimilars. Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, is generally shown through analytical studies, animal studies, and a clinical study or studies. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. A product shown to be biosimilar or interchangeable with an FDA-approved reference biological product may rely in part on the FDA's previous determination of safety and effectiveness for the reference product for approval, which can potentially reduce the cost and time required to obtain approval to market the 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 that applicant's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of its product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. At this juncture, it is unclear whether products deemed "interchangeable" by the FDA will, in fact, be readily substituted by pharmacies, which are governed by state pharmacy law.

A biological product can also obtain pediatric market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of existing exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued "Written Request" for such a study.

Other Healthcare Laws

Pharmaceutical companies are subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business and may constrain the financial arrangements and relationships through which we research as well as sell, market and distribute any products for which we obtain marketing approval. Such laws include, without limitation, federal and state anti-kickback, fraud and abuse, false claims, data privacy and security and physician and other healthcare provider transparency laws and regulations. If our operations are found to be in violation of any of such laws or any other governmental regulations that apply, they may be subject to penalties, including, without limitation, administrative, civil and criminal penalties, damages, fines, disgorgement, the curtailment or restructuring of operations, integrity oversight and reporting obligations, exclusion from participation in federal and state healthcare programs and imprisonment.

Coverage and Reimbursement

Sales of any product depend, in part, on the extent to which such product will be covered by third-party payors, such as federal, state, and foreign government healthcare programs, commercial insurance and managed healthcare organizations, and the level of reimbursement for such product by third-party payors. Decisions regarding the extent of coverage and amount of reimbursement to be provided are made on a plan-by-plan basis. 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 obtained. These third-party payors are increasingly reducing reimbursements for medical products, drugs and services. In addition, the U.S. government, state legislatures and foreign governments have continued implementing cost-containment programs, including price controls, restrictions on coverage and reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit sales of any product. Decreases in third-party reimbursement for any product or a decision by a third-party payor not to cover a product could reduce physician usage and patient demand for the product and also have a material adverse effect on sales.

Healthcare Reform

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, each as amended, collectively known as the ACA, was enacted, which substantially changed the way healthcare is financed by both governmental and private insurers, and significantly affected the pharmaceutical industry. The ACA contains a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement adjustments and changes to fraud and abuse laws. By way of example, the ACA:

- increased the minimum level of Medicaid rebates payable by manufacturers of brand name drugs from 15.1% to 23.1% of the average manufacturer price;
- required collection of rebates for drugs paid by Medicaid managed care organizations;
- required manufacturers to participate in a coverage gap discount program, under which they must agree to offer 70 percent point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturers' outpatient drugs to be covered under Medicare Part D; and
- imposed a non-deductible annual fee on pharmaceutical manufacturers or importers who sell "branded prescription drugs" to specified federal government programs.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. On March 11, 2021, the American Rescue Plan Act of 2021 was signed into law, which eliminated the statutory Medicaid drug rebate cap, beginning January 1, 2024. The rebate was previously capped at 100% of a drug's average manufacturer price, or AMP. Most recently, on August 16, 2022, the Inflation Reduction Act of 2022, or IRA, was signed into law. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Secretary of the Department of Health and Human Services (HHS) 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 programs is currently subject to legal challenges. For that and other reasons, it is currently unclear how the IRA will be effectuated.

Moreover, there has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries, proposed and enacted legislation and executive orders issued by the President designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. Individual states in the United States have also become increasingly active in implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

Data Privacy and Security Laws

Numerous state, federal and foreign laws, regulations and standards govern the collection, use, access to, confidentiality and security of health-related and other personal information, and could apply now or in the future to our operations or the operations of our partners. In the United States, numerous federal and state laws and regulations, including data breach notification laws, health information privacy and security laws and consumer protection laws and regulations govern the collection, use, disclosure, and protection of health-related and other personal information. In addition, certain foreign laws govern the privacy and security of personal data, including health-related data. Privacy and security laws, regulations, and other obligations are constantly evolving, may conflict with each other to complicate compliance efforts, and can result in investigations, proceedings, or actions that lead to significant civil and/or criminal penalties and restrictions on data processing.

Competition

The pharmaceutical and biotechnology industries are characterized by rapidly advancing technologies, intense competition, government regulation and a strong emphasis on proprietary products. While we believe that our technology, knowledge and scientific resources provide us with certain competitive advantages, we face competition from many sources, including foreign and domestic pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions. Many of these competitors may have access to greater capital and resources than us. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel. Any product candidates that we successfully develop and commercialize will compete with new immunotherapies that may become available in the future. Our competitors include larger and better funded biopharmaceutical, biotechnology and therapeutics companies, specifically companies focused on cancer immunotherapies, such as Amgen, Inc., AstraZeneca plc, BMS, Genentech, Inc., GlaxoSmithKline PLC, Merck & Co., Inc., Novartis AG, Pfizer Inc., Roche Holding Ltd and Sanofi S.A. On the other hand, many of these companies are developing immunotherapeutics which may have potential to be used in concert with Decoy20 and in this regard, we view them as potentially complimentary.

With respect to our lead candidate, Decoy20, there are a number of companies that are developing possible treatments for cancer, however, we believe we are the only company using systemic administration of killed, non-pathogenic Gram-negative bacteria with reduced lipopolysaccharide-endotoxin to stimulate innate and adaptive immune system pathways.

Our success will be based in part upon our ability to successfully commercialize Decoy20 and to identify, develop and manage a portfolio of therapeutics that are safer and more effective than competing products in our target indications. Our market opportunity has the potential to be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer side effects, are more convenient or are less expensive than any therapeutics we may develop. Our competitive position will also be dependent upon our ability to attract and retain qualified personnel, to obtain patent protection or otherwise develop proprietary products or processes, and protect our intellectual property, to differentiate our product from other therapeutics and to secure sufficient capital resources for the period between technological conception and commercial sales. The availability of reimbursement from government and other third-party payors will also significantly affect the pricing and competitiveness of our products. Our competitors may also obtain FDA or other regulatory approval for their products more rapidly or with broader applications than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market.

Intellectual Property

Our success depends, at least in part, on our ability to protect our proprietary technology and intellectual property, and to operate without infringing or violating the proprietary rights of others. We rely on a combination of patent, trademark, trade secret and copyright laws, know-how, intellectual property licenses and other contractual rights (including confidentiality and invention assignment agreements) to protect our proprietary technology and intellectual property, including related intellectual property rights.

Patents

As of March 12, 2025, we own 58 granted patents and 11 pending patent applications to use within our field of business. Our patents and patent applications generally relate to compositions and methods for treating cancer and infectious diseases, and our patents and any patents that issue from our pending patent applications are expected to expire at various dates between 2033 and 2043.

We intend to submit patent applications for each new product and technology that we develop. The patent outlook for companies like ours is generally uncertain and may involve complex legal and factual questions. Our ability to maintain and consolidate our proprietary position for our technology will depend on our success in obtaining effective claims and enforcing those claims once granted. We do not know whether any of our patent applications or any patent applications that we may license will result in the issuance of any patents. Our issued patents and those that may be issued in the future, or patents that we may exclusively license, may be challenged, narrowed, circumvented or found to be invalid or unenforceable, which could limit our ability to stop competitors from marketing related products or the length of term of patent protection that we may have for our products. We cannot be certain that we were the first to invent the inventions claimed in our owned patents or patent applications. In addition, our competitors may independently develop similar technologies or duplicate any technology developed by us, and the rights granted under any issued patents may not provide us with any meaningful competitive advantages against these competitors. Furthermore, because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any of our products can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantage of the patent.

Trade Secrets and Confidential Information

In addition to patents, we rely on trade secrets and know-how to develop and maintain our competitive position. Trade secrets and know-how can be difficult to protect. We rely on, among other things, confidentiality and invention assignment agreements to protect our proprietary know-how and other intellectual property that may not be patentable, or that we believe is best protected by means that do not require public disclosure. For example, we require our employees to execute confidentiality agreements in connection with their employment relationships with us, and to disclose and assign to us inventions conceived in connection with their services to us. However, there can be no assurance that these agreements will be enforceable or that they will provide us with adequate protection. We also seek to preserve the integrity and confidentiality of our data, trade secrets and know-how by maintaining physical security of our premises and physical and electronic security of our information technology systems.

We may be unable to obtain, maintain and protect the intellectual property rights necessary to conduct our business, and may be subject to claims that we infringe or otherwise violate the intellectual property rights of others, which could materially harm our business. For a more comprehensive summary of the risks related to our intellectual property, see Item 1A. "Risk Factors - Risks Related to Our Intellectual Property."

Environmental Matters

We are subject to various 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. Although we generally contract with third parties for the operations that involve the disposal of hazardous materials and wastes, we cannot eliminate the risk of contamination or injury from these materials. Based on information currently available to us, we do not expect environmental costs and contingencies to have a material adverse effect on us. However, 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. 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. See Part I. Item 1A. "Risk Factors – Risks Related to Healthcare Laws and Other Legal Compliance Matters - *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 believe that our business, operations and facilities are being operated in compliance in all material respects with applicable environmental and health and safety laws and regulations.

Human Capital Management

As of December 31, 2024, we had seven full-time employees. None of our employees are represented by labor unions or covered by collective bargaining agreements.

We believe that our future success will depend, in part, on our continued ability to attract, hire and retain qualified personnel. In particular, we depend on the skills, experience and performance of our senior management and research personnel. We compete for qualified personnel with other biotechnology, medical device, pharmaceutical and healthcare companies, as well as universities and non-profit research institutions.

We provide competitive compensation and benefits programs to help meet the needs of our employees. In addition to salaries, these programs include incentive compensation plan, pension, healthcare and insurance benefits, paid time off, and family leave, among others. We also use targeted equity-based grants with vesting conditions to facilitate retention of personnel, particularly for our key employees.

The success of our business is fundamentally connected to the well-being of our people. Accordingly, we are committed to the health and safety of our employees and we consider our relations with our employees to be good.

Available Information

We maintain a corporate website at http://www.indaptusrx.com. The information contained on, or that can be accessed through, our website is neither a part of nor incorporated into this Annual Report.

Copies of our reports on Forms 10-K, Forms 10-Q and Forms 8-K, may be obtained, free of charge, electronically through our corporate website at http://www.indaptusrx.com as soon as reasonably practicable after we file such material electronically with, or furnish to, the SEC. Additionally, the SEC maintains an Internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC at www.sec.gov.

Item 1A. Risk Factors.

You should carefully consider the factors described below, together with all of the other information contained in this Annual Report, including the audited consolidated financial statements and the related notes included in this Annual 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 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 year ended December 31, 2024, we reported a net loss of approximately $15.0 million and as of December 31, 2024, we had an accumulated deficit of approximately $60.4 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 December 31, 2024, we had approximately $5.8 million and during the twelve months ended December 31, 2024, we used $12.3 million of cash in operations and expect to continue to incur significant cash outflows and incur future additional losses to execute our operating plan. We believe that the cash and cash equivalents as of December 31, 2024 together with proceeds from our January 2025 financing, will enable us to fund our operating expenses and capital expenditure requirements into the second quarter of 2025. We will need to increase our capital resources through equity and/or debt financings. We may also seek to finance our cash needs through collaborations, strategic alliances, or license agreements with third parties and/or debt or equity financings. If sources of financing are available, they may result in substantial dilution to our stockholders. 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 date of this Annual Report, we have concluded that substantial doubt exists about our ability to continue as a going 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 audited consolidated financial statements included in this Annual 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 audited 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 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, 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, 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;
- the costs and timing of securing manufacturing arrangements for clinical or commercial production;
- the costs of contracting with third parties to provide sales and marketing capabilities for us or establishing such capabilities ourselves;
- the costs of acquiring or undertaking development and commercialization efforts for any future products, product candidates or technology;
- the costs associated with being a public company; and
- any cost that we may incur under future in- and out-licensing arrangements relating to one or more of our product candidates.

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 we may offer and sell from time to time shares of our common stock for aggregate gross proceeds of up to $3.7 million, and in 2024, we sold 152,000 shares of our common stock for aggregate gross proceeds of approximately $0.4 million. On August 6, 2024, we filed a prospectus supplement to reduce the amount of shares registered under the prospectus for the ATM to $0.00 and to suspend the ATM program, but the ATM Agreement remains in full force and effect. In August 2024, November 2024 and January 2025, we raised an aggregate of approximately $6.4 million, net of placement agent and other offering expenses. In addition, in February 2025, we entered into a Standby Equity Purchase Agreement pursuant to which we have the right, but not the obligation, to sell up to $20.0 million of our common stock during a 36 month period, subject to the restrictions and satisfaction of the conditions in the Standby Equity Purchase Agreement. 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) 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) 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), 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), regulations or other applicable requirements; and
- third parties being unwilling or unable to satisfy their contractual obligations to us in a timely manner.

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) 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) 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.

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 Biologics License Application (BLA) or 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 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, any resurgence of the virus or emergence of new variants may lead to further inspectional or administrative delays. 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 (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 clinical supply or 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 clinical supply or collaboration arrangements with biopharmaceutical companies for the development or commercialization of our current and potential future product candidates. For example, in October 2024, we entered into a clinical supply agreement with BeiGene to advance the clinical trial evaluation of Decoy20 in combination with BeiGene's anti-PD-1 antibody, tislelizumab (the "BeiGene Product") for the treatment of patients with advanced solid tumors (the "Combination Study"). Under our agreement with BeiGene, we will rely on BeiGene for the supply of the Beigene Product. If BeiGene cannot perform as agreed, we may be unable to initiate or complete the Combination Study in a timely manner or at all.

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 clinical supply and 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 clinical supply or 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 eliminate the statutory cap on the Medicaid drug rebate, beginning January 1, 2024 at 100% of a drug's 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 drug 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.

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" 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

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 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

If we fail to comply with the continued listing requirements of the Nasdaq Capital Market, our common stock may be delisted and the price of our common stock and our ability to access the capital markets could be negatively impacted.

Nasdaq has established certain standards for the continued listing of a security on the Nasdaq Capital Market. The standards for continued listing include, among other things, that the minimum bid price for the listed securities not fall below $1.00 per share for a period of 30 consecutive trading days and that we maintain a minimum of $2,500,000 in stockholders' equity.

On January 31, 2025, we were notified, or the Notification Letter, by the Nasdaq Listing Qualifications that we are not in compliance with the minimum bid price requirements set forth in Nasdaq Listing Rule 5550(a)(2), or the Rule, for continued listing on The Nasdaq Capital Market. The Notification Letter provides that the Company has 180 calendar days, or until July 30, 2025, to regain compliance with the Rule. To regain compliance, the bid price of our common stock must have a closing bid price of at least $1.00 per share for a minimum of 10 consecutive business days. In the event we do not regain compliance by July 30, 2025, we may then be eligible for an additional 180 days if we meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for The Nasdaq Capital Market, with the exception of the bid price requirement, and will need to provide written notice of our intention to cure the deficiency during the second compliance period. If we do not qualify for the second compliance period or fail to regain compliance during the second compliance period, then Nasdaq will notify us of its determination to delist our common stock, at which point we will have an opportunity to appeal the delisting determination to a Hearings Panel.

No assurance can be given that we will be able to regain compliance with the Rule. Failure to meet applicable Nasdaq continued listing standards could result in a delisting of our common stock. A delisting of our common stock from Nasdaq could materially reduce the liquidity of our common stock and result in a corresponding material reduction in the price of our common stock. In addition, delisting could harm our ability to raise capital through alternative financing sources on terms acceptable to us, or at all, and may result in the potential loss of confidence by investors, employees and fewer business development opportunities.

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 conflict in 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 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 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") rules. The requirements of these rules and regulations 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 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 1B. Unresolved Staff Comments.

We do not have any unresolved comments issued by the SEC staff.

Item 1C. Cybersecurity

Cybersecurity Risk Management and Strategy

We, through our third party service provider that manages our information technology systems and networks, have developed and implemented a cybersecurity risk management program intended to protect the confidentiality, integrity, and availability of our critical systems and information. Our cybersecurity risk management program includes a cybersecurity incident response plan.

We design and assess our program based on the National Institute of Standards and Technology Cybersecurity Framework (NIST CSF). This does not imply that we meet any particular technical standards, specifications, or requirements, only that we use the NIST CSF as a guide to help us identify, assess, and manage cybersecurity risks relevant to our business.

Our cybersecurity risk management program includes:

- risk assessments designed to help identify material cybersecurity risks to our critical systems, information, products, services, and our broader enterprise IT environment;
- designated team members are responsible for managing (1) our cybersecurity risk assessment processes, (2) our security controls, and (3) our response to cybersecurity incidents;
- the use of external service providers, where appropriate, to assess, test or otherwise assist with aspects of our security controls; and
- a cybersecurity incident response plan that includes procedures for responding to cybersecurity incidents.

We have not identified risks from known cybersecurity threats, that have materially affected or are reasonably likely to materially affect us, including our operations, business strategy, results of operations, or financial condition. See Item 1A. "Risk Factors – Our Risks Related to Our Business - *Our business and operations may suffer in the event of information technology system failures, cyberattacks or deficiencies in our cybersecurity.*"

Cybersecurity Governance

Our Board considers cybersecurity risk as part of its risk oversight function and oversees our cybersecurity and other information technology risks and management's implementation of our cybersecurity risk management program.

Our Board receives periodic reports from management on our cybersecurity risks. In addition, management updates the Board and the Audit Committee, as necessary, regarding any material cybersecurity incidents, as well as any incidents with lesser impact potential.

Our management team, including our Chief Operating Officer, is responsible for assessing and managing our material risks from cybersecurity threats. Our Chief Operating Officer has primary responsibility for our overall cybersecurity risk management program and supervises our retained provider of IT services and external cybersecurity consultants. Our Chief Operating Officer has experience supervising and managing company security and privacy departments.

Our management team supervises efforts to prevent, detect, mitigate, and remediate cybersecurity risks and incidents through various means, which may include briefings from external security personnel; threat intelligence and other information obtained from governmental, public or private sources, including external consultants engaged by us; and alerts and reports produced by security tools deployed in the IT environment.

Item 2. Properties

Our principal executive offices are located at 3 Columbus Circle, 15th Floor, New York, NY. In addition, we lease approximately 2,000 square feet of office space in San Diego, California under a lease agreement that was amended on April 19, 2023 and will expire on October 31, 2025. We believe that our facilities are sufficient to meet our current needs and that suitable additional space will be available as and when needed.

Item 3. 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.

As of March 12, 2025, there are 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 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

Our common stock is listed on the Nasdaq Capital Market under the name "Indaptus Therapeutics, Inc." and ticker symbol "INDP".

Holders

As of March 12, 2025, we had 22 record holders of our common stock. This number does not include the number of persons whose shares are in nominee or in "street name" accounts through brokers.

Dividend Policy

We have never declared or paid cash dividends to our shareholders, and we do not intend to pay cash dividends in the foreseeable future. We intend to reinvest any earnings in developing and expanding our business. Any future determination relating to our dividend policy will be at the discretion of our board of directors and will depend on a number of factors, including our financial condition, operating results, contractual restrictions, capital requirements, business prospects, our strategic goals and plans to expand our business, applicable law and other factors that our board of directors may deem relevant.

Securities Authorized for Issuance under Equity Compensation Plans

Information about our equity compensation plan under which the Company's equity securities are authorized for issuance is set forth in "Part III - Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters" of this Annual Report.

Recent Sales of Unregistered Securities

None.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

We did not repurchase any of our equity securities during the quarter ended December 31, 2024.

Item 6. [Reserved]

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

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 Annual Report. 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 I, Item 1A. "Risk Factors" in this Annual Report for a discussion of important factors that could cause actual results to differ materially from the results described below.

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 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 of both innate and adaptive immunological memory and, importantly, did not require provision of or targeting a tumor antigen in preclinical models. In 2023, we initiated a Phase 1 clinical trial with our lead clinical candidate, Decoy20, in patients with advanced solid tumors where currently approved therapies have failed. For further information regarding our business and operations, see "Part I. Item 1. Business."

Impact of Macroeconomic Conditions on our Operations

Economic developments such as 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 current economic 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.

Components of Operating Results

Research and Development Expenses

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 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 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;
- the scope, rate of progress and expenses of preclinical studies and clinical trials and other research and development activities;
- potential safety monitoring and other studies requested by regulatory 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 I. Item 1A. "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, finance administration and human resources, facility costs (including rent), professional service fees, and other general overhead costs to support our operations.

We expect our general and administrative expenses to increase 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

Year Ended December 31, 2024 compared to Year Ended December 31, 2023

The following tables set forth our results of operations for the years ended December 31, 2024 and 2023 and the relative dollar and percentage change between the two years.

	Year ended December 31,		Change (2024 to 2023)	
	2024	2023	($)	%
Operating expenses:				
Research and development	$ 7,251,097	$ 7,621,707	$ (370,610)	(4.9)%
General and administrative	8,114,654	8,756,767	(642,113)	(7.3)%
Total operating expenses	15,365,751	16,378,474	(1,012,723)	(6.2)%
Loss from operations	(15,365,751)	(16,378,474)	1,012,723	(6.2)%
Other income, net	343,724	955,003	(611,279)	(64.0)%
Net loss	$ (15,022,027)	$ (15,423,471)	$ 401,444	(2.6)%
Net loss attributable to common stockholders per share, basic and diluted	$ (1.61)	$ (1.83)	$ 0.22	(12.0)%
Weighted average number of shares used in calculating net loss per share, basic and diluted	9,355,710	8,401,047		

Research and Development Expenses

Our research and development expenses for the year ended December 31, 2024 amounted to approximately $7.2 million, a decrease of approximately $0.4 million, or approximately 4.9%, compared with approximately $7.6 million for the year ended December 31, 2023. This decrease was attributable primarily to a decrease of approximately $1.3 million for the development of our manufacturing processes of Decoy20 that were mainly conducted in 2023 and was offset by an increase of approximately $0.9 million in costs associated with our Phase 1 clinical trial.

General and Administrative Expenses

Our general and administrative expenses for the year ended December 31, 2024 amounted to approximately $8.1 million, a decrease of approximately $0.7 million, or approximately 7.3%, compared with approximately $8.8 million for the year ended December 31, 2023. This decrease was attributable primarily to a decrease of approximately $1.3 million in legal fees, recruitment costs, payroll and related expenses, franchise tax, and directors' and officers' insurance expenses, and was offset by an increase of approximately $0.6 million in investor relations and business development expenses.

Other Income

During the year ended December 31, 2024, our other income, net was approximately $0.3 million, which represented a decrease of approximately $0.6 million, or approximately 64.0%, as compared to the year ended December 31, 2023. The other income generated in the period consists primarily of income earned on the Company's cash and cash equivalent accounts, the balances of which were lower during the year ended December 31, 2024 compared to the year ended December 31, 2023.

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 January 2025, we completed a private placement for the sale and issuance by us of an aggregate of: (i) 2,109,383 shares of our common stock and (ii) warrants to purchase 2,109,383 shares of common stock. The shares and warrants were sold on a combined basis for consideration of $1.065 for one share and a warrant for aggregate gross proceeds of approximately $2.25 million.

In November 2024, we completed a registered direct offering, pursuant to which we sold and issued to certain investors 1,817,017 shares of our common stock in a registered direct offering. In addition, in a concurrent private placement, we issued to the investors unregistered warrants to purchase 1,817,017 shares of common. The combined purchase price for one share of common stock and one warrant was $1.175, resulting in gross proceeds of approximately $2.135 million.

In August 2024, we completed a registered direct offering, pursuant to which we sold and issued to certain investors, 1,643,837 shares of common stock. In addition, in a concurrent private placement, we issued to the investors unregistered warrants to purchase 1,643,837 shares of common stock. The combined purchase price for one share of common stock and one warrant was $1.825, resulting in gross proceeds of approximately $3.0 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 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 $3.7 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. In 2024, we sold 152,000 shares of our common stock for aggregate gross proceeds of approximately $0.4 million. On August 6, 2024, we filed a prospectus supplement to reduce the amount of shares registered under the prospectus for the ATM to $0.00 and to suspend the ATM program, but the ATM Agreement remains in full force and effect.

In February 2025, we entered into a SEPA with Yorkville pursuant to which we have the right, but not the obligation, to sell up to $20.0 million of our common stock during a 36 month period, subject to the restrictions and satisfaction of the conditions in the SEPA. Upon execution of the SEPA, we issued to Yorkville 305,960 commitment shares. No shares of common stock have been sold under the SEPA.

We believe that the cash and cash equivalents of approximately $5.8 million that we had as of December 31, 2024 together with net proceeds of $2.0 million from our January 2025 financing, will enable us to fund our operating expenses and capital expenditure requirements into the second quarter of 2025. We will need to increase our capital resources through equity or debt financings, and we may need to do so sooner than we expect. We may also seek to finance our cash needs through collaborations, strategic alliances, or license agreements with third parties. If sources of financing are available, they may result in substantial dilution to our stockholders. 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. If we are unable to consummate a financing or other transaction, we may need to delay, reduce, or eliminate our research and development programs, which could adversely affect our business prospects, or cease operations. These conditions raise substantial doubt regarding our ability to continue as a going concern within one year after the date of this prospectus. For additional information, see Note 1 to our consolidated financial statements included elsewhere in this Annual 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 $12.3 million for the year ended December 31, 2024, compared with net cash used in operating activities of approximately $13.4 million for the year ended December 31, 2023. The approximately $1.1 million decrease in net cash used was primarily attributable to changes in operating assets and liabilities.

Investing Activities

There was no net cash provided by or used in investing activities for the year ended December 31, 2024. Net cash provided by investing activities was approximately $17.1 million for the year ended December 31, 2023, which was related to the maturity of $24.0 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 year ended December 31, 2024 was approximately $4.8 million, which was provided by issuance and sale of our common stock under the ATM Agreement and issuance and sale of our common stock and warrants in the August 2024 Offering and in the November 2024 Offering. There was no net cash provided by or used in financing activities for the year ended December 31, 2023.

Funding Requirements

Our operating expenses increased in 2024 and are expected to continue to increase in the future in connection with our ongoing activities, particularly as we expect to continue to ramp up our clinical development activities and incur expenses associated 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 and marketable securities as of December 31, 2024 are adequate to fund our ongoing activities into the second quarter of 2025.

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, 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;
- the costs and timing of securing manufacturing arrangements for clinical or commercial production;
- the costs of contracting with third parties to provide sales and marketing capabilities for us or establishing such capabilities ourselves;
- the costs of acquiring or undertaking development and commercialization efforts for any future products, product candidates or technology;
- the magnitude of our general and administrative 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 consolidated financial statements included elsewhere in this Annual Report and "Risk Factors" in Item 1A. of this Annual 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 December 31, 2024 were approximately $0.1 million and are due in the next twelve months. For additional details regarding our lease, see Note 7 to our consolidated financial statements included in this Annual 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 consolidated financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these consolidated financial statements requires us to make estimates that affect the reported amounts of our assets, liabilities and expenses. Significant accounting policies employed by us, including the use of estimates, are presented in the notes to our annual financial statements included in this Annual Report. 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.

We believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our consolidated financial statements:

Accounting for Research and Development Costs

We record the costs associated with services provided by CROs and CMOs as they are incurred. Though the scope and timing of work are generally based on signed agreements, some judgement is involved in determining periodic expenses because payment flows do not always match the periods over which services and materials are provided to us. As a result, our management is required to make estimates of services received and efforts expended pursuant to agreements established with these third-parties at each period-end date. During the year ended December 31, 2024, we incurred approximately $7.2 million of research and development expenses, of which approximately $4.0 million were for services provided by our CROs and CMOs. As of December 31, 2024, we recorded an accrued liability of approximately $0.8 million for expenses incurred, but not yet invoiced, and prepaid expenses and non-current other assets of approximately $0.8 million for payments made that relate to future periods. Overestimating or underestimating the services received or efforts expended could cause us to overstate or understate research and development expenses incurred within a reporting period, and related accrued and prepaid expenses.

Stock-Based Compensation

Compensation expense related to stock options granted is measured at the grant date based on the estimated fair value of the award and is recognized over the requisite service period of the individual grant, generally equal to the vesting period, on a straight-line basis. We determine the estimated fair value of each stock option on the date of grant using the Black-Scholes valuation model which uses assumptions regarding a number of complex and subjective variables. The risk-free interest rate is

based on the U.S. Treasury yield for a period consistent with the expected term of the option in effect at the time of the grant. Expected volatility is based on an analysis of the historical volatility of a peer group of companies. The expected term represents the period that we expect our stock options to be outstanding. The expected term assumption is estimated using the simplified method set forth in the U.S. Securities and Exchange Commission's Staff Accounting Bulletin Topic 14, which is the mid-point between the option vesting date and the expiration date. We have never declared or paid dividends on our common stock and have no plans to do so in the foreseeable future. Changes in these assumptions may lead to variability with respect to the amount of stock compensation expense we recognize related to stock options.

Recently Issued Accounting Pronouncements

Certain recently issued accounting pronouncements are discussed in Note 2, Significant Accounting Policies, to the consolidated financial statements included in Item 8. "Financial Statements and Supplementary Data" of this Annual Report.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

We are a smaller reporting company as defined in Rule 12b-2 of the Exchange Act and are not required to provide the information otherwise required under this Item 7A.

Item 8. Financial Statements and Supplementary Data.

INDAPTUS THERAPEUTICS, INC.
CONSOLIDATED FINANCIAL STATEMENTS

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and Board of Directors
Indaptus Therapeutics, Inc.

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Indaptus Therapeutics, Inc. (the "Company") as of December 31, 2024 and 2023, the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for each of the years then ended, and the related notes (collectively, the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the consolidated financial position of the Company as of December 31, 2024 and 2023, and the consolidated results of its operations and its cash flows for each of the years then ended, in conformity with U.S. generally accepted accounting principles.

Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has experienced recurring losses, negative cash flows from operations, and has limited capital resources. These matters raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

Critical audit matters are matters arising from the current period audit of the consolidated financial statements that were communicated or required to be communicated to the audit committee and that (1) relate to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. We determined that there are no critical audit matters.

/s/ Haskell & White LLP
HASKELL & WHITE LLP

We have served as the Company's auditor since 2021.

Irvine, California
March 13, 2025

INDAPTUS THERAPEUTICS, INC.

Consolidated Balance Sheets

	December 31, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 5,786,753	$ 13,362,053
Prepaid expenses and other current assets	831,577	633,156
Total current assets	6,618,330	13,995,209
Non-current assets:		
Property and equipment, net	-	735
Right-of-use asset	82,175	173,206
Other assets - deposits to third parties	638,251	754,728
Total non-current assets	720,426	928,669
Total assets	$ 7,338,756	$ 14,923,878
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and other current liabilities	$ 3,309,717	$ 2,672,327
Operating lease liability, current portion	84,164	101,705
Total current liabilities	3,393,881	2,774,032
Non-current liabilities:		
Operating lease liability, net of current portion	-	73,348
Total non-current liabilities	-	73,348
Total liabilities	3,393,881	2,847,380
Commitments and contingencies (Note 7)		
Stockholders' equity:		
Common stock: $0.01 par value, 200,000,000 shares authorized as of December 31, 2024 and December 31, 2023; 12,013,901 shares issued and outstanding as of December 31, 2024 and 8,401,047 shares issued and outstanding as of December 31, 2023	120,139	84,011
Preferred stock: $0.01 par value, 5,000,000 shares authorized as of December 31, 2024 and December 31, 2023; no shares issued or outstanding	-	-
Additional paid in capital	64,263,919	57,409,643
Accumulated deficit	(60,439,183)	(45,417,156)
Total stockholders' equity	3,944,875	12,076,498
Total liabilities and stockholders' equity	$ 7,338,756	$ 14,923,878

See accompanying notes to the consolidated financial statements and report of independent registered public accounting firm

INDAPTUS THERAPEUTICS, INC.

Consolidated Statements of Operations and Comprehensive Loss

	For the year ended December 31,	
	2024	2023
Operating expenses:		
Research and development	$ 7,251,097	$ 7,621,707
General and administrative	8,114,654	8,756,767
Total operating expenses	15,365,751	16,378,474
Loss from operations	(15,365,751)	(16,378,474)
Other income, net	343,724	955,003
Net loss	$ (15,022,027)	$ (15,423,471)
Net loss available to common stockholders per share of common stock, basic and diluted	$ (1.61)	$ (1.83)
Weighted average number of shares used in calculating net loss per share, basic and diluted	9,355,710	8,401,047
Net loss	$ (15,022,027)	$ (15,423,471)
Other comprehensive income:		
Reclassification adjustment for interest earned on marketable securities included in net loss	-	(430,993)
Change in unrealized gain on marketable securities	-	334,559
Comprehensive loss	$ (15,022,027)	$ (15,519,905)

See accompanying notes to the consolidated financial statements and report of independent registered public accounting firm

INDAPTUS THERAPEUTICS, INC.

Consolidated Statements of Stockholders' Equity

	Common stock		Additional paid in	Accumulated	Accumulated Other Comprehensive	
	Shares	Amount	Capital	deficit	Income	Total
Balance, January 1, 2023	8,401,047	$ 84,011	$54,443,705	$(29,993,685)	$ 96,434	$ 24,630,465
Stock-based compensation	-	-	2,965,938	-	-	2,965,938
Reclassification adjustment for interest earned on marketable securities included in net loss	-	-	-	-	(430,993)	(430,993)
Change in unrealized gain on marketable securities	-	-	-	-	334,559	334,559
Net loss	-	-	-	(15,423,471)	-	(15,423,471)
Balance, December 31, 2023	8,401,047	$ 84,011	$57,409,643	$(45,417,156)	$ -	$ 12,076,498
Stock-based compensation	-	-	2,305,849	-	-	2,305,849
Issuance of shares of common stock, net of issuance costs (Note 6b)	152,000	1,520	352,591	-	-	354,111
Issuance of shares of common stock and warrants, net of issuance costs (Note 6c)	1,643,837	16,438	2,445,532	-	-	2,461,970
Issuance of shares of common stock and warrants, net of issuance costs (Note 6d)	1,817,017	18,170	1,750,304	-	-	1,768,474
Net loss	-	-	-	(15,022,027)	-	(15,022,027)
Balance, December 31, 2024	12,013,901	$120,139	$64,263,919	$(60,439,183)	$ -	$ 3,944,875

See accompanying notes to the consolidated financial statements and report of independent registered public accounting firm

INDAPTUS THERAPEUTICS, INC.

Consolidated Statements of Cash Flows

	For the year ended December 31,	
	2024	2023
Cash flows from operating activities:		
Net loss	$ (15,022,027)	$ (15,423,471)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	735	1,284
Stock-based compensation	2,305,849	2,965,938
Interest earned on marketable securities	-	(430,993)
Changes in operating assets and liabilities:		
Prepaid expenses and other current and non-current assets	(81,944)	161,800
Accounts payable and other current liabilities	474,057	(680,520)
Operating lease right-of-use asset and liability, net	142	647
Net cash used in operating activities	(12,323,188)	(13,405,315)
Cash flows from investing activities:		
Purchase of marketable securities	-	(6,859,432)
Maturity of marketable securities	-	24,000,000
Net cash provided by investing activities	-	17,140,568
Cash flows from financing activities:		
Proceeds from issuance of shares of common stock and warrants	5,510,591	-
Issuance costs	(762,703)	-
Net cash provided by financing activities	4,747,888	-
Net (decrease) increase in cash and cash equivalents	(7,575,300)	3,735,253
Cash and cash equivalents at beginning of year	13,362,053	9,626,800
Cash and cash equivalents at end of year	$ 5,786,753	$ 13,362,053
Noncash investing and financing activities		
ASC 842 lease renewal option exercise	$ -	$ 236,506
Transaction costs in accounts payable and other current liabilities	$ 163,333	$ -
Change in accumulated other comprehensive income	$ -	$ (96,434)
Supplemental cash flow disclosures		
Cash paid for income taxes	$ 1,600	$ 1,600

See accompanying notes to the consolidated financial statements and report of independent registered public accounting firm

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 operations (see below), competition from substitute products and services from larger companies, protection of proprietary technology, patent litigation, and dependence on key individuals.

Going concern and management's plans

The Company has incurred net losses and utilized cash in operations since inception. For the year ended December 31, 2024, the Company incurred a net loss of approximately $15.0 million, and as of December 31, 2024, the Company had an accumulated deficit of approximately $60.4 million. In addition, during the year ended December 31, 2024, the Company used approximately $12.3 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 consolidated financial statements, it has adequate cash to fund its ongoing activities into the second quarter of 2025 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, such as through the registered direct offerings and concurrent private placements that the Company completed in August 2024 (the "August 2024 Offering") and in November 2024 (the "November 2024 Offering"), and through the private placement in January 2025 (the "January 2025 Offering"). Following these offerings, the Company raised a total of approximately $6.3 million, net of placement agent and other offering expenses in the amount of approximately $1.1 million. For more details, see Note 6(c), 6(d) and 6(e). In addition, in February 2025, the Company entered into a Standby Equity Purchase Agreement pursuant to which the Company has the right, but not the obligation, to sell up to $20.0 million of the Company's common stock during a 36-month period, subject to the restrictions and satisfaction of the conditions in the Standby Equity Purchase Agreement. For more details, see Note 6(f). 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 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 consolidated financial statements of the Company have been prepared in accordance with accounting principles generally accepted in the United States of America ("US GAAP").

Principles of consolidation

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

Use of estimates

The preparation of 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 and makes adjustments when facts and circumstances dictate. These estimates are based on information available as of the date of the 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	
	For the year ended December 31,	
	2024	2023
Outstanding stock options	2,519,419	1,979,196
Warrants	3,935,282	3,090,787

Cash and cash equivalents

The Company considers all highly liquid investments with a maturity of three months or less when purchased to be cash equivalents. As of December 31, 2024, and 2023, cash and cash equivalents consist primarily of checking and money market deposits. The Company's cash balances exceed those that are federally insured; however, the Company believes it is not exposed to significant credit risk due to the financial strength of the depository institutions in which the cash and cash equivalents are held. To date, the Company has not recognized any losses caused by uninsured balances.

Property and equipment

Property and equipment assets are stated at cost less accumulated depreciation. Depreciation is calculated using the straight-line method over the estimated useful lives of the assets. The Company uses an estimated useful life of three years for employee-related computers and other office equipment and five years for furniture. Leasehold improvements are amortized over the shorter of the lease-term or the estimated useful life of the related asset.

Patents

The Company expenses patent costs, including related legal costs, as incurred and records such costs within general and administrative expense.

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.

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 to support the Company's operations.

Income taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. A valuation allowance is recorded for deferred tax assets if it is more likely than not that some portion or all of the deferred tax assets will not be realized in the foreseeable future. As of December 31, 2024, and 2023, the Company has recorded a full valuation allowance against its deferred tax assets.

The Company recognizes the effect of income tax positions only if those positions are more likely than not of being sustained. Recognized income tax positions are measured at the largest amount that is greater than 50% likely of being realized. Changes in recognition or measurement are reflected in the period in which the change in judgment occurs. The Company records interest related to unrecognized tax benefits in interest expense and penalties in general and administrative expenses.

Stock-based compensation

The Company measures and records the expense related to stock-based payment awards based on the fair value of those awards as determined using the Black-Scholes-Merton ("Black-Scholes") model as of the date of grant. The Company recognizes stock-based compensation expense over the requisite service period of the individual grant, generally equal to the vesting period, on a straight-line basis.

The Black-Scholes model requires the use of highly subjective and complex assumptions, which determine the fair value of stock-based payment awards, including the option's expected term and the price volatility of the underlying stock. The Company estimates the fair value of options granted by using the Black-Scholes model with the following assumptions:

Expected Volatility—The Company estimates volatility for option grants by evaluating the historical volatility of a peer group of companies for the period immediately preceding the option grant for a term that is approximately equal to the options' expected term.

Expected Term—The expected term of the Company's options represents the period that the stock-based payment awards are expected to be outstanding. The expected term is estimated using the simplified method for employee stock options since the Company does not have adequate historical exercise data to estimate the expected term.

Risk-Free Interest Rate—The risk-free interest rate is based on the implied yield currently available on U.S. Treasury zero-coupon issues with a term that is equal to the options' expected term at the grant date.

Dividend Yield—The Company has not declared or paid dividends to date and does not anticipate declaring dividends. As such, the dividend yield has been estimated to be zero.

The Company has elected to recognize forfeitures as they occur.

Fair value measurements

Fair value is defined as the exchange price that would be received for an asset or an exit price that would be paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. The Company follows the established framework for measuring fair value and providing disclosures about fair value measurements.

The accounting guidance classifies fair value measurements in one of the following three categories for disclosure purposes:

Level 1: Quoted prices in active markets for identical assets or liabilities.

Level 2: Inputs other than Level 1 prices for similar assets or liabilities that are directly or indirectly observable in the marketplace.

Level 3: Unobservable inputs which are supported by little or no market activity and values determined using pricing models, discounted cash flow methodologies, or similar techniques, as well as instruments for which the determination of fair value requires significant judgment or estimation.

ASC 820, *Fair Value Measurement*, requires all entities to disclose the fair value of financial instruments, both assets and liabilities, for which it is practicable to estimate fair value, and defines the fair value of a financial instrument as the amount at which the instrument could be exchanged in a current transaction between willing parties. As of December 31, 2024, and 2023, the recorded values of cash and cash equivalents, prepaid expenses, and accounts payable and other current liabilities approximate their fair values due to the short-term nature of these items.

Recently adopted accounting pronouncements

In November 2023, the FASB issued ASU No. 2023-07, Improvements to Reportable Segment Disclosures. The FASB amended the guidance in ASC 280, Segment Reporting ("ASC 280"), to require a public entity to disclose significant segment expenses and other segment items on an annual and interim basis and to provide in interim periods all disclosures about a reportable segment's profit or loss and assets that are currently required annually. Public entities with a single reportable segment are required to provide the new disclosures and all the disclosures required under ASC 280. The guidance is applied retrospectively to all periods presented in financial statements unless it is impracticable. This new guidance is effective for public business entities for annual periods beginning after December 15, 2023, and for interim periods beginning after December 15, 2024. The Company adopted this new standard effective December 31, 2024. See Note 9, Segment Information, for disclosures related to the adoption of ASU 2023-07.

Recently issued accounting pronouncements

In November 2024, the FASB issued ASU No. 2024-03, Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures. This ASU will require entities to provide enhanced disclosures, in a tabular format, related to certain expense categories included in the statement of operations. The ASU aims to increase transparency and provide investors with more detailed information about the nature of expenses reported on the face of the income statement. The new ASU is effective for annual reporting periods beginning after December 15, 2026 and interim reporting periods beginning after December 15, 2027. Early adoption is permitted. The Company is currently evaluating the impact of the adoption of this standard on the related disclosures

In December 2023, the FASB issued ASU No. 2023-09, Improvements to Income Tax Disclosures. This ASU does not change accounting for income taxes but requires new disclosures focusing on two areas, the effective rate reconciliation and taxes paid. This new standard is effective for public business entities for annual periods beginning after December 15, 2024. Early adoption is permitted. The Company is currently evaluating the impact of the adoption of this standard on the related disclosures.

NOTE 3: PREPAID EXPENSES AND OTHER CURRENT ASSETS

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

	For the year ended December 31,	
	2024	2023
Prepaid insurance	$ 506,489	$ 554,097
Prepaid research and development	150,000	17,309
Other prepaid expenses	175,088	61,750
Total prepaid expenses and other current assets	$ 831,577	$ 633,156

NOTE 4: ACCOUNTS PAYABLE AND OTHER CURRENT LIABILITIES

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

	For the year ended December 31,	
	2024	2023
Accounts payable	$ 870,229	$ 806,004
Accrued employee costs	1,371,498	1,213,054
Accrued professional fees	72,054	39,165
Accrued research and development	860,958	439,024
Accrued board fees	117,750	117,750
Delaware franchise taxes payable	-	40,000
Other accrued expenses	17,228	17,330
Total accounts payable and other current liabilities	$ 3,309,717	$ 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 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 year ended December 31, 2024, is presented in the table below:

		Weighted average		
	Number of options	Exercise price	Remaining contractual life (in years)	Intrinsic value
Outstanding as of January 1, 2024	2,050,197	$ 10.90	7.9	$ 36,363
Granted	838,250	$ 1.54	-	$ -
Forfeited and cancelled	(625)	$ -	-	$ -
Outstanding as of December 31, 2024	2,887,822	$ 8.06	7.6	$ -
Exercisable as of December 31, 2024	1,854,764	$ 11.54	6.8	$ -
Vested and expected to vest as of December 31, 2024	2,887,822	$ 8.06	7.6	$ -

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

	For the year ended December 31,	
	2024	2023
Research and development	$ 624,480	$ 792,273
General and administrative	1,681,369	2,173,665
Total stock-based compensation expense	$ 2,305,849	$ 2,965,938

As of December 31, 2024, total compensation cost not yet recognized related to unvested stock options was approximately $1.0 million, which is expected to be recognized over a weighted-average period of approximately 1.5 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 years ended December 31, 2024 and 2023 are presented in the table below. The weighted average fair value of stock options issued during the years ended December 31, 2024 and 2023 was $1.31 and $1.43 per share, respectively.

	2024	2023
Exercise price	$ 1.54	$ 1.70
Expected term (in years)	5.8	5.8
Volatility	114.78%	110.9%
Risk free rate	4.0%	3.7%
Dividend yield	0.0%	0.0%

The following table presents the exercise price of outstanding stock options as of December 31, 2024:

Exercise price	Options outstanding
$0.01 - $8.00	1,861,499
$8.01 - $16.00	992,250
$16.01 or higher	34,073
Total	2,887,822

NOTE 6: CAPITALIZATION

a. As of December 31, 2024 and December 31, 2023, the Company had 200,000,000 shares of common stock authorized and 12,013,901 and 8,401,047 shares issued and outstanding, respectively. As of December 31, 2024 and December 31, 2023, the Company had 5,000,000 shares of preferred stock authorized. There were no shares of preferred stock issued or outstanding as of December 31, 2024 and 2023. As of December 31, 2024 and December 31, 2023, there were warrants outstanding to purchase an aggregate of 6,675,853 and 3,090,787 shares of common stock, respectively. As of December 31, 2024, these warrants are exercisable at a weighted average price of $6.52 and their weighted average remaining contractual term is 3.5 years.

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 2024, the Company sold 152,000 shares of the Company's common stock for aggregate gross proceeds of approximately $0.4 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. On August 6, 2024, the Company filed a prospectus supplement to reduce the amount of shares registered under the prospectus for the ATM to $0.00 and to suspend the ATM program, but the ATM Agreement remains in full force and effect.

c. On August 8, 2024, the Company completed a registered direct offering, pursuant to which the Company sold and issued to certain investors, including an officer of the Company, 1,643,837 shares of the Company's common stock at a purchase price per share of $1.825. In addition, in a concurrent private placement, the Company also issued to the purchasers in the August 2024 Offering unregistered warrants to purchase 1,643,837 shares of the Company's common stock (the "August 2024 Warrants"). The August 2024 Warrants are immediately exercisable at an exercise price of $1.70 per share and expire five years from the date of issuance. The total net proceeds were approximately $2.5 million, after deducting placement agent and other offering expenses in the amount of approximately $0.5 million. In September 2024, the Company filed a registration statement to register the resale by the investors of the shares of common stock issuable upon exercise of the August 2024 Warrants. The registration statement was declared effective on September 20, 2024.

d. On November 22, 2024, the Company completed a registered direct offering, pursuant to which the Company sold and issued to certain investors, including an officer of the Company, 1,817,017 shares of the Company's common stock at a purchase price per share of $1.175. In addition, in a concurrent private placement, the Company also issued to the purchasers in the November 2024 Offering unregistered warrants to purchase 1,817,017 shares of the Company's common stock (the "November 2024 Warrants"). The November 2024 Warrants are immediately exercisable at an exercise price of $1.05 per share and expire five years from the date of issuance. The total net proceeds were approximately $1.8 million, after deducting placement agent and other offering expenses in the amount of approximately $0.35 million. In December 2024, the Company filed a registration statement to register the resale by the investors of the shares of common stock issuable upon exercise of the November 2024 Warrants. The registration statement was declared effective on December 31, 2024. In addition, in connection with the November 2024 Offering, the Company issued to the placement agent and its designees warrants to purchase an aggregate of 124,212 shares of common stock at an exercise price of $1.3125. The placement agent warrants are exercisable six months from the date of issuance and expire on the fifth anniversary of the issue date. The fair value of a warrant to purchase one share of common stock that was issued to the placement agent was $0.93.

e. On January 16, 2025, the Company completed a private placement offering pursuant to which the Company sold and issued to certain investors an aggregate of 2,109,383 shares of common stock and warrants to purchase 2,109,383 shares of common stock (the "January 2025 Warrants"). The shares and January 2025 Warrants were sold on a combined basis for consideration of $1.065 for one share and one January 2025 Warrant. The January 2025 Warrants are immediately exercisable at an exercise price of $0.94 per share and expire five years from the date of issuance.

The total net proceeds were approximately $2.0 million, after deducting placement agent and other offering expenses in the amount of approximately $0.25 million. In February 2025, the Company filed a registration statement to register the resale by the investors of the shares of common stock and shares of common stock issuable upon exercise of the January 2025 Warrants. The registration statement was declared effective on February 11, 2025. In addition, in connection with the January 2025 Offering, the Company issued to the placement agent and its designees warrants to purchase an aggregate of 147,656 shares of common stock at an exercise price of $1.175. The placement agent warrants are exercisable six months from the date of issuance and expire on the fifth anniversary of the issue date. The fair value of a warrant to purchase one share of common stock that was issued to the placement agent was $0.74.

f. On February 12, 2025, the Company entered into a Standby Equity Purchase Agreement (the "SEPA") with YA II PN, LTD., a Cayman Islands exempt limited company ("Yorkville"), which provides that, upon the terms and subject to the restrictions and satisfaction of the conditions in the SEPA, Yorkville is committed to purchase up to an aggregate of $20.0 million of the Company's shares of common stock over a 36-month period. At the Company's option, the shares of common stock would be purchased by Yorkville from time to time at a price equal to 97% of the lowest of the three daily VWAPs during a three consecutive trading day period commencing on the date that the Company, subject to certain limitations, delivers a notice to Yorkville that the Company is committing Yorkville to purchase such shares of common stock. The Company may also specify a certain minimum acceptable price per share in each advance. The Company will control the timing and amount of sales of the Company's shares to Yorkville. As consideration for Yorkville's irrevocable commitment to purchase shares of the Company's common stock upon the terms of and subject to restrictions and satisfaction of the conditions set forth in the SEPA, upon execution of the SEPA, the Company issued to Yorkville 305,960 shares of common stock, as commitment shares. Under the applicable Nasdaq Rules and pursuant to the SEPA, in no event may the Company issue or sell to Yorkville more than 2,823,244 shares of common stock (the "Exchange Cap"), which is 19.99% of the shares of common stock outstanding immediately prior to the execution of the SEPA, unless (i) the Company obtains stockholder approval to issue shares of common stock in excess of the Exchange Cap, or (ii) the average price of all applicable sales of common stock under the SEPA equals or exceeds $0.81722 per share (which represents the lower of (i) the Nasdaq Official Closing Price (as reflected on Nasdaq.com) on the trading day immediately preceding the effective date or (ii) the average Nasdaq Official Closing Price of the common stock (as reflected on Nasdaq.com) for the five trading days immediately preceding the effective date). On February 12, 2025, the Company filed a Form S-1 covering the resale of up to 10,000,000 shares of common stock comprised of (i) 305,960 commitment shares, and (ii) up to 9,694,040 shares of common stock reserved for issuance and sale to Yorkville under the SEPA. The Form S-1 was declared effective on February 13, 2025.

NOTE 7: COMMITMENTS AND CONTINGENCIES

Litigation

From time to time, the Company could become involved in 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, the Company entered into a noncancelable two-year operating lease agreement for approximately 2,000 square feet of office space in San Diego, California. The base rent was $7,999 per month with an increase of 3% after the first anniversary of the lease term commencement, which was November 1, 2022.

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 annual lease payments and a reconciliation to the Company's operating lease liability under the Company's noncancelable operating lease as of December 31, 2024 are as follows:

Total minimum lease payments in 2025	$	86,862
Less: amount representing interest		(2,698)
Present value of operating lease liability		84,164
Less: current portion		(84,164)
Operating lease liability, net of current portion	$	-

The Company recognized rent expense of $101,847 and $100,742 during the years ended December 31, 2024 and 2023, respectively. Total cash payments for the operating lease totaled $101,705 and $99,254 during the years ended December 31, 2024 and 2023, respectively.

NOTE 8: INCOME TAXES

As of December 31, 2024, the Company had net operating loss carry forwards that may be available to reduce future years' taxable income.

The Company's provision for income taxes consisted of the following:

	For the year ended December 31,	
	2024	2023
Computed "expected" tax benefit	$ (3,154,290)	$ (3,238,593)
State taxes, net of federal benefit	(11,768)	1,304
Non-deductible items	230,890	61,842
Change in deferred tax asset valuation allowance	2,454,200	2,509,496
Stock-based compensation	482,045	613,167
Return-to-provision adjustments	2	41,316
Other	621	13,918
Income tax expense	$ 1,700	$ 2,450

Deferred income taxes reflect the net tax effects of (a) temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes, and (b) operating losses and tax credit carryforwards.

The Company's net deferred tax assets were comprised of the following as of December 31, 2024 and 2023:

	2024	2023
Deferred tax assets:		
Net operating losses	$ 53,447,116	$ 51,846,000
Capitalized research and development	2,959,591	2,162,872
Stock-based compensation	288,756	261,052
Accruals	249,495	220,923
Operating lease liabilities	17,760	36,761
Other	616	559
Total gross deferred tax assets	56,963,334	54,528,167
Deferred tax liabilities:		
Right-of-use asset	(17,340)	(36,373)
Gross deferred tax liabilities	(17,340)	(36,373)
Less: Deferred tax asset valuation allowance	(56,945,994)	(54,491,794)
Total net deferred tax assets	$ -	$ -

Deferred income tax assets and liabilities are recorded for differences between the financial statement and tax basis of the assets and liabilities that will result in taxable or deductible amounts in the future based on enacted laws and rates applicable to the periods in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amount expected to be realized

ASC 740 requires that the tax benefit of net operating losses, temporary differences and credit carryforwards be recorded as an asset to the extent that management assesses that realization is "more likely than not." Realization of the future tax benefits is dependent on the Company's ability to generate sufficient taxable income within the carryforward period. Because of the Company's recent history of operating losses, management believes that recognition of the deferred tax assets arising from the above-mentioned future tax benefits is currently not likely to be realized and, accordingly, has provided a full valuation allowance for the years ended December 31, 2024 and 2023. The net change in total valuation allowance for the years ended December 31, 2024 and 2023 was an increase of $2.5 million and increase of $2.5 million respectively.

At December 31, 2024, the Company has United States federal and state net operating loss (NOL) carryforwards of $35.3 million and $7.6 million, respectively. The federal NOL carryforwards generated in pre-2018 tax years of $0.8 million will begin to expire in 2036 while federal NOLs generated after 2017 of $34.4 million will carry forward indefinitely. The state NOL carryforwards of $7.6 million will begin to expire in 2035 unless previously utilized. At December 31, 2024, the Company also had Israel NOL carryforwards of $197.9 million. The Israel NOLs carry forward indefinitely.

The Company's ability to utilize its net operating losses may be limited under Section 382 and 383 of the Internal Revenue Code. The limitations apply if an ownership change, as defined by Section 382, occurs. Generally, an ownership change occurs when certain shareholders increase their aggregate ownership by more than 50 percentage points over their lowest ownership percentage in a testing period (typically three years). Although the Company has not undergone a Section 382 analysis, it is possible that the utilization of the net operating losses, could be substantially limited. Additionally, U.S. tax laws limit the time during which these carryforwards may be utilized against future taxes. As a result, the Company may not be able to take full advantage of these carryforwards for federal and state tax purposes. Future changes in stock ownership may also trigger an ownership change and, consequently, a Section 382 limitation.

The Company recognizes the benefit of tax positions taken or expected to be taken in its tax returns in the consolidated financial statements when it is more likely than not that the position will be sustained upon examination by authorities. Recognized tax positions are measured at the largest amount of benefit that is greater than 50% likely of being realized upon settlement. As of December 31, 2024 and 2023 the Company has not recorded any unrecognized tax benefits.

The Company records interest related to unrecognized tax benefits in interest expense and penalties in general and administrative expenses. As of December 31, 2024 and 2023, the Company recorded no accrued interest and penalties related to unrecognized tax benefits. The Company does not expect any significant changes in its tax positions that would warrant recognition of a liability for unrecognized income tax benefits during the next 12 months.

The Company files U.S. federal and various state income tax returns and is subject to the examination for tax years back to 2021 and 2020 for federal and state purposes, respectively, and its NOL's dating back to inception are subject to adjustment by the taxing authorities if claimed on future tax filings for which the statute remain open to examination. The Company also files Israeli tax returns and is subject to examination for tax years back to 2020. The Company is not currently under audit by the Internal Revenue Service or other similar national, state and local authorities.

NOTE 9: SEGMENT INFORMATION

Operating segments are defined as components of an entity about which separate discrete information is available for evaluation by the chief operating decision maker in deciding how to allocate resources in assessing performance. The Company operates as a single reporting segment, focusing on the development of a novel and patented systemically administered anti-cancer and anti-viral immunotherapy. The Company's chief operating decision maker ("CODM") is the chief executive officer.

The accounting policies of the segment are the same as those described in the summary of significant accounting policies. The CODM assesses performance for the segment based on operating expenses as reported in the accompanying consolidated statement of operations. The Company expects to continue to incur significant expenses and operating losses for the foreseeable future as it advances the development of its product candidates through pre-clinical and clinical trials. In addition, the measure of segment assets is reported on the accompanying consolidated balance sheet as total assets.

As such, the CODM uses cash forecast models in deciding how to invest into the segment. Such cash forecast models are reviewed to assess the entity-wide operating results and performance. Net loss is used to monitor budget versus actual results. Monitoring budgeted versus actual results is used in assessing performance of the segment.

The following table presents reportable segment loss, including significant expenses regularly provided to the CODM, attributable to the Company's reportable segment for the years ended December 31, 2024 and 2023:

	Year ended December 31,	
	2024	2023
Research and development:		
External research and development	$ 4,355,449	$ 4,683,828
Internal personnel costs	2,895,648	2,937,879
Total research and development	7,251,097	7,621,707
General and administrative	8,114,654	8,756,767
Other income, net	(343,724)	(955,003)
Net loss	$ 15,022,027	$ 15,423,471

NOTE 10: SUBSEQUENT EVENTS

The Company evaluated subsequent events from December 31, 2024, the date of these consolidated financial statements, through March 13, 2024, which represents the date the consolidated financial statements were issued, for events requiring recognition or disclosure in the consolidated financial statements for the year ended December 31, 2024. The Company concluded that no events have occurred that would require recognition or disclosure in the consolidated financial statements, except for the January 2025 Offering that was completed on January 16, 2025, as described in Note 6(e) and for the SEPA that was entered with Yorkville on February 12, 2025, as described in Note 6(f).

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures. Disclosure 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 December 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 December 31, 2024.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over our financial reporting, as such term is defined in Rule 13a-15(f) under the Exchange Act.

Our management conducted an assessment of the effectiveness of our internal control over financial reporting based on the criteria set forth in "Internal Control- Integrated Framework (2013)" issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our assessment, our management concluded that as of December 31, 2024, our internal control over financial reporting was effective.

Attestation Report of the Independent Registered Public Accounting Firm

This Annual Report does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting due to an exemption provided to issuers that are not "large accelerated filers" nor "accelerated filers" under applicable SEC rules.

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 December 31, 2024 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

During the three months ended December 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 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as each term is defined in Item 408(a) of Regulation S-K.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

PART III

Item 10. Directors and Executive Officers.

The following table sets forth information relating to our executive officers and directors as of March 12, 2025.

Name	Age	Position
Executive Officers		
Jeffrey A. Meckler	58	Chief Executive Officer and Director
Michael J. Newman, Ph.D.	69	Chief Scientific Officer and Director
Nir Sassi	49	Chief Financial Officer
Walt A. Linscott, Esq.	65	Chief Operating Officer
Roger J. Waltzman	58	Chief Medical Officer
Non-Executive Directors		
Dr. Roger J. Pomerantz	68	Chairman of the Board of Directors
Hila Karah	56	Director
Anthony J. Maddaluna	72	Director
William B. Hayes	59	Director
Mark J. Gilbert, M.D.	64	Director
Robert E. Martell, M.D., Ph.D.	62	Director

Biographical information with respect to our executive officers and directors is provided below.

Information about Our Executive Officers

Jeffrey A. Meckler has served as our Chief Executive Officer since July 2021 and member of our board of directors since inception in February 2021. Previously, Mr. Meckler served as our sole officer from inception to July 2021, Intec Israel's Vice Chairman of the board of directors from April 2017, as Intec Israel's Chief Executive Officer from July 2017 and as President and Secretary and director of Intec Parent, Inc. from March 2021 until the Merger. Mr. Meckler has served on numerous public and private corporate boards and since October 2014 has served as a director of Travere Therapeutics (Nasdaq: TVTX). Mr. Meckler served as Chief Executive Officer and a director of CoCrystal Pharma, Inc., a pharmaceutical company, from April 2015 to July 2016. He has also served as a director of QLT, Inc. (Nasdaq: QLTI), a biotechnology company, from June 2012 to November 2016, as well as the Managing Director of The Andra Group, a life sciences consulting firm since 2009. Mr. Meckler also served as Chief Executive Officer of Trieber Therapeutics from January 2017 to July 2017. Earlier in his career, Mr. Meckler held a series of positions at Pfizer Inc. in manufacturing systems, market research, business development, strategic planning and corporate finance, which included playing a significant role in acquisitions and divestitures. Mr. Meckler is the past President and continues to serve on the board of directors of Children of Bellevue, a non-profit organization focused on advocating and developing pediatric programs at Bellevue Hospital Center. Mr. Meckler holds a B.S. in Industrial Management and M.S. in Industrial Administration from Carnegie Mellon University. In addition, Mr. Meckler received his J.D. from Fordham University School of Law. We believe that Mr. Meckler is qualified to serve on our board of directors because of his extensive executive leadership experience in the biopharmaceutical industry, including his service at Pfizer, and his experience serving on public company boards.

Michael J. Newman, Ph.D. has served as our Chief Scientific Officer and a member of our board of directors since August 2021. Dr. Newman is a pharmaceutical/biotechnology executive with over 40 years of experience carrying out and managing oncology research and development, in addition to undergraduate and graduate research and training in microbiology. He was the Founder, President, Chief Executive Officer and a member of the board of directors of Decoy (from August 2013 to August 2021). His previous positions also include faculty appointments in Biochemistry at Brandeis University (from 1984 to 1987) and the Roche Institute of Molecular Biology (from 1987 to 1992), Senior Associate Director of Oncology at Sandoz Pharmaceuticals (world-wide head of Cancer Biology), and Executive Director of Oncology at Novartis Pharmaceuticals (Head of Cancer Biology in the U.S.) (from 1992 to 1997), and senior management at several Biotechnology companies (from 1998 to 2012). Dr. Newman received a bachelor's degree in Biology from the University of California at San Diego, a Ph.D. in Cell and Developmental Biology from Harvard Medical School (National Science Foundation Pre-Doctoral Fellow), and carried out post-doctoral research at Cornell University. We believe that Dr. Newman is qualified to serve on our board of directors because of his extensive scientific and research background, as well as his experience as founder and CEO of Decoy.

Nir Sassi has served as our Chief Financial Officer since July 2021 and served as Intec Israel's Chief Financial Officer from March 2010 until the Merger (other than from January 2015 to August 2016, during which period Mr. Sassi served as Intec Israel's VP Finance), and its President from March 2021 until the Merger. Prior to his service with Intec Israel, Mr. Sassi served as a Senior Manager at PricewaterhouseCoopers Israel, an accounting firm, from 2002 until 2010, including two years relocation to the PricewaterhouseCoopers New York office. Mr. Sassi is a certified public accountant in Israel and has a bachelor's degree in economics and accounting from Ben Gurion University in Be'er Sheva, Israel.

Walt A. Linscott, Esq. has served as our Chief Operating Officer since March 2023. Prior to that, he served as our Chief Business Officer from July 2021 until March 2023. Mr. Linscott joined Intec Israel in October 2017 and served as its Chief Business Officer from July 2018 until the Merger. Previously, from October 2017 to July 2018, Mr. Linscott served as Intec Israel's Chief Administrative Officer. Prior to his service with Intec Israel, Mr. Linscott co-founded a global consulting enterprise in October 2014 providing strategic advice to developing companies and most recently served as the President and Chief Operating Officer of Treiber Therapeutics, Inc. from March 2017 to October 2017. Mr. Linscott also has held senior level executive positions at public and private medical device and pharmaceutical companies including Cocrystal Pharma, Inc., from July 2015 to March 2017, Carestream Health, Inc., from January 2011 to January 2015 and Solvay Pharmaceuticals, Inc., from 2001 to 2005. In addition to this experience, he was an associate and partner at Thompson Hine LLP from 1990 to 2001, and again as a partner from 2005 to 2010 where he founded the firm's Atlanta, Georgia office, served as Partner in Charge and Chair of the firm's Life Science Practice Group. Mr. Linscott holds a Master of Science in Experimental and Translational Therapeutics from the University of Oxford, a Postgraduate Diploma in Global Business from the University of Oxford and a Postgraduate Diploma in Entrepreneurship from Cambridge University. He earned a bachelor's degree from Syracuse University and a Juris Doctor from the University of Dayton School of Law. Mr. Linscott served on active duty as an Officer in the United States Marine Corps prior to attending law school.

Roger Waltzman M.D., M.B.A. has served as our Chief Medical Officer since August 2023. Prior to that, he served as Chief Medical Officer of Molecular Templates from 2019 to 2023 and in multiple senior drug development roles at Novartis Oncology from 2007 to 2013, where he played a leading role in the development of imatinib, nilotinib, and ruxolitinib. From 2013 to 2016, Dr. Waltzman was the Full Development Head of Malaria Drug Development at Novartis. More recently, Dr. Waltzman was CMO at Rgenix (now Inspirna), where he supervised the development of immuno-oncology and metabolic inhibitor assets through Phase 1 a/b. Previously, he served as CSO at Jaguar Health and Napo Pharmaceuticals, where he led scientific aspects of development and commercialization of Mytesi® (crofelemer). Before joining the industry, Dr. Waltzman held assistant professorships in medical oncology and palliative care at Saint Vincent's Hospital and Mount Sinai School of Medicine in New York. He completed his fellowship in hematology/oncology at Memorial Sloan Kettering Cancer Center. Dr. Waltzman earned a Master of Business Administration at Columbia Business School and a Doctor of Medicine and Bachelor of Arts from Brown University.

Non-Employee Directors

Dr. Roger J. Pomerantz has served as our Chairman since July 2021 and previously served on Intec Israel's board of directors from March 2018 until the Merger. Dr. Pomerantz served as Chairman and Chief Executive Officer of Contrafect Corporation (Nasdaq: CFRX) from April 2019 to November 2023. Prior to that, he served as Vice Chairman of Contrafect from May 2014 to April 2019. Previously, Dr. Pomerantz was a Venture Partner at Flagship Pioneering from 2014 through 2019. In addition, from November 2013 to December 2019, Dr. Pomerantz served as Chairman of the board of directors of Seres Therapeutics, Inc. (Nasdaq: MCRB), a biotechnology company, and as its President and Chief Executive Officer from June 2014 to January 2019. Prior to joining Seres, Dr. Pomerantz was Worldwide Head of Licensing & Acquisitions, Senior Vice President at Merck & Co., Inc., where he oversaw all licensing and acquisitions at Merck Research Laboratories, including external research, out-licensing regional deals, and academic alliances. Previously, he served as Senior Vice President and Global Franchise Head of Infectious Diseases at Merck. Prior to joining Merck, Dr. Pomerantz was Global Head of Infectious Diseases for J&J. Dr. Pomerantz has. Since February 2020, he served as Chairman of Collplant Biotechnologies (Nasdaq: CLPT), since May 2022 he served as Vice Chairman of Enlivex Therapeutics Ltd. (Nasdaq: ENLV), and was previously a member of the board of directors of Viracta (Nasdaq: VIRX) from June 2020 until December 2024, Rubius Therapeutics (Nasdaq: RUBY) from 2014 to 2019 and Evelo Therapeutics (Nasdaq: EVLO) from 2015 to 2016. Dr. Pomerantz earned his B.A. in biochemistry at the Johns Hopkins University and his M.D. at the Johns Hopkins School of Medicine. He completed his internal medicine internship and residency training, and his subspecialty clinical and research training in infectious diseases and virology at the Massachusetts General Hospital of Harvard Medical School. His post-doctoral research training in molecular retrovirology was obtained at both Harvard Medical School and the Whitehead Institute of the Massachusetts Institute of Technology (MIT). Dr. Pomerantz also served as the Chief Resident at the Massachusetts General Hospital. Following his medical-scientist training, he was an Endowed, Tenured Professor of Medicine and Molecular Pharmacology and Chairman of the Infectious Diseases Department of Thomas Jefferson University in Philadelphia. Dr. Pomerantz is an

internationally recognized expert in HIV molecular pathogenesis and latency. He has developed ten approved infectious disease drugs in important diseases including HIV, HCV, tuberculosis, and Clostridium difficile infection. We believe Dr. Pomerantz is qualified to serve on our board of directors because of his significant scientific, executive and board leadership experience in drug development and in the pharmaceutical industry.

Hila Karah has served on our board since July 2021 and previously served as a member of Intec Israel's board of directors since December 2009 until the Merger. Ms. Karah is a managing Partner of Pitango HealthTech VC and an experienced board director. Prior to Pitango she served as an independent business consultant to private and public companies on strategy, operations, financing, regulatory and corporate governance. From 2006 until 2013, Ms. Karah was the chief investment officer of Eurotrust Ltd., a family office, where she focused primarily on investments in life science, internet and high-tech companies. Prior to joining Eurotrust, Ms. Karah served as a senior analyst at Perceptive Life Sciences Ltd., a New York-based life healthcare focused hedge fund. Prior to her position at Perceptive, Ms. Karah was a research analyst at Oracle Partners Ltd., a healthcare-focused hedge fund based in Connecticut. Ms. Karah has served on the board of Cyren Ltd., a cyber security company (Nasdaq, TASE: CYRN), since 2008 and the board of Dario Health Corp. (Nasdaq: DRIO) since 2014. She also serves on the board of several private companies. Ms. Karah has a BA in molecular and cell biology from the University of California, Berkeley, and has studied at the UCSB – UCSF Joint Medical Program. We believe Ms. Karah is qualified to serve on our board of directors because of her longstanding service with Intec Israel, her investment career in life science companies, her scientific background and experience serving on public company boards.

Anthony J. Maddaluna has served on our board since July 2021 and previously served on Intec Israel's board of directors since December 2017 until the Merger. Mr. Maddaluna has more than 40 years of experience in the pharmaceutical manufacturing industry, including leadership positions in plants, regions and globally. From January 2011 to December 2016, Mr. Maddaluna held a series of positions at Pfizer Inc., most recently serving as the Executive Vice President and President of Pfizer Global Supply. Prior to that Mr. Maddaluna served as Senior Vice President of Pfizer Global Manufacturing Strategy and Supply Network Transformation from 2008 until 2011, and as Vice President of Pfizer Global Manufacturing Europe Area from 1998 until 2008. Mr. Maddaluna served as a director of Albany Molecular Research Inc. from February 2016 until its acquisition by The Carlyle Group and GTCR in August 2017 and currently serves on the board of managers for the private company. Mr. Maddaluna holds a B.S. in Chemical Engineering from Northeastern University and an M.B.A. from Southern Illinois University. We believe Mr. Maddaluna is qualified to serve on our board of directors because of his extensive experience in the pharmaceutical manufacturing industry, including his service at Pfizer, and his experience serving on company boards.

William B. Hayes has served on our board since July 2021 and previously served on Intec Israel's board of directors since June 2018 until the Merger. Most recently, Mr. Hayes was Executive Vice President, Chief Financial Officer and Treasurer of Laboratory Corporation of America Holdings (LabCorp) (NYSE: LH), a diagnostics laboratory company. Mr. Hayes joined LabCorp in 1996, where he was responsible for day-to-day operations of the revenue cycle function. He rose through a series of promotions and in 2005 was named Executive Vice President, Chief Financial Officer and Treasurer of LabCorp, a role he held until his retirement in 2014. Prior to LabCorp, Mr. Hayes was at KPMG for nine years in their audit department. Since October 2019, Mr. Hayes has served on the board of Builders FirstSource, a supplier and manufacturer of building materials (Nasdaq: BLDR), and currently chairs its audit committee. Previously, Mr. Hayes served as a director from March 2016 for Patheon N.V. (NYSE: PTHN), a pharmaceutical manufacturing company, until its acquisition by Thermo Fisher in late 2017. Mr. Hayes holds a Bachelor of Science in accounting from the University of North Carolina at Greensboro. We believe Mr. Hayes is qualified to serve on our board of directors because of his accounting background and experience serving on public company boards.

Mark J. Gilbert has served on our board of directors since November 2021. Dr. Gilbert brings more than 30 years of experience in global medical and clinical research and development, and management of medical affairs. From March 2019 to March 2022, Dr. Gilbert served as Executive Vice President of Research and Development at Acepodia, Inc., a clinical-stage biotechnology company addressing gaps in cancer care and since June 2021, Dr. Gilbert has served as a Clinical Development Advisor to Decoy Biosystems, Inc., the Company's wholly owned-subsidiary. In addition, from October 2020 to January 2024, Dr. Gilbert served as the Chairman of the Scientific Advisory Board at Inceptor Bio, LLC, a biotechnology company developing multiple next- generation cell and gene therapy platforms for underserved and difficult-to-treat cancers, after January 2024 he remains an SAB member, and from October 2020, he serves as a Strategic Advisor at Kineticos Ventures, a firm providing advisory services and capital to emerging life sciences firms. Prior to these positions, between November 2013 and January 2020, Dr. Gilbert was the Chief Medical Officer of Juno Therapeutics Inc., a biopharmaceutical company, where he led the clinical development of some of the first CAR-T cell therapies. Before that, Dr. Gilbert held leadership positions at Bayer Schering Pharma AG, where he served as Vice President and Head of Global Clinical Development, Therapeutic Area Oncology; Berlex Pharmaceuticals, Inc., where he served as Vice President of Medical Affairs, Oncology, and Vice President

and Head of Global Medical Development Group, Oncology; and Immunex Corporation, where he served as Senior Medical Director, Clinical Research and Development. Between May 2019 and May 2021, Dr. Gilbert served as an Independent Director of Silicon Therapeutics, Inc., a fully integrated drug design and development company. Dr. Gilbert earned a Bachelor of Science degree in Biochemistry from the University of Iowa and a Medical Doctor degree from the University of Iowa College of Medicine. He trained in internal medicine, infectious disease and medical oncology at the University of California, San Francisco, and the University of Washington, respectively. We believe Dr. Gilbert is qualified to serve on our board of directors because of his significant scientific and executive in drug development and in the pharmaceutical industry.

Robert E. Martell, M.D., Ph.D. has served on our board of directors since February 2023. Dr. Martell brings more than 20 years of experience in the pharmaceutical industry. Dr. Martell is Chief Scientific Officer at Curis, having previously served as Head of Research & Development. From September 2011 to May 2018, Dr. Martell served on Curis' Board of Directors. He is also co-founder of Epi-Cure Pharmaceuticals, a privately held early-stage biotechnology company, and served as its president and member of board of directors from 2016 to 2018. Dr. Martell served as Chief Medical Officer of Tesaro, Inc., a biopharmaceutical company developing Zejula and Varubi from 2012 to 2015; as Chief Medical Officer at MethylGene, a publicly traded biopharmaceutical focused on cancer therapeutics from 2005 to 2009; as Director of Oncology Global Clinical Research at Bristol-Myers Squibb, a biopharmaceutical company developing Sprycel, Erbitux and Ixempra from 2002 to 2005; and as Associate/Deputy Director at Bayer Corporation Pharmaceutical Division developing Nexavar from 2000 to 2002. In addition, Dr. Martell is a part-time treating physician at Champlain Valley Hematology Oncology and he has held a number of academic positions, including at Tufts Medical Center since 2009, where he has served in various roles including Associate Chief in the Division of Hematology/Oncology, Director of the Neely Center for Clinical Cancer Research, Leader of the Cancer Center's Program in Experimental Therapeutics and Attending Physician; at Yale University School of Medicine as Assistant Clinical Professor of Oncology from 2001 to 2005; and as Assistant Professor at Duke Medical Center from 1998 to 2000. Dr. Martell received a B.A. in chemistry from Kalamazoo College, a Ph.D. in Pharmacology from University of Michigan and an M.D. from Wayne State University. He completed his Internal Medicine internship and residency at Duke University Medical Center, and his Fellowship in Medical Oncology also at Duke.

Board Leadership Structure

Our Board is committed to promoting effective, independent governance of the Company. Our Board believes it is in the best interests of the stockholders and the Company for the Board to have the flexibility to select the best director to serve as Chairman at any given time, regardless of whether that director is an independent director or the Chief Executive Officer. Consequently, we do not have a policy governing whether the roles of Chairman of the Board and Chief Executive Officer should be separate or combined. This decision is made by our Board, based on the best interests of the Company considering the circumstances at the time.

Currently, the offices of the Chairman of the Board and the Chief Executive Officer are held by two different people. Dr. Pomerantz is our independent, non-executive Chairman of the Board and Mr. Meckler is our Chief Executive Officer. The Chief Executive Officer is responsible for the day to day leadership and performance of the Company, while the Chairman of the Board provides guidance to the Chief Executive Officer and sets the agenda for Board meetings and presides over meetings of the Board. We believe that separation of the positions reinforces the independence of the Board in its oversight of the business and affairs of the Company, and creates an environment that is more conducive to objective evaluation and oversight of management's performance, increasing management accountability and improving the ability of the Board to monitor whether management's actions are in the best interests of the Company and its stockholders. Furthermore, we believe that Dr. Pomerantz is especially suited to serve as our Chairman of the Board, in light of his significant strategic management experience in the U.S. healthcare industry, which provides him with a unique perspective on the best methods of growth for a life sciences company.

However, our Board of Directors will continue to periodically review our leadership structure and may make such changes in the future as it deems appropriate.

Role of the Board in Risk Oversight

One of the key functions of our Board is informed oversight of our risk management process. Our Board does not have a standing risk management committee, but rather administers this oversight function directly through our Board as a whole, as well as through various standing committees of our Board that address risks inherent in their respective areas of oversight. In particular, our Board is responsible for monitoring and assessing strategic risk exposure. Our Board considers cybersecurity risk as part of its risk oversight function and oversees our cybersecurity and other information technology risks and management's implementation of our cybersecurity risk management program. Our Audit Committee has the responsibility

to consider and discuss our major financial risk exposures and the steps management will take to monitor and control such exposures, including guidelines and policies to govern the process by which risk assessment and management is undertaken. The Audit Committee also monitors compliance with legal and regulatory requirements and considers and approves or disapproves any related person transactions. Our Compensation Committee assesses and monitors whether our compensation plans, policies and programs comply with applicable legal and regulatory requirements. The Board does not believe that its role in the oversight of our risks affects the Board's leadership structure.

Clawback Policy

Our Board of Directors has adopted a Policy for Recovery of Erroneously Awarded Compensation (the "Clawback Policy"), in accordance with the Nasdaq listing standards and Exchange Act Rule 10D-1, which applies to our current and former executive officers. Under the Clawback Policy, we are required to recoup the amount of any Erroneously Awarded Compensation (as defined in the Clawback Policy) on a pre-tax basis within a specified lookback period in the event of any Financial Restatement (as defined in the Clawback Policy), subject to limited impracticability exception.

Policies and Practices Related to the Grant of Certain Equity Awards

From time to time, we award stock options to our employees, including the named executive officers. Historically, the Company we awarded new-hire option grants on or soon after a new hire's employment start date and periodic annual refresh employee option grants, which refresh grants are typically approved at a meeting of the compensation committee or board. Non-employee directors receive automatic initial and annual stock option grants, at the time of a director's appointment or election to the board and at the time of each annual meeting of our stockholders, respectively. For additional information on our non-employee director compensation policy see below under the heading, "Director Compensation."

We do not otherwise maintain any written policies on the timing of awards of stock options, stock appreciation rights, or similar instruments with option-like features. It is the Company's practice to not grant any awards to its named executive officers when in possession of any material nonpublic information, and to wait until such material nonpublic information has been fully disclosed, widely disseminated to the public and at least two full business days has passed after such material nonpublic information has been disclosed.

Code of Business Conduct and Ethics

We have a Code of Business Conduct and Ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. The Code of Business Conduct and Ethics is publicly available on our website at http://www.indaptusrx.com. We intend to satisfy the disclosure requirement under Item 5.05 of Form 8-K regarding amendment to, or waiver from, a provision of our Code of Business Conduct and Ethics, as well as Nasdaq's requirement to disclose waivers with respect to directors and executive officers, by posting such information on our website at texhe address and location specified above. The information contained on our website is not incorporated by reference into this Annual Report.

Insider Trading Policy

We have adopted an insider trading policy that governs the purchase, sale, and/or other transactions of our securities by our directors, officers and certain other covered persons, and which is reasonably designed to promote compliance with applicable insider trading laws, rules and regulations, and any listing standards applicable to us. A copy of our insider trading policy is filed as Exhibit 19.1 to this Annual Report on Form 10-K. In addition, with regard to any trading in our own securities, it is our policy to comply with the federal securities laws and the applicable exchange listing requirements.

Committees of the Board

Our Board has established four standing committees—Audit, Compensation, Nominating, and Science and Technology. Each of Audit, Compensation and Nominating Committee operates under a written charter that has been approved by our Board.

The members of each of the Board committees and committee Chairpersons are set forth in the following chart.

Name	Audit	Compensation	Nominating	Science and Technology
Mark J. Gilbert, M.D.				X
William B. Hayes	Chairperson	X		
Hila Karah	X		Chairperson	
Anthony J. Maddaluna		Chairperson	X	X
Robert E. Martell, M.D., Ph.D.	X			X
Michael J. Newman, Ph.D.				Chairperson

Audit Committee

Our Audit Committee's responsibilities include:

- appointing, approving the compensation of, and assessing the independence of our independent registered public accounting firm;
- monitoring the rotation of the partners of our independent registered public accounting firm on our audit engagement team and considering periodically the rotation of auditing firms;
- overseeing the work of our independent registered public accounting firm;
- reviewing and discussing with management and the independent registered public accounting firm the results of the annual audit, including our annual financial statements and related disclosures, and the results of the review by the independent registered public accounting firm of our quarterly financial statements and related disclosures;
- discussing with management and the independent registered public accounting firm the adequacy of our internal control over financial reporting, disclosure controls and procedures, compliance with legal and regulatory requirements, and code of business conduct and ethics;
- discussing with management and the independent registered public accounting firm our risk management policies;
- establishing policies regarding hiring employees from the independent registered public accounting firm and procedures for the receipt and retention of accounting related complaints and concerns;
- meeting independently with our independent registered public accounting firm and management;
- reviewing and providing oversight of any related person transactions, including establishing such policies and procedures as appropriate to facilitate such review; and
- preparing the audit committee report required by the SEC rules (which is included on page 11 of this proxy statement).

The Audit Committee charter is available on the Investors page of our website at *www.indaptusrx.com*. The members of the Audit Committee are Mr. Hayes, Ms. Karah, and Dr. Martell. Mr. Hayes serves as the Chairperson of the committee. Our Board has affirmatively determined that each of Mr. Hayes, Ms. Karah, and Dr. Martell is independent for purposes of serving on an audit committee under Rule 10A-3 promulgated under the Exchange Act and the Nasdaq Rules, including those related to Audit Committee membership.

The members of our Audit Committee meet the requirements for financial literacy under the applicable Nasdaq rules. In addition, our Board of Directors has determined that Mr. Hayes qualifies as an "audit committee financial expert," as such term is defined in Item 407(d)(5) of Regulation S-K, and under the similar Nasdaq Rules requirement that the Audit Committee have a financially sophisticated member.

Compensation Committee

Our Compensation Committee is responsible for assisting the Board in the discharge of its oversight responsibilities relating to the evaluation of our executive officers (including the Chief Executive Officer), determining the compensation of our executive officers, and overseeing the management of risks associated therewith. In fulfilling its purpose, our Compensation Committee has the following principal duties:

- reviewing and approving, or recommending for approval by the Board, our overall compensation strategy and policies, including evaluating risks associated with our compensation policies and practices;
- reviewing and approving, or recommending for approval by the Board, the compensation of our CEO and our other executive officers;

- overseeing and administering our cash and equity incentive plans;
- reviewing and making recommendations to the Board of Directors with respect to non-employee director compensation;
- reviewing and discussing annually with management our "Compensation Discussion and Analysis," to the extent required; and
- preparing the annual compensation committee report, to the extent required by SEC rules.

The Compensation Committee generally considers the Chief Executive Officer's recommendations when making decisions regarding the compensation of executive officers (other than the Chief Executive Officer). Pursuant to the Compensation Committee's charter, which is available on the Investors page of our website at *www.indaptusrx.com*, the Compensation Committee has the authority to retain or obtain the advice of compensation consultants, legal counsel and other advisors to assist in carrying out its responsibilities. The Compensation Committee did not engage the services of a compensation consultant in 2023.

The Compensation Committee may delegate its authority under its charter to one or more subcommittees as it deems appropriate from time to time. The Compensation Committee may also delegate to an officer the authority to grant equity awards to certain employees, as further described in its charter and subject to the terms of our equity plans.

The members of our Compensation Committee are Mr. Maddaluna and Mr. Hayes. Mr. Maddaluna serves as the Chairperson of the Compensation Committee. Each member of the Compensation Committee qualifies as an independent director under Nasdaq's heightened independence standards for members of a compensation committee and as a "non-employee director" as defined in Rule 16b-3 of the Exchange Act.

Nominating Committee

Our Nominating Committee's responsibilities include:

- identifying individuals qualified to become Board members;
- recommending to the Board the persons to be nominated for election as directors and to each Board committee;
- reviewing with the Chief Executive Officer and making recommendations to the Board with respect to our succession plans for the Chief Executive Officer and other executive officers;
- reviewing and making recommendations to the Board the composition and chairperson of each Board committee; and
- overseeing the evaluation of the Board and its committees.

The Nominating Committee charter is available on the Investors page of our website at *www.indaptusrx.com*. The members of our Nominating Committee are Ms. Karah and Mr. Maddaluna. Ms. Karah serves as the Chairperson of the Nominating Committee. The Nominating Committee has the authority to consult with outside advisors or retain search firms to assist in the search for qualified candidates or consider director candidates recommended by our stockholders.

Science and Technology Committee

Our Science and Technology Committee's responsibilities include:

- reviewing and advising on our drug development strategy, including the selection of therapeutic targets, the design and execution of clinical trials, and the regulatory pathway for approval;
- assessing our research pipeline and recommending changes or improvements to ensure a sustainable and diverse portfolio of drug candidates;
- evaluating our intellectual property strategy and overseeing the implementation of appropriate measures to protect our discoveries and inventions; and
- reviewing our manufacturing strategy and overseeing the quality controls put in place to meet regulatory requirements.

The members of our Science and Technology Committee are Dr. Gilbert, Mr. Maddaluna, Dr. Martell, and Mr. Newman. Mr. Newman serves as the Chairperson of the Science and Technology Committee.

Item 11. Executive Compensation.

Our named executive officers for 2024, which consist of our principal executive officer and the next two most-highly compensated executive officers who were serving as executive officers as of December 31, 2024 are:

- Jeffrey A. Meckler, Chief Executive Officer and Director;
- Walt. A. Linscott, Esq., Chief Operating Officer; and
- Roger J. Waltzman, M.D., Chief Medical Officer

Summary Compensation Table

The following table sets forth all of the compensation awarded to, earned by or paid to our named executive officers during 2024 and 2023.

Name and Principal Position	Year	Salary ($)	Bonus ($)	Stock Awards ($)	Option Awards[1] ($)	Non-equity Incentive Plan Compensation	All Other Compensation[2] ($)	Total ($)
Jeffrey A. Meckler,.....	2024	575,000	—	—	219,421	287,500	75,296	1,157,217
Chief Executive Office	2023	565,000	—	—	134,221	223,175	78,853	1,001,249
Walt A. Linscott, Esq.,.....	2024	475,000	—	—	182,156	237,500	75,744	970,400
Chief Operating Officer	2023	425,000	—	—	53,688	212,500	78,851	770,039
Roger Waltzman, M.D.....	2024	500,000	—	—	182,156	200,000	46,723	928,879
Chief Medical Officer	2023	196,742	20,000[3]	—	140,811	196,000	32,612	586,165

(1) The amounts reported do not reflect the amounts actually received by our named executive officers. Instead, in accordance with SEC rules, these amounts reflect the grant date fair value of stock options granted to our named executive officers during the fiscal years ended December 31, 2024 and 2023, as computed in accordance with Financial Accounting Standard Board Accounting Standards Codification Topic 718 for stock-based compensation transaction. As required by SEC rules, the amounts shown exclude the impact of estimated forfeitures related to service-based vesting conditions. Assumptions used in the calculation of these amounts are included in Note 5 to our consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2024, which was filed with the SEC on March 13, 2025. Our named executive officers will only realize compensation with regard to these options to the extent the trading price of our common stock is greater than the exercise price of such options.

(2) For 2024 and 2023, referenced amount is for the Company paid portion of medical and life insurance premiums, and Company 401(k) contributions.

(3) Amount represents a sign on bonus paid to Dr. Waltzman in 2023.

Narrative Description to Summary Compensation Table

Base Salaries

In general, base salaries for our named executive officers are initially established through arm's length negotiation at the time the executive is hired, taking into account such executive's qualifications, experience and prior salary. Base salaries of our named executive officers are approved and reviewed annually by our Compensation Committee or Board of Directors and adjustments to base salaries are based on the scope of an executive's responsibilities, individual contribution, prior experience and sustained performance. Decisions regarding salary increases may take into account an executive officer's current salary, equity ownership, and the amounts paid to an executive officer's peers inside our company by conducting an internal analysis, which compares the pay of an executive officer to other members of the management team. Base salaries are also reviewed in the case of promotions or other significant changes in responsibility. Base salaries are not automatically increased if the Board of Directors and Compensation Committee believe that other elements of the named executive officer's compensation are more appropriate in light of our stated objectives. This strategy is consistent with our intent of offering compensation that is both cost-effective, competitive and contingent on the achievement of performance objectives.

The actual base salaries paid to all of our named executive officers for 2024 are set forth in the "Summary Compensation Table" above.

In January 2024, our Compensation Committee approved base salary increases for 2024 for Mr. Meckler, Dr. Waltzman and Mr. Linscott to $575,000, $500,000 and $475,000, respectively. These base salary increases represented adjustments of approximately 1.8%, 2.0% and 11.8%, respectively. In January 2025, our Compensation Committee approved base salary increases for 2025 for Mr. Meckler, Dr. Waltzman and Mr. Linscott to $595,000, $518,000 and $491,000, respectively. These base salary increases represented adjustments of approximately 3.5%, 3.6% and 3.4%, respectively.

Annual Cash Performance Bonuses

Each named executive officer is also eligible for a performance bonus based upon the achievement of certain corporate performance goals and objectives approved by our Compensation Committee and Board of Directors.

Bonuses are set based on a percentage of the executive's base salary as of the end of the bonus year and are expected to be paid out in the first quarter of the following year. The target levels for 2024 executive bonuses were as follows: 50% for Mr. Meckler, 50% for Mr. Linscott and 40% for Dr. Waltzman. All final bonus payments to our named executive officers are determined by our Compensation Committee or our Board of Directors. The actual bonuses awarded in any year, if any, may be more or less than the target, depending on individual performance and the achievement of corporate objectives and may also vary based on other factors at the discretion of the Compensation Committee.

For 2024, the corporate performance objectives for our named executive officers were related to clinical milestones, research and development goals, business development opportunities, financing objectives and human capital management objectives. These performance objectives and areas of emphasis were used as a guide by the Compensation Committee and Board of Directors in determining overall corporate performance for these executives as they represented those areas in which they were expected to focus their efforts during the year. Both qualitative and quantitative guidelines were established for purposes of evaluating performance relating to these corporate objectives during 2024. Based on its review of our overall performance relative to our corporate objectives, the Compensation Committee determined that every goal was achieved or exceeded for annual bonus plan purposes.

The overall achievement level was then used to determine each named executive officer's bonus. The bonuses paid to our named executive officers for 2024 are set forth in the "Summary Compensation Table" above.

Equity Compensation

The goals of our long-term, equity-based incentive awards are to align the interests of our named executive officers and other employees, non-employee directors and consultants with the interests of our stockholders. Because vesting is based on continued employment, our equity-based incentives also encourage the retention of our named executive officers through the vesting period of the awards. In determining the size of the long-term equity incentives to be awarded to our named executive officers, we take into account a number of internal factors, such as the relative job scope, the value of existing long-term incentive awards, individual performance history, prior contributions to us and the size of prior grants.

To reward and retain our named executive officers in a manner that best aligns employees' interests with stockholders' interests, we use stock options as the primary incentive vehicles for long-term compensation. We believe that stock options are an effective tool for meeting our compensation goal of increasing long-term stockholder value by tying the value of the stock options to our future performance. Because employees are able to profit from stock options only if our stock price increases relative to the stock option's exercise price, we believe stock options provide meaningful incentives to employees to achieve increases in the value of our stock over time.

The exercise price of each stock option grant is the fair market value of our common stock on the grant date, as determined by our Board of Directors from time to time. Stock option awards granted to our named executive officers generally vest as to one-third of the total shares on the first anniversary of the grant date and thereafter the remaining shares vest in equal quarterly installments over the following 24 months. From time to time, our Compensation Committee may, however, determine that a different vesting schedule is appropriate.

In January 2024, Mr. Meckler, Mr. Linscott and Dr. Waltzman and were granted stock options to purchase 100,000 shares, 75,000 shares and 75,000 shares of our common stock, respectively. The stock options vest as to one-third of the total shares on January 22, 2025 and thereafter the remaining shares vest in equal quarterly installments over the following 24 months. In October 2024, Mr. Meckler, Mr. Linscott and Dr. Waltzman were granted stock options to purchase 75,000 shares of our common stock, each. The stock options are fully vest following 18 months from grant date.

We have had no program, plan or practice pertaining to the timing of stock option grants to named executive officers coinciding with the release of material non-public information. Stock options granted to our named executive officers may be subject to accelerated vesting in certain circumstance. For additional discussion, please see "Employment Agreements and Potential Payments on Employment Termination" below.

Other Elements of Compensation

Retirement Plans

Effective January 1, 2023, we maintain a 401(k) retirement savings plan that allows eligible employees to contribute a portion of their compensation, within limits prescribed by the Internal Revenue Code, on a pre-tax basis through contributions to the plan. Our named executive officers are eligible to participate in the 401(k) plan. We believe that providing a vehicle for tax-deferred retirement savings through our 401(k) plan adds to the overall desirability of our executive compensation package and further incentivizes our named executive officers in accordance with our compensation policies.

Employee Benefits and Perquisites

Our named executive officers are eligible to participate in our health and welfare plans. We pay for the health and welfare benefits of our named executive officers. We do not provide our named executive officers with any other significant perquisites or other personal benefits.

No Tax Gross-Ups

We do not make gross-up payments to cover our named executive officers' personal income taxes that may pertain to any of the compensation paid or provided by our company.

Outstanding Equity Awards at Fiscal Year-End

The following table sets forth information concerning outstanding option awards as of December 31, 2024, for each named executive officer:

Option Awards

Name	Grant Date	Number of Securities Underlying Unexercised Options Exercisable (#)	Number of Securities Underlying Unexercised Options Unexercisable (#)	Equity incentive plan awards: Number of securities underlying unexercised unearned options exercise price (#)	Option Exercise Price ($)	Option Expiration Date[1]
Jeffrey A. Meckler, Chief Executive Officer.....	04/10/17	1,500	—	—	425.6	04/10/27
	05/01/17	813	—	—	425.6	05/01/27
	12/11/17	4,750	—	—	536.0	12/11/27
	06/28/18	1,250	—	—	355.2	06/28/25
	04/04/19	1,562	—	—	611.2	04/04/26
	07/15/20	3,750	—	—	24.6	07/15/27
	08/04/21 [2]	375,000	—	—	8.87	8/4/2031
	01/26/22 [3]	183,333	16,667	—	4.90	01/26/32
	01/18/23 [4]	58,333	41,667	—	1.61	01/18/33
	01/22/24 [5]	—	100,000	—	1.74	01/22/34
	10/09/24 [6]	—	75,000	—	1.105	10/09/34
Walt A. Linscott, Esq., Chief Operating Officer ...	10/23/17	750	—	—	684.8	10/23/27
	12/11/17	1,750	—	—	684.8	12/11/27
	01/22/19	1,125	—	—	610.4	01/22/26
	09/13/19	2,500	—	—	72.0	09/13/26
	02/17/20	1,125	—	—	34.3	02/17/27
	09/16/20	1,250	—	—	25.7	09/16/27
	08/04/21 [2]	210,000	—	—	8.87	8/4/2031
	01/26/22 [3]	42,029	3,821	—	4.90	01/26/32
	01/18/23 [4]	23,333	16,667	—	1.61	01/18/33
	01/22/24 [5]	—	75,000	—	1.74	01/22/34
	10/09/24 [6]	—	75,000	—	1.105	10/09/34
Roger J. Waltzman, Chief Medical Officer						
	08/07/23 [7]	37,500	52,500	—	1.85	08/07/33
	01/22/24 [5]	—	75,000	—	1.74	01/22/34
	10/09/24 [6]	—	75,000	—	1.105	10/09/34

(1) The options have a seven-year term or ten-year term as noted in the table subject to earlier expiration upon termination.

(2) The options vest over a period of three years from August 4, 2021, 33.3% on the first anniversary of such date and 8.33% every three months thereafter, ending August 4, 2024.

(3) The options vest over a period of three years from January 26, 2022, 33.3% on the first anniversary of such date and 8.33% every three months thereafter, ending January 26, 2025.

(4) The options vest over a period of three years from January 18, 2023, 33.3% on the first anniversary of such date and 8.33% every three months thereafter, ending January 18, 2026.

(5) The options vest over a period of three years from January 22, 2024, 33.3% on the first anniversary of such date and 8.33% every three months thereafter, ending January 18, 2027.

(6) The options vest over a period of three years from October 9, 2024, 33.3% on the first anniversary of such date and 8.33% every three months thereafter, ending October 9, 2027.

(7) The options vest over a period of three years from August 7, 2023, 33.3% on the first anniversary of such date and 8.33% every three months thereafter, ending August 7, 2026.

Employment Agreements and Potential Payments on Employment Termination

Set forth below is a description of the employment agreements with our named executive officers and a summary of the benefits that would be payable upon termination of employment or in connection with a change in control to our named executive officers under their employment agreements with us.

Jeffrey A. Meckler

We have entered into an employment agreement with Jeffrey A. Meckler (the "Meckler Employment Agreement"), which superseded and replaced his employment agreement dated December 11, 2017 with Intec Pharma, Inc., a subsidiary of Intec Israel, to serve as our Chief Executive Officer. The Meckler Employment Agreement provides for an annual base salary, subject to review for an upward adjustment on at least an annual basis. Mr. Meckler is eligible to participate in an annual executive bonus plan, pursuant to which he may earn an annual target bonus of up to 50% of his base salary, based on the achievement of certain individual and company-wide objectives, which shall be established by our Board of Directors on an annual basis. The Board may, in its discretion, grant Mr. Meckler a bonus in excess of the target bonus if the performance criteria are exceeded or for such additional contributions that the Board may choose to recognize.

Upon termination of Mr. Meckler's employment by us without cause or Mr. Meckler's resignation for good reason, Mr. Meckler will be entitled to a severance benefit equal to (i) twelve months of his base salary as in effect prior to the termination date, payable in bi-monthly installments and (ii) an amount equal to Mr. Meckler's cost of continued health insurance coverage for twelve months. In addition, if Mr. Meckler is entitled to receive a bonus for the year of termination based on the achievement of pre-determined performance goals (and ignoring any continuation of employment requirements), Mr. Meckler (or his representatives) shall be entitled to receive such bonus on the same basis as the other participants in the bonus plan, except that the bonus amount shall be prorated based on the percentage of days Mr. Meckler was employed relative to the total number of days in the bonus earning period.

If Mr. Meckler's employment is terminated by us without cause or by Mr. Meckler for good reason during the one year period immediately following a change in control or six months before a change in control, then Mr. Meckler will be entitled to receive, (i) eighteen months of his base salary as in effect prior to the termination date, payable in bi-monthly installments, (ii) an amount equal to Mr. Meckler's cost of continued health insurance coverage for eighteen months, (iii) his target annual bonus for the year of termination, which shall be paid within 30 days of termination, and (iv) full accelerated vesting of all of outstanding equity incentive awards upon the later of the change in control or Mr. Meckler's termination of employment.

In the event that Mr. Meckler's employment terminates by reason of his death or disability, and Mr. Meckler is entitled to receive a bonus for the year of termination based on the achievement of pre-determined performance goals (and ignoring any continuation of employment requirements), Mr. Meckler (or his representatives) shall be entitled to receive such bonus on the same basis as the other participants in the bonus plan, except that the bonus amount shall be prorated based on the percentage of days Mr. Meckler was employed relative to the total number of days in the bonus earning period.

Walt A. Linscott, Esq.

We have entered into an employment agreement with Walt A. Linscott, Esq. (the "Linscott Employment Agreement"), which supersedes and replaces his employment agreement dated October 23, 2017 with Intec Pharma, Inc., a subsidiary of Intec Israel. The Linscott Employment Agreement provides for an annual base salary, subject to review for an upward

adjustment on at least an annual basis. Mr. Linscott is eligible to participate in an annual executive bonus plan, pursuant to which he may earn an annual target bonus of up to 50% of his base salary, based on the achievement of certain individual and company-wide objectives, which shall be established by the Company's Board of Directors on an annual basis. The Board may, in its discretion, grant Mr. Linscott a bonus in excess of the target bonus if the performance criteria are exceeded or for such additional contributions that the Board may choose to recognize.

Upon termination of Mr. Linscott's employment by us without cause or Mr. Linscott's resignation for good reason, Mr. Linscott will be entitled to a severance benefit equal to (i) twelve months of his base salary as in effect prior to the termination date, payable in bi-monthly installments and (ii) an amount equal to Mr. Linscott's cost of continued health insurance coverage for twelve months. In addition, if Mr. Linscott is entitled to receive a bonus for the year of termination based on the achievement of pre-determined performance goals (and ignoring any continuation of employment requirements), Mr. Linscott (or his representatives) shall be entitled to receive such bonus on the same basis as the other participants in the bonus plan, except that the bonus amount shall be prorated based on the percentage of days Mr. Linscott was employed relative to the total number of days in the bonus earning period.

If Mr. Linscott's employment is terminated by us without cause or by Mr. Linscott for good reason during the one year period immediately following a change in control or six months before a change in control, then Mr. Linscott will be entitled to receive, (i) eighteen months of his base salary as in effect prior to the termination date, payable in bi-monthly installments, (ii) an amount equal to Mr. Linscott's cost of continued health insurance coverage for eighteen months, (iii) his target annual bonus for the year of termination, which shall be paid within 30 days of termination, and (iv) full accelerated vesting of all of outstanding equity incentive awards upon the later of the change in control or Mr. Linscott's termination of employment.

In the event that Mr. Linscott's employment terminates by reason of his death or disability, and Mr. Linscott is entitled to receive a bonus for the year of termination based on the achievement of pre-determined performance goals (and ignoring any continuation of employment requirements), Mr. Linscott (or his representatives) shall be entitled to receive such bonus on the same basis as the other participants in the bonus plan, except that the bonus amount shall be prorated based on the percentage of days Mr. Linscott was employed relative to the total number of days in the bonus earning period.

Roger J. Waltzman

We have entered into an employment agreement with Roger J. Waltzman (the "Waltzman Employment Agreement"). The Waltzman Employment Agreement provides for an annual base salary, subject to review for an upward adjustment on at least an annual basis. Dr. Waltzman is eligible to participate in an annual executive bonus plan, pursuant to which he may earn an annual target bonus of up to 40% of his base salary, based on the achievement of certain individual and company-wide objectives, which shall be established by the Company's Board of Directors on an annual basis. The Board may, in its discretion, grant Dr. Waltzman a bonus in excess of the target bonus if the performance criteria are exceeded or for such additional contributions that the Board may choose to recognize.

Upon termination of Dr. Waltzman's employment by us without cause or Dr. Waltzman's resignation for good reason, Dr. Waltzman will be entitled to a severance benefit equal to (i) twelve months of his base salary as in effect prior to the termination date, payable in bi-monthly installments and (ii) an amount equal to Dr. Waltzman's cost of continued health insurance coverage for twelve months. In addition, if Dr. Waltzman is entitled to receive a bonus for the year of termination based on the achievement of pre-determined performance goals (and ignoring any continuation of employment requirements), Dr. Waltzman (or his representatives) shall be entitled to receive such bonus on the same basis as the other participants in the bonus plan, except that the bonus amount shall be prorated based on the percentage of days Dr. Waltzman was employed relative to the total number of days in the bonus earning period.

If Dr. Waltzman's employment is terminated by us without cause or by Dr. Waltzman for good reason during the one year period immediately following a change in control or six months before a change in control, then Dr. Waltzman will be entitled to receive, (i) twelve months of his base salary as in effect prior to the termination date, payable in bi-monthly installments, (ii) an amount equal to Dr. Waltzman's cost of continued health insurance coverage for eighteen months, (iii) his target annual bonus for the year of termination, which shall be paid within 30 days of termination, and (iv) full accelerated vesting of all of outstanding equity incentive awards upon the later of the change in control or Dr. Waltzman's termination of employment.

In the event that Dr. Waltzman's employment terminates by reason of his death or disability, and Dr. Waltzman is entitled to receive a bonus for the year of termination based on the achievement of pre-determined performance goals (and ignoring any continuation of employment requirements), Dr. Waltzman (or his representatives) shall be entitled to receive such bonus on the same basis as the other participants in the bonus plan, except that the bonus amount shall be prorated based on the percentage of days Dr. Waltzman was employed relative to the total number of days in the bonus earning period.

Securities Authorized for Issuance under Equity Compensation Plans

The following table gives information as of December 31, 2024 about shares of our common stock that may be issued upon the exercise of options under the Indaptus Therapeutics, Inc. 2021 Stock Incentive Plan (the "2021 Plan"):

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights[1]	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in first column)
Equity compensation plan approved by security holders[2]	2,887,822	$ 8.06	103,608
Equity compensation plans not approved by security holders	—	—	—

(1) Represents stock options outstanding under the 2021 Plan.

(2) Our 2021 Plan has an evergreen provision that allows for an annual increase on each January 1 from January 1, 2025 and ending on and including January 1, 2029, equal to the lesser of (A) 5% of the aggregate number of shares of our shares of common stock outstanding on the final day of the immediately preceding calendar year or (B) such smaller number of shares as is determined by our Board of Directors.

Pay Versus Performance Table

The following table sets forth information concerning the compensation of our named executive officers, or NEOs, the compensation actually paid to our NEOs, as determined under SEC rules (and described below), our total shareholder return and our net loss, in each case for each of the fiscal years ended December 31, 2022, 2023 and 2024:

(a) Year	(b) Summary Compensation Table Total for PEO ($)	(c) Compensation Actually Paid to PEO ($)[1]	(d) Average Summary Compensation Table Total for non-PEO NEOs ($)	(e) Average Compensation Actually Paid to Non-PEO NEOs ($)[1]	(f) Value of Initial Fixed $100 Investment Based on: Total Shareholder Return ($)	(h) Net Loss ($)
2024	$ 1,157,217	$ 1,029,281	$ 949,640	$ 845,621	$ 48	$ (15,022,027)
2023	$ 1,001,249	$ 1,122,094	$ 744,039	$ 799,786	$ 121	$ (15,423,471)
2022	$ 1,680,532	$ (38,385)	$ 1,062,955	$ 500,074	$ 41	$ (14,322,798)

(1) Amounts represent compensation actually paid to our PEO and the average compensation actually paid to our remaining NEOs for the relevant fiscal year, as determined under SEC rules, which includes the individuals indicated in the table below for each fiscal year:

Year	PEO	Non-PEO NEOs
2024	Jeffrey A. Meckler	Walt A. Linscott, Esq. and Roger Waltzman M.D.
2023	Jeffrey A. Meckler	Walt A. Linscott, Esq. and Michael J. Newman, Ph.D.
2022	Jeffrey A. Meckler	Walt A. Linscott, Esq. and Boyan Litchev, M.D.

The amounts reported in the "Compensation Actually Paid to PEO" and "Average Compensation Actually Paid to Non-PEO NEOs" columns do not reflect the actual compensation paid to or realized by our PEO or our non-PEO NEOs during each applicable year. The calculation of compensation actually paid for purposes of this table includes point-in-time fair values of stock awards and these values will fluctuate based on our stock price and various accounting valuation assumptions. See the Summary Compensation Table for certain other compensation of our PEO and our non-PEO NEOs for each applicable fiscal year.

Compensation actually paid to our NEOs represents the "Total" compensation reported in the Summary Compensation Table for the applicable fiscal year, as adjusted as follows:

	2024	
Adjustments	**PEO**	**Average non-PEO NEOs**
Deduction for Amounts Reported under the "Stock Awards" and "Option Awards" Columns in the Summary Compensation Table for Applicable FY	$ (219,421)	$ (182,156)
Increase based on ASC 718 Fair Value of Awards Granted during Applicable FY that Remain Unvested as of Applicable FY End, determined as of Applicable FY End	123,369	106,209
Decrease for Awards Granted during Prior FY that were Outstanding and Unvested as of Applicable FY End, determined based on change in ASC 718 Fair Value from Prior FY End to Applicable FY End	(46,684)	(29,455)
Increase for Awards Granted during Prior FY that Vested During Applicable FY, determined based on change in ASC 718 Fair Value from Prior FY End to Vesting Date	14,800	1,383
TOTAL ADJUSTMENTS	**$ (127,936)**	**$ (104,019)**

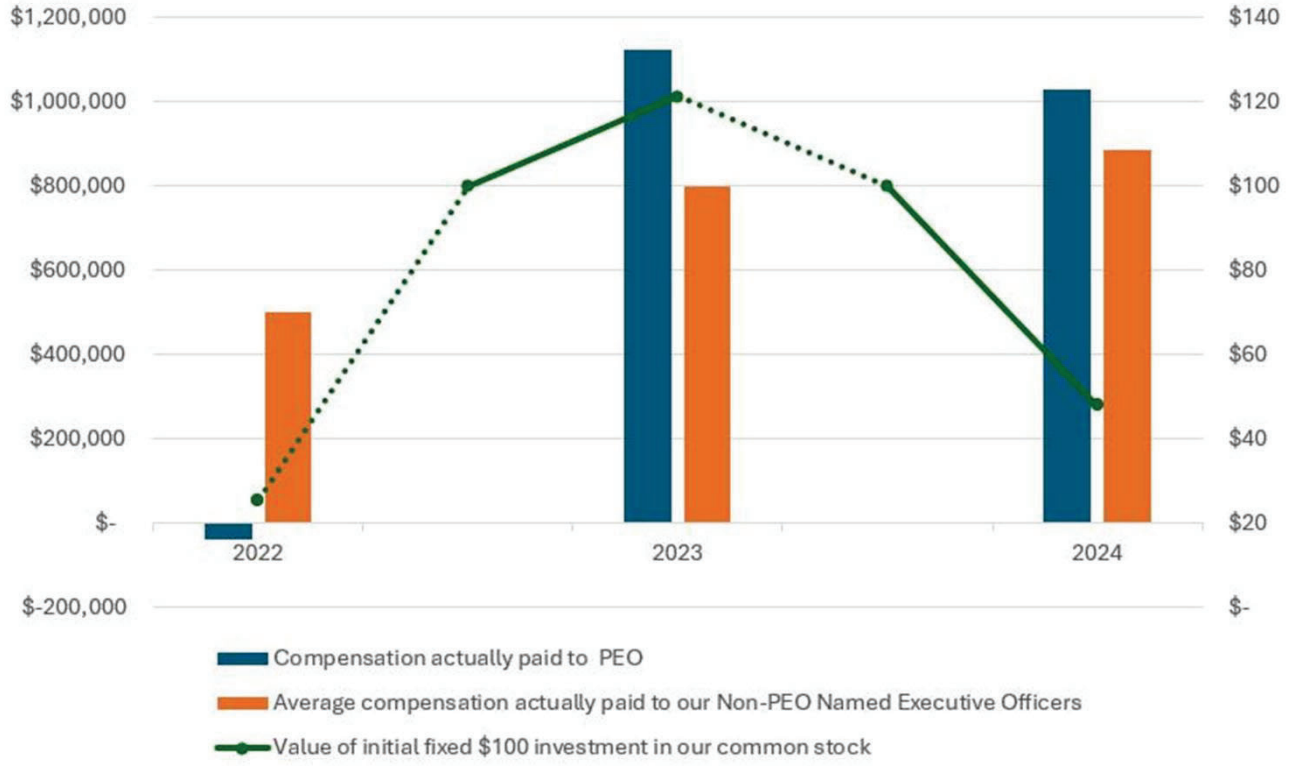
Fair value or change in fair value, as applicable, of equity awards in the "Compensation Actually Paid" columns was determined by reference to a Black Scholes value as of the applicable year-end or vesting date(s), determined based on the same methodology as used to determine grant date fair value but using the closing stock price on the applicable revaluation date as the current market price and with an estimated expected life using the simplified method, and in all cases based on volatility and risk free rates determined as of the revaluation date based on the expected life period and based on an expected dividend rate of 0%. For additional information on the assumptions used to calculate the valuation of the awards, see Note 5 to our consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2024, which was filed with the SEC on March 13, 2025.

Narrative Disclosure to Pay Versus Performance Table

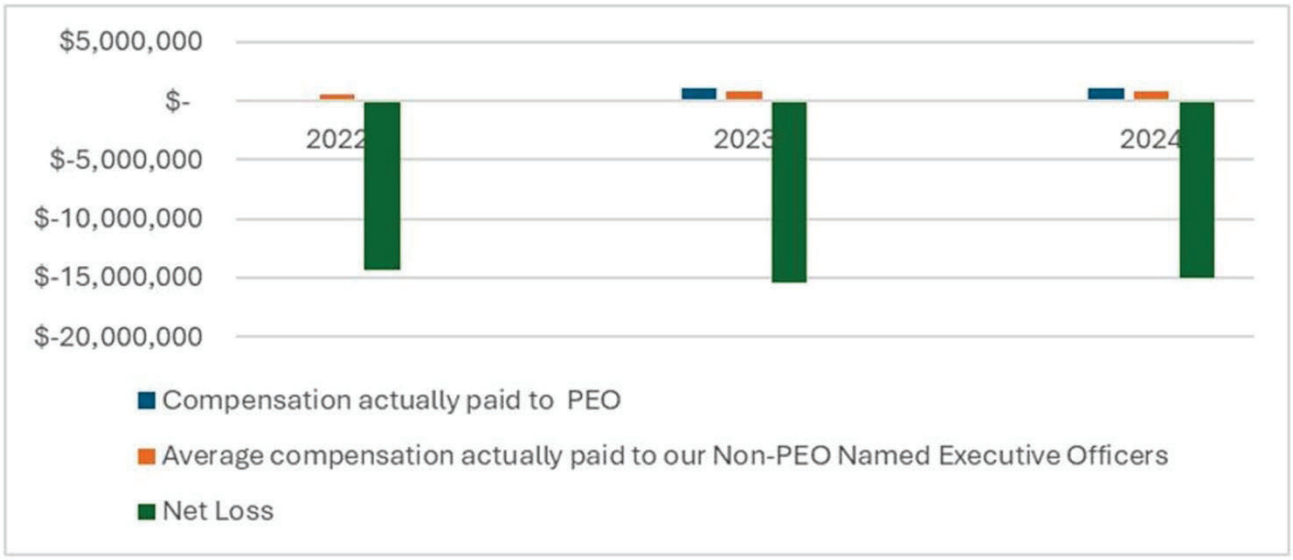
Relationship Between Financial Performance Measures

The graph below compares the compensation actually paid to our PEO and the average of the compensation actually paid to our remaining NEOs, with our cumulative TSR for the fiscal years ended December 31, 2022, 2023 and 2024.

TSR amounts reported in the graph assume an initial fixed investment of $100. We do not pay dividends.



The graph below compares the compensation actually paid to our PEO and the average of the compensation actually paid to our remaining NEOs, with our net loss for the fiscal years ended December 31, 2022, 2023 and 2024.



Director Compensation

The following table provides certain information concerning the compensation for services rendered in all capacities by each non-employee director serving on our Board during the year ended December 31, 2024, other than Mr. Meckler, our Chief Executive Officer who did not receive additional compensation for their service as a director and whose compensation is set forth in the Summary Compensation Table under the section entitled Executive Compensation above. Dr. Newman, our Chief Scientific Officer, is also an employee and executive officer, who did not receive additional compensation for his service as a director. Dr. Newman is not one of our named executive officers for 2024 and so he does not appear in the Summary Compensation Table. Because Dr. Newman is an employee and an executive officer, he is not required to be included in the table below.

Name	Fees earned ($)	Stock awards ($)	Option awards ($)[1]	All other compensation ($)	Total ($)
Roger J. Pomerantz	150,000	—	66,000	—	216,000
Hila Karah	65,500	—	27,500	—	93,000
Anthony J. Maddaluna	69,000	—	27,500	—	96,500
William B. Hayes	71,000	—	27,500	—	98,500
Robert E. Martell	61,500	—	27,500	—	89,000
Mark Gilbert	54,000	—	27,500	—	81,500

(1) The amounts reported do not reflect the amounts actually received by our non-employee directors. Instead, in accordance with SEC rules, these amounts reflect the grant date fair value of stock options granted to our non-employee directors during the fiscal year ended December 31, 2024, as computed in accordance with Financial Accounting Standard Board Accounting Standards Codification Topic 718 for stock-based compensation transaction. As required by SEC rules, the amounts shown exclude the impact of estimated forfeitures related to service-based vesting conditions. Assumptions used in the calculation of these amounts are included in Note 5 to our consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2024, which was filed with the SEC on March 13, 2025. Our non-employee directors who have received options will only realize compensation with regard to these options to the extent the trading price of our common stock is greater than the exercise price of such options. As of December 31, 2024, our non-employee directors held the following numbers of stock options: Dr. Pomerantz, 182,000 stock options; Ms. Karah 53,781 stock options, Mr. Maddaluna 53,500 stock options, Mr. Hayes 53,500 stock options, Mr. Martell 32,500 stock options, and Dr. Gilbert 58,750 stock options.

Pursuant to our director compensation policy, the annual retainer for non-employee directors is $50,000 and the annual retainer for the chair of the Board of Directors is $150,000. Annual retainers for committee membership are as follows:

Audit committee chairperson	$	15,000
Audit committee member	$	7,500
Compensation committee chairperson	$	10,000
Compensation committee member	$	6,000
Nominating committee chairperson	$	8,000
Nominating committee member	$	5,000
Scientific and technology committee chairperson	$	8,000
Scientific and technology committee member	$	4,000

These fees are payable in advance in four equal quarterly installments during the first week of each quarter, provided that the amount of such payment will be prorated for any portion of such quarter that a director is not serving on our Board of Directors, on such committee or in such position. Non-employee directors are also reimbursed for reasonable out-of-pocket business expenses incurred in connection with attending meetings of the Board of Directors and any committee of the Board of Directors on which they serve and in connection with other business related to the Board of Directors. Directors may also be reimbursed for reasonable out-of-pocket business expenses authorized by the Board of Directors or a committee that are incurred in connection with attending conferences or meetings with management in accordance with a travel policy, as may be in effect from time to time.

In March 2023, the Board amended our director compensation policy to provide that, on the date an individual is first elected or appointed as a non-employee director, such individual will receive a grant of 25,000 stock options, and that, on the date of each annual meeting of stockholders, commencing with the annual meeting of stockholders for 2023, each non-employee director (other than the board chair) will receive a grant of 12,500 stock options and the board chair will receive 30,000 stock options. The initial stock options vest in over three years from the grant date in equal quarterly installments, subject to continued service on the Board and the options shall also vest in full immediately upon a director's death, disability or a change of control. The annual stock options vest in full on the first anniversary of the grant date, subject to continued service on the Board and the options shall also vest in full immediately upon a director's death, disability or a change of control.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The following table sets forth certain information with respect to holdings of our common stock by (i) stockholders who beneficially owned more than 5% of the outstanding shares of our common stock, and (ii) each of our directors (which includes all nominees), each of our named executive officers and all directors and executive officers as a group as of March 12, 2025, unless otherwise indicated. The number of shares beneficially owned by each stockholder is determined under rules issued by the SEC. Under these rules, beneficial ownership includes any shares as to which a person has sole or shared voting power or investment power. Applicable percentage ownership is based on 14,429,244 shares of common stock outstanding as of March 12, 2025. In computing the number of shares beneficially owned by a person and the percentage ownership of that person, shares of common stock subject to options, or other rights held by such person that are currently exercisable or will become exercisable within 60 days of March 12, 2025 are considered outstanding, although these shares are not considered outstanding for purposes of computing the percentage ownership of any other person.

Unless otherwise indicated, the address of each beneficial owner listed below is 3 Columbus Circle, 15th Floor, New York, NY 10019. We believe, based on information provided to us, that each of the stockholders listed below has sole voting and investment power with respect to the shares beneficially owned by the stockholder unless noted otherwise, subject to community property laws where applicable.

Name of Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned
Persons or entities holding 5% or more our outstanding common stock		
Glen R. Anderson	1,190,400[1]	8.2%
Matthew Joseph Nachtrab Revocable Trust dtd 12/15/2014	2,142,462[2]	13.8%
Yehuda Shimoni	1,644,300[3]	10.8%
Thomas Mollick	2,438,598[4]	15.7%
Named executive officers and directors		
Michael J. Newman, Ph.D.	1,752,164[5]	11.8%
Jeffrey A. Meckler	1,035,636[6]	6.8%
Roger Waltzman, M.D.	83,750[7]	*
Walt A. Linscott, Esq.	325,750[8]	2.2%
Hila Karah	41,281[9]	*
Anthony J. Maddaluna	41,670[10]	*
William B. Hayes	41,000[11]	*
Dr. Roger J. Pomerantz	153,000[12]	1.1%
Mark Gilbert, M.D.	46,250[13]	*
Robert E. Martell, M.D., Ph.D.	20,000[14]	*
All executive officers and directors as a group (11 persons)	3,690,334[15]	22.3%

* Less than one percent.

(1) Based solely upon a Schedule 13G/A filed with the SEC on August 17, 2023. 1,076,482 shares are held by the Anderson Family Trust U/A/D January 7, 2017 in which Glen R. Anderson is a trustee of the Anderson Family Trust and shares voting and dispositive control with his spouse, and 113,918 shares are held by Mr. Anderson over which he has sole voting and dispositive power. The business address of Mr. Anderson is 101 South 200 East, Suite 700, Salt Lake City, UT 84111.

(2) Consists of (i) 1,071,231 shares of common stock, and (ii) 1,071,231 shares of common stock issuable upon exercise of warrants which are subject to either a 4.99% or 9.99% beneficial ownership limitation. The amounts and percentages in the table do not give effect to such beneficial ownership limitation.

(3) Consists of (i) 865,158 shares of common stock, and (ii) 779,142 shares of common stock issuable upon exercise of warrants which are subject to either a 4.99% or 9.99% beneficial ownership limitation. The amounts and percentages in the table do not give effect to such beneficial ownership limitation.

(4) Consists of (i) 1,212,837 shares of common stock, and (ii) 1,135,761 shares of common stock issuable upon exercise of warrants which are subject to either a 4.99% or 9.99% beneficial ownership limitation. The amounts and percentages in the table do not give effect to such beneficial ownership limitation.

(5) Consists of (i) 1,341,524 shares of common stock held by the Michael J. Newman Trust, dated January 21, 2008, Michael J. Newman, Trustee; (ii) 26,832 shares of common stock held by Janet Lee Harris, Trustee of the Janet Harris Living Trust, executed on March 25, 2009. Ms. Harris is the spouse of Dr. Newman, and as such, Dr. Newman is deemed to beneficially own such shares; and (iii) 383,808 shares of common stock issuable upon exercise of outstanding options, of which 7,208 will vest within 60 days of days of March 12, 2025.

(6) Consists of (i) 202,859 shares of common stock, (ii) 127,485 shares of common stock issuable upon exercise of warrants, and (ii) 705,292 shares of common stock issuable upon exercise of outstanding options, of which 16,667 will vest within 60 days of days of March 12, 2025.

(7) Consists of 83,750 shares of common stock issuable upon exercise of outstanding options, of which 13,750 will vest within 60 days of March 12, 2025.

(8) Consists of (i) 150 shares of common stock and (ii) 325,750 shares of common stock issuable upon exercise of outstanding options, of which 9,583 will vest within 60 days of March 12, 2025.

(9) Consists of 41,281 shares of common stock issuable upon exercise of outstanding options.

(10) Consists of (i) 670 shares of common stock and (ii) 41,000 shares of common stock issuable upon exercise of outstanding options.

(11) Consists of 41,000 shares of common stock issuable upon exercise of outstanding options.

(12) Consists of 154,000 shares of common stock issuable upon exercise of outstanding options.

(13) Consists of 46,250 shares of common stock issuable upon exercise of outstanding options.

(14) Consists of 20,000 shares of common stock issuable upon exercise of outstanding options.

(15) Consists of (i) 1,572,035 shares of common stock, (ii) 127,485 shares of common stock issuable upon exercise of warrants, and (ii) 1,957,242 shares of common stock issuable upon exercise of outstanding options, of which 53,875 will vest within 60 days of days of March 12, 2025.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

Policies and Procedures for Related Person Transactions

In accordance with our audit committee charter, the Audit Committee is required to approve related party transactions. In general, the Audit Committee will review any proposed transaction that has been identified as a related person transaction under Item 404 of Regulation S-K, which means a transaction, arrangement or relationship in which we and any related person (as defined below) are participants in which the amount involved exceeds the lesser of $120,000 or one percent of the average of the Company's total assets at fiscal year-end for the last two completed fiscal years, and in which any related person had, has or will have a direct or indirect material interest. A "related person" includes (i) a director, director nominee or executive officer of the Company, (ii) any immediate family member of the foregoing, or (iii) a security holder known to be a beneficial owner of more than 5% of any class of our voting securities.

Other than the compensation agreements and other arrangements described under "Executive Compensation" and the transactions described below, since January 1, 2022, there has not been and there is not currently proposed, any transaction or series of similar transactions to which we were, or will be, a participant in which the amount involved exceeded, or will exceed, $120,000 (or, if less, 1% of the average of our total assets at December 31, 2023 and 2022, as applicable) and in which any related person, had, or will have, a direct or indirect material interest.

Participation in 2024 Financings

August 2024 Financing

On August 8, 2024, we completed a registered direct offering, pursuant to which we sold and issued to certain investors 1,643,837 shares of our common stock. In addition, in a concurrent private placement, we issued to the investors unregistered warrants to purchase 1,643,837 shares of our common stock. The warrants are immediately exercisable at an exercise price of $1.70 per share and expire five years from the date of issuance. The combined purchase price for one share of common stock and one warrant was $1.825, resulting in gross proceeds of approximately $3.0 million, before deducting placement agent and other offering expenses in the amount of approximately $0.5 million. One of the purchasers was Jeffrey Meckler, our Chief Executive Officer and director, who purchased 84,932 shares of common stock and warrants to purchase 84,932 shares of common stock (at the same price and upon the same terms as the other purchasers.

November 2024 Financing

On November 25, 2024, we completed a registered direct offering, pursuant to which we sold and issued to certain investors 1,817,017 shares of our common stock. In addition, in a concurrent private placement, we issued to the investors unregistered warrants to purchase 1,817,017 shares of our common stock. The warrants are immediately exercisable at an exercise price of $1.05 per share and expire five years from the date of issuance. The combined purchase price for one share of common stock and one warrant was $1.175, resulting in gross proceeds of approximately $2.13 million, before deducting placement agent and other offering expenses in the amount of approximately $0.345 million. One of the purchasers was Jeffrey Meckler, our Chief Executive Officer and director, who purchased 42,553 shares of common stock and warrants to purchase 42,553 shares of common stock (at the same price and upon the same terms as the other purchasers.

Director and Officer Indemnification and Insurance

We have entered into indemnification agreements with each of our directors and executive officers. These agreements, among other things, require us or will require us to indemnify each director and executive officer to the fullest extent permitted by Delaware law, including indemnification of expenses such as attorneys' fees, judgments, fines and settlement amounts incurred by the director or executive officer in any action or proceeding, including any action or proceeding by or in right of us, arising out of the person's services as a director or executive officer.

We also maintain an insurance policy that insures our directors and executive officers against certain liabilities, including liabilities arising under applicable securities laws.

Item 14. Principal Accountant Fees and Services.

The following table summarizes the fees of Haskell & White LLP, our independent registered public accounting firm, billed to us for their professional services for each of the last two fiscal years:

Fee Category	2024	2023
Audit Fees	$ 221,000	$ 210,000
Audit Related Fees	—	—
Tax Fees	—	—
All Other Fees	—	—
Total Fees	$ 221,000	$ 210,000

Audit Fees

Audit fees for the fiscal years ended December 31, 2024 and 2023 include fees for professional services rendered for the audit and quarterly review of our financial statements included in our annual report on Form 10-K and quarterly reports on Form 10-Q filed with the SEC, and services provided in connection with SEC filings, including consents and comfort letters.

Audit Committee Pre-Approval Policy and Procedures

On a periodic basis, the Audit Committee reviews and generally pre-approves the services (and related fee levels or budgeted amounts) that may be provided by Haskell & White LLP without first obtaining specific pre-approval from the Audit Committee. The Audit Committee may revise the list of general pre-approved services from time to time, based on subsequent determinations. Our Audit Committee pre-approves all audit, review, and attest services proposed to be performed by our independent auditor that have not been generally pre-approved, including the scope of services to be performed and the compensation to be paid to the auditor, prior to commencement of such engagements of the independent auditor. Our Audit Committee has authorized all auditing and non-auditing services provided by Haskell & White LLP during the fiscal year ended December 31, 2024 and the fees paid for such services.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

(a)(1) Financial Statements.

The financial statements required by this item are listed in Item 8. "Financial Statements and Supplementary Data" in this Annual Report.

(a)(2) Financial Statement Schedules.

The financial statement schedules are omitted because they are either not applicable or the information required is presented in the financial statements and notes thereto under Item 8. "Financial Statements and Supplementary Data" in this Annual Report.

(a)(3) Exhibits.

The following is a list of exhibits filed as part of this Annual Report.

Exhibit Index

Exhibit No.	Exhibit Description
2.1++	Agreement and Plan of Merger and Reorganization, dated as of March 15, 2021, by and among Intec Pharma Ltd., Intec Parent, Inc., Dillon Merger Sub Inc., Domestication Merger Sub Ltd., and Decoy Biosystems, Inc. (incorporated herein by reference to Exhibit 2.1 to Intec Israel's Report on Form 8-K filed with the SEC on March 15, 2021)
2.2	Agreement and Plan of Merger, dated as of April 27, 2021, by and among Intec Pharma Ltd., Intec Parent, Inc. and Domestication Merger Sub Ltd. (incorporated herein by reference to Exhibit 2.1 to Intec Israel's Report on Form 8-K filed with the SEC on April 30, 2021)
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	Amended and Restated Bylaws of Indaptus Therapeutics, Inc., dated as of January 22, 2024 (incorporated herein by reference to Exhibit 3.1 of the Company's Current Report on Form 8-K filed with the SEC on January 23, 2024)
3.3	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 to the Company's Current Report on Form 8-K filed with the SEC on August 6, 2021)
4.1	Description of Securities Registered under Section 12 (incorporated herein by reference to Exhibit 4.1 of the Company's Annual Report on Form 10-K filed with the SEC on March 21, 2021)
4.2	Form of Ordinary Share Purchase Warrant of Intec Parent, Inc. (incorporated herein by reference to Exhibit 10.2 to Intec Israel's Current Report on Form 8-K filed with the SEC on May 6, 2020)
4.3	Form of Series A Common Stock Purchase Warrant of Intec Parent, Inc. (incorporated herein by reference to Exhibit 10.3 to Indaptus' Current Report on Form 8-K filed with the SEC on July 29, 2021)
10.1+	Indaptus Therapeutics, Inc. Amended and Restated 2021 Stock Incentive Plan (incorporated herein by reference to Exhibit 10.1 to Indaptus' Current Report on Form 8-K filed with the SEC on June 7, 2024)
10.2+	Form of Option Award Agreement (incorporated herein by reference to Exhibit 10.2 of the Company's Annual Report on Form 10-K filed with the SEC on March 13, 2024)
10.3+	Form of Indemnification Agreement (incorporated herein by reference to Exhibit 10.5 of the Company's Current Report on Form 8-K filed with the SEC on August 6, 2021)
10.4+	Employment Agreement between Jeffrey Meckler and Indaptus Therapeutics, Inc., effective as of August 4, 2021 (incorporated herein by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on August 6, 2021)

Exhibit No.	Exhibit Description
10.5+	Employment Agreement between Michael J. Newman, Ph.D. and Indaptus Therapeutics, Inc., effective as of August 4, 2021 (incorporated herein by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K filed with the SEC on August 6, 2021)
10.6+	Employment Agreement between Walt Linscott and Indaptus Therapeutics, Inc., effective as of August 4, 2021 (incorporated herein by reference to Exhibit 10.3 of the Company's Current Report on Form 8-K filed with the SEC on August 6, 2021)
10.7+	Employment Agreement between Nir Sassi and Indaptus Therapeutics, Inc., effective as of January 1, 2022 (incorporated herein by reference to Exhibit 10.6 of the Company's Annual Report on Form 10-K filed with the SEC on March 21, 2022)
10.8+	Employment Agreement between Roger J. Waltzman and Indaptus Therapeutics, Inc., effective as of August 7, 2023 (incorporated herein by reference to Exhibit 10.8 of the Company's Annual Report on Form 10-K filed with the SEC on March 13, 2024)
10.9+	Indaptus Therapeutics, Inc. Non-Employee Director Compensation Program (Effective April 2, 2023) (incorporated herein by reference to Exhibit 10.1 of the Company's Quarterly Report on Form 10-Q filed with the SEC on May 11, 2023)
10.10	Form of Securities Purchase Agreement, dated July 23, 2021, between Intec Parent, Inc. and each purchaser identified on the signature pages hereto (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on July 29, 2021)
10.11	Form of Registration Rights Agreement, dated July 23, 2021, between Intec Parent, Inc. and each purchaser identified on the signature pages hereto (incorporated herein by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K filed with the SEC on July 29, 2021)
10.12	At the Market Offering Agreement, dated June 1, 2022, by and between Indaptus Therapeutics, Inc. and H.C. Wainwright & Co., LLC (incorporated by reference to Exhibit 1.2 of the Company's Registration Statement on Form S-3 filed on September 1, 2022)
10.13	Placement Agent Agreement, dated as of July 23, 2024, by and between Indaptus Therapeutics, Inc. and Paulson Investment Company, LLC (incorporated by reference to Exhibit 1.1 to the Company's Current Report on Form 8-K filed on August 8, 2024)
10.14	Form of Securities Purchase Agreement (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on August 8, 2024)
10.15	Form of Warrant (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on August 8, 2024)
10.16	Placement Agent Agreement, dated as of October 29, 2024, by and between Indaptus Therapeutics, Inc. and Paulson Investment Company, LLC, and Amendment No. 1 to Placement Agent Agreement, dated as of November 20 2024 (incorporated by reference to Exhibit 1.1 to the Company's Current Report on Form 8-K filed on November 22, 2024)
10.17	Form of Securities Purchase Agreement (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on November 22, 2024)
10.18	Form of Warrant (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on November 22, 2024)
10.19	Form of Placement Agent Warrant (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed on November 22, 2024)
10.20	Placement Agent Agreement, dated as of January 12, 2025, by and between Indaptus Therapeutics, Inc. and Paulson Investment Company, LLC as amended by the First Amendment to the Placement Agent Agreement, dated as of December 30, 2024 (incorporated by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K filed on January 14, 2025)
10.21	Form of Securities Purchase Agreement (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on January 14, 2025)
10.22	Form of Warrant (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on January 14, 2025)
10.23	Form of Placement Agent Warrant (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed January 14, 2025)

Exhibit No.	Exhibit Description
10.24	Form of Standby Equity Purchase Agreement dated as of February 12, 2025 by and between the Company and YA II PN Ltd. (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed February 12, 2025)
19.1*	Insider Trading Policy
21.1	List of Subsidiaries (incorporated herein by reference to Exhibit 21.1 to the Company's Annual Report on Form 10-K filed with the SEC on March 21, 2022)
23.1*	Consent of Haskell & White LLP, independent registered public accounting firm
31.1*	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a)under the Securities Exchange Act of 1934, as amended, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
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
97.1	Indaptus Therapeutics, Inc. Policy for Recovery of Erroneously Awarded Compensation (incorporated herein by reference to Exhibit 97.1 of the Company's Annual Report on Form 10-K filed with the SEC on March 13, 2024)
101.INS*	Inline XBRL Instance Document (the Instance Document does not appear in the interactive data file because its XBRL tags are embedded within the Inline XBRL 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 and contained in Exhibits 101)

* Filed herewith

\# Furnished herewith

\+ Indicates management contract or compensatory plan.

++ The schedules to the agreement have been omitted pursuant to Item 601(a)(5) of Regulation S-K. A copy of any omitted schedule will be furnished to the SEC upon request.

Item 16. Form 10-K Summary

None.

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: March 13, 2025

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

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints Jeffrey Meckler and Nir Sassi, and each of them acting individually, as his attorney-in-fact, each with full power of substitution, for him in any and all capacities, to sign any and all amendments to this Report on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming our signatures as they may be signed by our said attorney to any and all amendments to said Report.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Name	Title	Date
/s/ Jeffrey A. Meckler Jeffrey A. Meckler	Chief Executive Officer and Director (Principal Executive Officer)	March 13, 2025
/s/ Nir Sassi Nir Sassi	Chief Financial Officer (Principal Financial and Accounting Officer)	March 13, 2025
/s/ Michal J. Newman, Ph.D. Michael J. Newman, Ph.D.	Chief Scientific Officer and Director	March 13, 2025
/s/ Roger J. Pomerantz, M.D. Dr. Roger J. Pomerantz, M.D.	Chairman of the Board of Directors	March 13, 2025
/s/ Hila Karah Hila Karah	Director	March 13, 2025
/s/ Anthony J. Maddaluna Anthony J. Maddaluna	Director	March 13, 2025
/s/ Mark J. Gilbert Mark J. Gilbert	Director	March 13, 2025
/s/ William B. Hayes William B. Hayes	Director	March 13, 2025
/s/ Robert E. Martell, M.D., Ph.D. Robert E. Martell, M.D., Ph.D.	Director	March 13, 2025

Exhibit 19.1

INDAPTUS THERAPEUTICS, INC.

INSIDER TRADING POLICY

This Insider Trading Policy (the "**Policy**") sets forth the policy for directors, officers, employees, consultants and contractors of Indaptus Therapeutics, Inc. and its subsidiaries (the "**Company**") with respect to transactions in the Company's securities or securities of certain other publicly traded companies while in possession of confidential information.

Applicability of Policy

This Policy applies to all transactions in the Company's Securities, including the purchase, sale or other disposition of ordinary shares, preferred shares, restricted shares or units, options and warrants for ordinary shares, bonds and any other securities the Company may issue from time to time, such as convertible debentures and other derivative securities relating to the Company's shares, whether or not issued by the Company, such as exchange-traded options (the "**Company's Securities**"). It applies to all directors, officers, employees, consultants and contractors of the Company as well as members of their immediate families, members of their households and corporations, trusts or other entities under their control (collectively, "**Insiders**"). Directors, officers, employees, consultants and contractors of the Company are responsible for ensuring that members of their immediate families and members of their households comply with this Policy. This Policy also applies to any person who receives Material Non-Public Information (as defined below) from any Insider.

General Policy

It is against Company policy for any Insider to make an unauthorized disclosure of any nonpublic information acquired in the work-place or as a result of their position with the Company. It is also against Company policy for any Insider to misuse Material Nonpublic Information in securities trading. The Company has established procedures for releasing material information in a manner that is designed to achieve broad public dissemination of the information to the public immediately upon its release. As a director, officer, employee, consultant or contractor of the Company, you may not, therefore, disclose Material Nonpublic information to anyone outside the Company, including family members and friends. You also may not discuss the Company or its business in an internet "chat room" or similar internet-based forum.

Specific Policies

1. Trading on Material Nonpublic Information

No Insider shall engage in any transaction involving a purchase or sale of the Company's Securities, including any offer to purchase or offer to sell, during any period commencing with the date that he or she possesses Material Nonpublic Information concerning the Company, and ending at the commencement of trading on the next Trading day following two full Trading days following the date of public disclosure of that information, or at such time as such nonpublic information is no longer material. As used herein, the term "**Trading Day**" shall mean a day on which the Nasdaq stock market is open for trading.

Transactions that may be necessary or justifiable for independent reasons (such as the need to raise money for an emergency expenditure) are not excepted from the Policy. The securities laws do not recognize such mitigating circumstances, and, in any event, even the appearance of an improper transaction must be avoided to preserve the Company's reputation for adhering to the highest standards of conduct.

2. Short Sales

No Insider shall engage in a short sale of the Company's Securities. A short sale is in general a sale of securities not owned by the seller. Transactions in certain put and call options for the Company's Securities may in some instances constitute a short sale. Short sales may evidence an expectation on the part of the seller that the securities will decline in value, and therefore have the potential to signal to the market that the seller lacks confidence in the Company's prospects. In addition, short sales may reduce a seller's incentive to seek to improve the Company's performance.

3. Publicly Traded Options

A transaction in publicly-traded options to purchase or sell the Company's Securities is, in effect, a bet on the short-term movement of the Company's Securities and therefore may create the appearance that the director, officer, employee, consultant or contractor of the Company is trading based on inside information. Transactions in options also may focus the Insider's attention on short-term performance at the expense of the Company's long-term objectives. Accordingly, transactions in puts, calls or other derivative securities, on an exchange or in any other organized market, by any Insider are prohibited by this Policy. Option positions arising from certain types of hedging transactions are governed by the section below captioned "Hedging Transactions.

4. Standing Orders

Standing orders should be used only for a very brief period of time and must be pre-cleared by the Chief Financial Officer. A standing order placed with a broker to sell or purchase securities at a specified price leaves you with no control over the timing of the transaction. A standing order transaction executed by the broker when you are aware of Material Nonpublic Information may result in unlawful insider trading. Transactions pursuant to a plan adopted in accordance with Rule 10b5-1 of the Securities Exchange Act of 1934, as amended (the "**Exchange Act**"), discussed below, may be permitted.

5. Hedging Transactions

Certain forms of hedging or monetization transactions, such as zero-cost collars and forward sale contracts, allow an employee to lock in much of the value of his or her share holdings, often in exchange for all or part of the potential for upside appreciation in the shares. These transactions allow the Insider to continue to own the securities, but without the full risks and rewards of ownership. When that occurs, Insider may no longer have the same objectives as the Company's other shareholders. For these reasons, hedging transactions are prohibited under this Policy.

6. Margin Accounts and Pledges

Securities held in a margin account may be sold by the broker without the customer's consent if the customer fails to meet a margin call. Similarly, securities pledged (or hypothecated) as collateral for a loan may be sold in foreclosure if the borrower defaults on the loan. A margin or foreclosure sale that occurs when the pledgor is aware of Material Nonpublic Information may, under some circumstances, result in unlawful insider trading. Because of this danger, Insiders are prohibited from pledging the Company's Securities or holding Company's Securities in a margin account.

7. Short-Term Trading

Short-term trading of the Company's Securities may be distracting to the person and may unduly focus the person on the Company's short-term stock market performance instead of the Company's long-term business objectives. For these reasons, if you purchase or sell Company Securities, you may not conduct an opposite way transaction in any Company Securities of the same class for at least six (6) months after the purchase or sale, unless you first pre-clear the proposed transaction with the Chief Financial Officer.

8. Tipping

No Insider shall disclose (commonly known as a "tip") Material Nonpublic Information to any other person (including family members) where such information may be used, or there is a reasonable basis to believe that such information may be used, by such person to his or her profit by trading (buying or selling) in the securities of companies to which such information relates, nor shall such person or related person make recommendations or express opinions on the basis of Material Nonpublic Information as to trading in the Company's Securities.

9. Advice Concerning Trading

No Insider may give trading advice of any kind about the Company or the Company's Securities to anyone while possessing Material Nonpublic information about the Company. An Insider should always advise others, preferably in writing or electronically, not to trade in the Company's Securities if doing so might violate the law or this policy. The Company strongly discourages any Insider from giving trading advice concerning the Company's Securities or the Company to third parties even when such persons do not possess Material Nonpublic information about the Company or the Company's Securities.

10. Confidentiality of Nonpublic Information

Nonpublic information relating to the Company is the property of the Company and the unauthorized disclosure of such information is forbidden. In the event any Insider receives any inquiry for information from outside the Company, such as from a journalist, stock analyst or investor, the inquiry should be referred to the Company's Chief Executive Officer or any designee of the Chief Executive Officer who is responsible for coordinating and overseeing the release of such information to the investing public, analysts and others in compliance with applicable laws and regulations.

11. Post-Termination Transactions

If you are in possession of Material Nonpublic Information when your employment or other service to the Company terminates or ceases, you may not trade in the Company's Securities until that information has become public or is no longer material.

Potential Criminal and Civil Liability and/or Disciplinary Action

1. Liability for Insider Trading

Pursuant to federal and state securities laws, any person violating U.S. insider trading laws may be subject to penalties of up to $5,000,000 ($25,000,000 for an entity) and up to 20 years in jail for engaging in transactions in the Company's Securities at a time when they have knowledge of Material Nonpublic Information regarding the Company.

2. Liability for Tipping

Insiders may also be liable for improper transactions by any person (commonly referred to as a "tippee") to whom they have disclosed Material Nonpublic Information regarding the Company or to whom they have made recommendations or expressed opinions on the basis of such information as to trading in the Company's Securities. The Securities and Exchange Commission (the "**SEC**") has imposed large penalties even when the disclosing person did not profit from the trading. The SEC, the stock exchanges and the Financial Industry Regulatory Authority use sophisticated electronic surveillance techniques to uncover insider trading. In recent years, criminal prosecution of insiders has become much more common, particularly when such persons were aware of their obligations under the securities laws and elected to ignore those obligations in acting on, or in tipping others concerning, Material Nonpublic Information.

3. Liability of Control Persons

If the Company or its supervisory personnel fail to take appropriate steps to prevent illegal insider trading, they may be subject to the following penalties:

(a) A civil penalty of up to the greater of $2,140,973 (subject to adjustment for inflation) or three times the amount of profit gained or loss avoided by the employee violator; and

(b) A criminal penalty of up to $5,000,000 and up to 20 years in jail for individual violators and/or a fine of $25,000,000 for the Company.

4. Possible Disciplinary Actions

Insiders who violate this Policy may also be subject to disciplinary action by the Company, which may include ineligibility for future participation in the Company's equity incentive plans or termination of employment.

Trading Guidelines and Requirements

1. Black-Out Periods and Trading Window

a. *Financial Black-Out Period*. The period beginning at the close of market on the 14th day of the last month of a fiscal quarter and ending at the commencement of trading on the next Trading Day following two full Trading Days after the date of public disclosure of the financial results for that fiscal quarter is a particularly sensitive period of time for transactions in the Company's Securities from the perspective of compliance with applicable securities laws. This sensitivity arises because directors, officers and certain employees involved in the preparation of the financial results will often possess Material Nonpublic Information about the expected financial results for the quarter during that

period. This period of time is referred to as a "financial black-out" period. Accordingly, all officers, directors and employees are prohibited from trading during a financial black-out period except for transactions specifically permitted pursuant to the "Certain Exceptions" section below.

b. *Special Black-Out Periods*. In addition, from time to time Material Nonpublic Information regarding the Company may be pending or there may be material developments known to the Company and not yet disclosed to the public. The Company may impose a special "black-out" period on all directors and officers (and those other Insiders identified by the Company from time to time and who have been notified that they have been so identified) prohibiting them from trading in the Company's Securities during a special black-out period and such persons should not disclose to others the fact of such suspension of trading.

c. *Mandatory Trading Window Related to Financial Information*. To ensure compliance with this Policy and applicable federal and state securities laws, the Company requires that all Insiders refrain from conducting transactions involving the purchase or sale of the Company's Securities other than during the period (the "**Trading Window**") commencing at the open of market on the third Trading Day following the date of public disclosure of the financial results for a particular fiscal quarter or year and continuing until the close of market on the 14th day prior to the end of the third calendar month of the next fiscal quarter. During the Trading Window, if the Company is in a special black-out period, the Company requires that all directors and officers and those certain identified Insiders refrain from conducting transactions involving the purchase or sale of the Company's Securities even though the Trading Window may otherwise be open. The prohibition against trading during the financial black-out period and special black-out period encompasses the fulfillment of "limit orders" by any broker for an Insider and the brokers with whom any such limit order is placed must be so instructed at the time it is placed.

It should be noted, however, that even during a Trading Window, any person possessing Material Nonpublic Information concerning the Company, whether or not subject to the financial or special black-out periods, should not engage in any transactions in the Company's Securities (except for transactions specifically described in the "Certain Exceptions" section below) until such information has been known publicly for at least two full Trading Days, whether or not the Company has recommended a suspension of trading to that person. Trading in the Company's Securities during the Trading Window is <u>not</u> a "safe harbor," and all Insiders should use good judgment at all times and pre-clear all trades in accordance with the following paragraph.

2. <u>Pre-Clearance of Trades</u>

All Insiders must refrain from purchasing, selling or otherwise disposing of (including by gift) or transacting in the Company's Securities without first complying with the Company's "pre-clearance" process, even if the trade would take place in a Trading Window. Each Insider must contact the Chief Financial Officer prior to commencing any trade in the Company's Securities with information regarding the proposed transaction. The Chief Financial Officer will consult as necessary with senior management of the Company before clearing any proposed trade. All trades that are pre-cleared must be effected within five business days of receipt of the pre-clearance. A pre-cleared trade (or any portion of a pre-cleared trade) that has not been effected during the five business day period must be submitted for pre-clearance determination again prior to execution. Notwithstanding receipt of preclearance, if the Insider becomes aware of Material Nonpublic Information, or becomes subject to a blackout period before the transaction is effected, the transaction may not be completed. Transactions under a previously established Rule 10b5-1 Trading Plan that has been preapproved in accordance with this Policy are not subject to further pre-clearance.

3. <u>Individual Responsibility</u>

Every Insider has the individual responsibility to comply with this Policy. He or she may, from time to time, have to forego a proposed transaction in the Company's Securities even if he or she planned to make the transaction before learning of the Material Nonpublic Information and even though he or she believes he or she may suffer an economic loss or forego anticipated profit by waiting.

As part of your individual responsibility, you should take every practicable step to preserve the confidentiality of information. For example:

(a) Don't discuss material information in elevators, hallways, restaurants, airplanes, taxicabs or any place where you can be overheard;

(b) Don’t gossip about confidential information;

(c) Don’t read confidential documents in public places or discard them where they can be retrieved by others;

(d) Don’t carry confidential documents in elevators, hallways, etc. in an exposed manner;

(e) Beware of the carrying quality of conversations conducted on speaker telephones in offices, and the potential for eavesdropping on conversations conducted on car or airplane telephones, on marine radios etc.;

(f) Don’t leave confidential documents in unattended conference rooms; don’t leave confidential documents behind when the conference is over;

(g) Cover confidential documents on your desk before you leave your room; don’t leave confidential papers lying where visitors can see them;

(h) Be careful when giving out the whereabouts of personnel not in the office or revealing the presence of specific visitors to the office. The mere fact of a meeting or the destination of a trip may reveal something confidential; and

(i) Under no circumstances are employees to provide confidential Company documents or other information to third parties, without express consent of the supervisor. This includes, but is not limited to, any confidential Company documents or information relating to customers, competitors or suppliers of the Company.

(j) Obviously, a list such as this can only be suggestive. It is the responsibility of each employee to take whatever practicable steps are appropriate to preserve the confidentiality of information.

Applicability of Policy to Inside Information Regarding Other Companies

This Policy also applies to Material Nonpublic Information relating to other companies with which the Company conducts business, including proposed business combinations (“**Business Partners**”), when that information is obtained in the course of employment with, or other services performed on behalf of, the Company. Civil and criminal penalties, and termination of employment, may result from trading on inside information regarding the Company’s Business Partners. All Insiders should treat Material Nonpublic Information about the Company’s Business Partners with the same care required with respect to information related directly to the Company. Similarly, you must not discuss Material Nonpublic Information relating to the Company’s Business Partners in an internet “chat room” or similar internet-based forum.

Definition of “Material Nonpublic Information”

It is not possible to define all categories of Material Nonpublic Information. However, information should be regarded as material if there is a reasonable likelihood that it would be considered important (within the total mix of information) to an investor in making an investment decision regarding the purchase or sale of the Company’s Securities. Either positive or negative information may be material.

While it may be difficult under this standard to determine whether particular information is material, there are various categories of information that are particularly sensitive and, as a general rule, should always be considered material. Examples of such information may include:

(a) financial results;

(b) news of major clinical or development milestones;

(c) early indications of clinical trial results;

(d) known but unannounced clinical trial results;

(e) known but unannounced analyses of clinical trial results;

(f) significant communications to or from regulatory agencies, or other significant regulatory developments;

(g) significant developments related to intellectual property;

(h) significant developments related to collaboration relationships;

(i) proposals, plans or agreements, even if preliminary in nature, involving mergers, acquisitions, divestitures, recapitalizations, strategic alliances, licensing arrangements, or purchases or sales of substantial assets;

(j) impending bankruptcy or financial liquidity problems;

(k) cybersecurity or data security incidents;

(l) share splits;

(m) new equity or debt offerings;

(n) positive or negative developments in outstanding litigation;

(o) significant litigation exposure due to actual or threatened litigation; and

(p) changes in senior management, the Company's auditors or the board of directors.

Nonpublic information is information that has not been previously disclosed to the general public and is otherwise not available to the general public. To be "public" the information must have been disseminated in a manner designed to reach investors generally, and the investors must be given the opportunity to absorb the information.

Certain Exceptions

The following transactions are not subject to the prohibitions of the Policy under "Trading Guidelines and Requirements" above.

1. Share Option Exercises

The Company's Policy does not apply to the exercise of an Insider share option if the shares acquired upon exercise are held rather than sold, or if the shares are surrendered to the Company in payment of the exercise price or in satisfaction of any tax withholding requirements in a manner permitted by the applicable equity award agreement, that in case do not involve a market sale of the Company's Securities. The Policy does apply, however, to any sale of shares as part of a broker-assisted cashless exercise of an option, or any other sale for the purpose of generating the cash needed to pay the exercise price of an option.

2. Restricted Share Awards and RSUs

This Policy does not apply to the vesting of restricted shares or restricted stock units, or the withholding or forfeiture of shares to pay for tax withholding obligations incident to such vesting.

3. Rule 10b5-1 Trading Plans and Non-Rule 10b5-1 Pre-Arranged Trading Programs

Rule 10b5-1 of the Exchange Act provides an affirmative defense against insider trading liability for transactions pursuant to a previously established written plan, contract or instruction to trade in the Company's stock, entered into in good faith and in accordance with the terms of Rule 10b5-1 at a time when the Insider was not aware of Material Nonpublic Information, even though the transaction in question may occur at a time when such person is aware of Material Nonpublic Information.

The trading restrictions set forth in this Policy, other than those specified transactions specifically prohibited under the "Specific Policies" section above, do not apply to transactions under a previously established contract, plan or instruction to trade in the Company's Securities that complies with all applicable requirements of Rule 10b5-1 (a "**Trading Plan**") or transactions under a "non-Rule 10b5-1 trading arrangement" as defined by Item 408 of Regulation S-K.

An Insider may enter into a Trading Plan or a non-Rule 10b5-1 trading arrangement only when he or she is not in possession of Material Nonpublic Information and only during a Trading Window.

Each such Trading Plan or non-Rule 10b5-1 trading arrangement must be submitted to and pre-approved by the Chief Financial Officer, who may impose such conditions on the implementation and operation of the Trading Plan as the Chief Financial Officer deems necessary or advisable. Insiders may not adopt more than one Trading Plan at a time except under the limited circumstances permitted by Rule 10b5-1 and subject to pre-approval by the Chief Financial Officer.

An individual may only modify a Trading Plan during a Trading Window and, in any event, when the individual does not possess Material Nonpublic Information. Modifications to and terminations of a Trading Plan or non-Rule 10b5-1 trading arrangement are subject to pre-approval by the Chief Financial Officer.

The Company reserves the right to bar any transactions in the Company's Securities, including transactions pursuant to a Trading Plan and any non-Rule 10b5-1 trading arrangements previously approved, if the Chief Financial Officer or the Board of Directors determines that such a bar is in the best interests of the Company. In addition, the Company does not permit any trades in such a Trading Plan or any non-Rule 10b5-1 trading arrangements to consist of any hedging transactions or other transactions prohibited by this Policy under the "Specific Policies" section above.

The Company reserves the right to publicly disclose, announce, or respond to inquiries from the media regarding the adoption, modification, or termination of a Trading Plan and non-Rule 10b5-1 trading arrangements, or the execution of transactions made under a Trading Plan.

Additional Guidance and Information – Directors and Officers

Directors and officers of the Company and certain other persons identified by the Company from time to time must also comply with the reporting obligations and limitations on short-swing transactions set forth in Section 16 of the Exchange Act. The Company does not permit short-swing and short sale transactions by executive officers or directors.

Priority of Statutory or Regulatory Trading Restrictions

The trading prohibitions and restrictions set forth in this Policy will be superseded by any greater prohibitions or restrictions prescribed by federal or state securities laws and regulations, e.g., contractual restrictions on the sale of securities (e.g. under lock-up agreements), short-swing trading by Section 16 parties or restrictions on the sale of securities subject to Rule 144 under the Securities Act. Any person who is uncertain whether other prohibitions or restrictions apply should ask the Chief Financial Officer.

Inquiries

Any person who has a question about this Policy or its application to any proposed transaction may obtain additional guidance from the Chief Financial Officer. Ultimately, however, the responsibility for adhering to this Policy and avoiding unlawful transactions rests with the individual Insider.

Certifications

All directors, officers, employees, consultants and contractors must certify their understanding of, and intent to comply with, this Policy. Please sign the certification attached hereto as Attachment 1.

Last Updated: June 14, 2023

ATTACHMENT 1

CERTIFICATIONS

I certify that:

1. I have read and understand the Company's Insider Trading Policy (the "Policy"). I understand that the Chief Financial Officer is available to answer any questions I have regarding the Policy.

2. Since the date this Policy became effective, or such shorter period of time that I have been a director, officer or other employee of the Company, I have complied with the Policy.

3. I will continue to comply with the Policy for as long as I am subject to the Policy.

Signature: _____

Date: _____

Print Name: _____

Exhibit 23.1

HASKELLWHITE
CERTIFIED PUBLIC ACCOUNTANTS | BUSINESS ADVISORS
THE VALUE OF EXPERIENCE

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements on Form S-1 (Nos. 333-269000, 333-259771, 333-282069 and 333-284026), the Registration Statements on Form S-3 (Nos. Nos. 333-267236, 333-230016 and 333-284707), and the Registration Statements on Form S-8 (333-259127, 333-270828 and 333-281466) of Indaptus Therapeutics, Inc. (the "Company") of our report dated March 13, 2025, relating to our audits of the Company's consolidated financial statements as of December 31, 2024 and 2023, and for each of the years then ended, included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2024 filed with the U.S. Securities and Exchange Commission.

Our report dated March 13, 2025 contains an explanatory paragraph that states the Company has experienced recurring losses, negative cash flows from operations, and has limited capital resources. These conditions raise substantial doubt about the Company's ability to continue as a going concern. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ Haskell& White LLP
HASKELL & WHITE LLP

Irvine, California
March 13, 2025

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Irvine, CA 92618
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Exhibit 31.1

CERTIFICATIONS

I, Jeffrey A. Meckler, certify that:

1. I have reviewed this Annual Report on Form 10-K for the year ended December 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: March 13, 2025

/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 Annual Report on Form 10-K for the year ended December 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: March 13, 2025

/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 Annual Report of Indaptus Therapeutics, Inc. (the "Company") on Form 10-K for the year ended December 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: March 13, 2025

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 Annual Report of Indaptus Therapeutics, Inc. (the "Company") on Form 10-K for the year ended December 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:

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

(d) 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: March 13, 2025